IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, ET AL. Petitioners, v. MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, ET AL., Respondents.	)	No. 22-1294

Respondents' Reply in Support of their Motion to Dismiss

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INTRODUCTION

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(h)(1), provides jurisdiction over certain types of actions. The Final Rule at issue in this case is not reviewable except in connection with a final order issued by the Environmental Protection Agency ("EPA") under 21 U.S.C. § 346a(g)(2)(C). This petition for review seeks to challenge EPA's Final Rule issued under § 346a(d) and, was filed prior to the issuance of any final order under 21 U.S.C. § 346a(g)(2)(C). Accordingly, EPA's Motion to Dismiss the Petition for lack of jurisdiction is not moot. Nor does the fact that EPA signed a final order under § 346a(g)(2)(C) cure the jurisdictional defect because that order will not be issued for purposes of judicial review until March 14, 2022.

ARGUMENT

I. EPA's Motion to Dismiss is not moot.

Petitioners have not sought to voluntarily dismiss their Petition, even though it seeks review of the Final Rule, which is not reviewable under § 346a(h) absent an order issued under § 346a(g)(2)(C). Nor have Petitioners cited another basis for jurisdiction for review of the Final Rule. Contrary to the Petitioners' claim, EPA's signing of an order under (g)(2)(C) does not automatically cure the jurisdictional defect of the original petition. Accordingly, EPA's Motion to Dismiss is not moot.

Petitioners' new petition, filed on February 28, 2022, also is not properly before the Court. That petition challenges EPA's Denial Order under § 346a(g)(2)(C);[1] however, the Court does not have jurisdiction over any petition for review of the Denial Order until it is issued, which is two weeks after publication of the Final Order in the Federal Register. *See* 28 U.S.C. § 2112 (authorizing EPA to promulgate rules that "provide for the time and manner of filing and the contents of the record in all proceedings instituted in the courts of appeals to enjoin, set aside, suspend, modify, or otherwise review or enforce [its] orders"); 40 C.F.R. § 23.10 (setting "the time and date of the issuance" of an order under § 346a(g)(2)(C) as 1 p.m. Eastern time two weeks after publication in the Federal Register). Accordingly, parties may file a petition for review of the Denial Order beginning March 14, 2022.

II. The Court lacks subject-matter jurisdiction.

A. Section 346a(h)'s exhaustion requirement expressly limits subject-matter jurisdiction.

Petitioners' argument that § 346a(h) merely establishes a discretionary exhaustion procedure and not an express jurisdictional limitation misreads the statute and relevant precedent. Section 346a(h)(1) enumerates the specific actions

[1] Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222 (Feb. 28, 2022) ("Denial Order").

reviewable; it expressly includes orders issued at the conclusion of the administrative review procedure under § 346a(g)(2)(C) and regulations subject to such an order and excludes final regulations issued in response to petitions under § 346a(d)(4)(A)((i). "Courts are required to give effect to Congress' express inclusions and exclusions, not disregard them." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018). Section 346a(h)(2), entitled "[J]urisdiction," further clarifies that "[u]pon the filing of such a petition"—*i.e.,* a petition for review of an order issued under § 346a(g)(2)(C) or a regulation that is the subject of said order—the court of appeals "shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of." By "explicitly limit[ing] subject matter jurisdiction" to review of "order issued under subsection … (g)(2)(C)" and "regulation that is the subject of such an order," § 346a(h) clearly indicates that Congress intended the exhaustion requirement to be a jurisdictional bar. *Ace Prop. & Casualty Ins. Co. v. Fed. Crop Ins. Corp.*, 440 F.3d 992, 998 (8th Cir. 2006).

Contrary to Petitioners' argument, this Court's decision in *Ace* supports EPA's reading of § 346a(h) and not Petitioners'. There, the Court examined the exhaustion requirement in the Reorganization Act, 7 U.S.C. § 6912(e), which provides that "a person shall exhaust all administrative appeal procedures … before the person may bring an action in a court of competent jurisdiction." The Court concluded that § 6912(e) was not jurisdictional because it is "directed at 'a

person'" and "[t]here is no language directed at courts or limiting federal district court jurisdiction." *Ace*, 440 F.3d at 998. The Court contrasted the exhaustion requirement in § 6912(e) to that in the Immigration and Nationalization Act ("INA"), 8 U.S.C. § 1252(d)(1), which the Eighth Circuit had found to impose a jurisdictional bar. *Ace*, 440 F.3d at 998. Specifically, the Court highlighted that unlike § 6912(e), the INA exhaustion requirement provides that "a *court* may review a final order of removal *only if* ... the alien has exhausted all administrative remedies available to the alien as of right," and thus "explicitly limits subject matter jurisdiction." *Ace*, 440 F.3d at 998 (citation omitted).

Viewed against *Ace*, the exhaustion requirement at issue here is like the jurisdictional bar reflected by the INA exhaustion requirement, not the exhaustion requirement in § 6912(e). Unlike § 6912(e), § 346a(h)(1) does not merely define a petitioner's obligations to exhaust—it enumerates the actions reviewable by the Court and specifically limits such actions to orders under subsection (g)(2)(C) and regulations subject to such orders. Contrary to Petitioners' argument, nothing in the text of § 346a(h)(2) negates the limitations in subsection (h)(1). Indeed, by referring to "such a petition," § 346a(h)(2) underscores the jurisdictional nature of the limitation in subsection (h)(1) to orders under (g)(2)(C) and those regulations that are subject to such orders. Further, like the INA exhaustion requirement examined in *Ace*, § 346a(h) explicitly speaks to the Court's subject matter

jurisdiction. As such, the exhaustion requirement in § 346a(h) is a jurisdictional bar.

Petitioners' attempt to argue that § 346a(h)(1) permits parties to file a petition for review *before* an order under § 346a(g)(2)(C) is issued because the text authorizes such petitions by persons "who will be adversely affected" by such order should also be rejected. The quoted text merely identifies which persons are authorized to file petitions for review—*i.e.,* those who will be adversely affected by an order issued under § 346a(g)(2)(C). It does not state that petitions for review may be filed in advance of EPA's issuance of a final order. To the contrary, § 346a(h)(1) only authorizes petitions for review of orders "issued" under § 346a(g)(2)(C) and regulations subject to such orders. And § 346a(h)(2) vests exclusive jurisdiction in the court of appeals only "[u]pon the filing of *such* a petition." Congress's use of the past tense to define the agency actions for which review may be sought clearly indicates an order must issue *before* a petition may be filed. Petitioners' alternative reading that § 346a(h)(1) authorizes parties to file petitions in anticipation of an order under § 346a(g)(2)(C) ignores the statute's plain text and is nonsensical.

Petitioners' attempt (at 17 n.4) to distinguish the Ninth Circuit's *LULAC* decision also fails. Although the *en banc* court did not rule on the jurisdictional issue, it granted EPA's petition for rehearing *en banc*, which pointed out the same

jurisdictional flaws present here. *See League of United Latin Am. Citizens v. EPA*, 914 F.3d 1189 (9th Cir. 2019).

Equally unavailing is Petitioners' argument that the exhaustion requirement in § 346a(h) is not a mandatory claims-processing rule, under which dismissal of the Petition would still be due. The reasons Petitioners state for their assertion that § 346a(h) is not even a claims-processing rule—*i.e.,* because it speaks to the types of claims the court may hear, as opposed to the actions a petitioner must take before filing a proper petition—only serve to further underscore the ways in which § 346a(h) reflects Congress's "clear and sweeping" intent to limit subject-matter jurisdiction. Put another way, if § 346a(h)'s exhaustion requirement does not meet the definition of a claims-processing rule, it is because it is expressed as a limit on the actions over which the court may exercise jurisdiction. Thus, Petitioners' argument that § 346a(h)'s exhaustion requirement is *neither* a jurisdictional limit nor a claims processing rule collapses on itself.

B. Section 346a(h)'s exhaustion requirements cannot and should not be waived.

As discussed above, the exhaustion requirement in § 346a(h) is jurisdictional because it limits the actions over which this Court may exercise jurisdiction. Even if it is not jurisdictional, § 346a(h) is at the very least a mandatory claims-processing rule because it specifies that a person may only seek judicial review of an "order issued under subsection … (g)(2)(C)" and a regulation "that is the

subject of such an order." An order issued under § 346a(g)(2)(C) is the culmination of the FFDCA's administrative objections process. Petitioners fail to explain how the exhaustion procedures in § 346a(g) are merely optional, given that Congress limited judicial review under § 346a(h)(1) to an order issued at the conclusion of that process. Nor do they point to any exceptions to § 346a(h)'s requirement of a final order concluding the objections process. Therefore, even if the exhaustion requirement in § 346a(h) is not jurisdictional (which it is), EPA must issue a final order under § 346a(g)(2)(C) before a person may file a petition for review.

In *United States v. Houck*, this Court affirmed that mandatory claims processing rules specified by Congress "must be enforced so long as the opposing party properly raises it." 2 F.4th 1082, 1084 (8th Cir. 2021) (citation omitted). Petitioners do not dispute that EPA has properly raised § 346a(h)(1)'s exhaustion requirement. Nor do they identify any statutory exceptions. Accordingly, the Court may not consider any equitable exceptions. *Houck*, 2 F.4th at 1084-85.

Petitioners do not establish entitlement to an exception, even if available. Futility is a narrow exception, granted only where there is a question whether the agency could provide effective relief. *Ace*, 440 F.3d at 1000. Petitioners attack the merits of EPA's Final Rule revoking chlorpyrifos tolerances, not whether EPA

would have the authority to stay or modify that rule in response to an administrative petition objecting to the rule.

Petitioners cannot claim an exception based on irreparable harm, as they will not be irreparably harmed by the revocation of chlorpyrifos tolerances pending judicial review; rather, the public interest weighs in favor of allowing EPA's revocation order to remain in effect to avoid harm from exposure to chlorpyrifos at unsafe levels. *See* Resp. Opp. to Mot. to Stay at 19-23.

Nor is it relevant whether Petitioners raise only a legal issue. As an initial matter, while Petitioners' stay motion raises only the legal issue whether EPA must consider all anticipated chlorpyrifos exposures when determining whether a tolerance is safe, their Petition for Review is not so limited. In any event, the "legal issues exception is extremely narrow and should only be invoked if the issues involved are ones in which the agency has no expertise or which call for factual determinations." *Ace*, 440 F.3d at 1001. Agency expertise is at the very heart of the highly complex, scientific determination whether chlorpyrifos tolerances are safe.

In sum, Petitioners provide no basis for the Court to ignore § 346a(h)'s mandatory exhaustion requirement.

C. Petitioners' attempt to re-argue their stay motion cannot cure the subject-matter defect.

Petitioners argue (at 10) that "this Court has jurisdiction to step in and halt the irreparable harm that will result" from EPA's denial of their administrative stay request. As set forth below, this attempt to re-argue their stay motion fails for four reasons.

First, although Section 705 of the Administrative Procedure Act authorizes courts to stay the effectiveness of agency action, it does not grant subject matter jurisdiction. *See* 5 U.S.C. § 705. Petitioners provide no other basis for the Court's jurisdiction over their Petition.

Second, the evidence does not support Petitioners' suggestion (at 10-11) that EPA "sat" on stay requests and objections to the Final Rule in order to avoid judicial review. To the contrary, EPA signed the nearly 200-page Order on February 22, 2022, after which it immediately informed the Court. *See* Resps.' Rule 28(j) Notice. It took EPA less than four months to respond to over 20 objections and stay requests—far shorter than the 24 months previously taken to respond to objections by environmental groups seeking to revoke tolerances.

Nor do Petitioners show that the Agency's actions constitute an end-run around judicial review. Petitioners' reliance (at 11) on *Solar Turbines Inc. v. Seif* is misplaced, as that decision merely held that EPA's withdrawal of an administrative order did not render a petition for review moot. *See* 879 F.2d 1073,

1079 (3d Cir. 1989). Here, EPA has not withdrawn an order, and in fact denied Petitioners' objections. *Byrd v. Haas* is similarly inapposite because, in that case, the Michigan Department of Corrections took *over five years* to even begin to analyze the plaintiff's request to worship with other members of his faith. *See* 17 F.4th 692, 699 (6th Cir. 2021). Here, EPA issued a final decision on objections and stay requests within four months.

Third, EPA did not constructively deny Petitioners' stay requests. In less than four months, EPA issued a nearly 200-page Order that carefully and thoughtfully responded to those stay requests. Nor is there support for Petitioners' argument (at 9, 14) that EPA "made" its decision to deny Petitioners' stay requests prior to signing the Denial Order. *See Bennett v. Spear,* 520 U.S. 154, 178 (1997) (agency action must be final to be reviewable); *Paralyzed Veterans of Am. v. Sec'y of Veterans Affairs*, 345 F.3d 1334, 1349 (Fed. Cir. 2003) ("[G]overnment officials are presumed to act in good faith and with regularity."). In any event, the remedy for agency inaction is a mandamus petition. Insofar as Petitioners sought such relief through their Petition, that request is now moot because EPA signed a Denial Order that will be issued for purposes of judicial review on March 14, 2022. Petitioners articulate no basis for this Court's jurisdiction over the stay denial, separate and apart from EPA's Denial Order.

Fourth, as Respondents explained in their Opposition to Petitioners' stay motion, Petitioners have not established irreparable harm that would be remedied by a stay. Resp. Opp. to Mot. for Stay at 18-22. Moreover, staying the Final Rule could result in harm to those exposed to chlorpyrifos through its continued use on currently registered food crops. *Id.* at 23. Petitioners nevertheless ask the Court to step into EPA's shoes to (1) finalize a *proposal* for a subset of 11 uses set forth under a separate regulatory process, and (2) stay the revocation of all other uses not addressed in that proposal without explaining how the Court is to decide, as a scientific matter, that those uses are safe under the FFDCA. *Id.* at 10-14. Such extraordinary relief is not justified by the harms Petitioners allege.

CONCLUSION

Because a final rule under 21 U.S.C. § 346a(d)(4)(A)(i) is not within the Court's jurisdiction until a final order is issued under § 346a(g)(2)(C), the Court must dismiss the Petition. Even if § 346a(h)'s exhaustion requirement is not jurisdictional, it is still a mandatory requirement.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, ET AL. Petitioners, v. MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, ET AL., Respondents.	No. 22-1422

Respondents' Opposition to Petitioners' Motion for Stay Pending Review

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INTRODUCTION

Petitioners' motion to stay EPA's decision under the Federal Food, Drug, and Cosmetic Act ("FFDCA") revoking unsafe chlorpyrifos tolerances should be denied.

First, there is no likelihood of success on the merits. Petitioners' argument that EPA erred in revoking all chlorpyrifos tolerances when it purportedly found 11 uses safe (in certain geographic areas and under certain conditions) mischaracterizes the statute and the record. As required under the FFDCA, EPA considered "*all* anticipated dietary exposures and other exposures" based on existing registered (*i.e.,* legally permitted) uses when determining that existing chlorpyrifos tolerances were unsafe. Even if it were lawful to consider only a subset of current uses, EPA never concluded that the 11 uses *are* safe. Petitioners rely on a *proposed* determination prepared for a separate regulatory proceeding under a different statute, in which EPA considered whether a proposed scenario of reduced uses of chlorpyrifos—a scenario that did not presently exist—would lead to exposures that EPA could find safe. In any event, despite captioning their motion as one for a "partial stay," Petitioners ask this Court to stay EPA's revocation of tolerances for *all* chlorpyrifos uses, not just the 11 so-called "designated safe uses."

Second, Petitioners' harm allegations do not satisfy the high bar of irreparable harm required for a stay. While Petitioners allege economic losses from the inability to sell and use chlorpyrifos, such losses alone are insufficient to warrant a stay.

Third, the balance of equities weighs against staying EPA's revocation of chlorpyrifos tolerances. Congress directed EPA to consider only safety in assessing tolerances. Based on an extensive assessment of the risks from chlorpyrifos exposures, EPA found the existing tolerances were not safe. Accordingly, the FFDCA's strict safety standard required that EPA revoke them. EPA's decision conforms to the Ninth Circuit's mandate that EPA act within 60 days to grant a revocation petition pending since 2007. Petitioners now ask this Court to put chlorpyrifos tolerances back into place without a safety finding, in direct contravention of Congress's command. Petitioners' motion to stay the revocation contravenes the FFDCA and the public interest and stands in tension with the relief granted by a sister circuit. The Court should deny Petitioners' motion.

BACKGROUND

A. Statutory and regulatory background

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, EPA establishes "tolerances," which are maximum levels of pesticide residue allowed in or on food. 21 U.S.C. § 346a. EPA may establish or leave in place a tolerance for a pesticide *only* if it determines that the tolerance is "safe," and must revoke or modify an existing tolerance if EPA determines that the tolerance is not "safe." *Id.* § 346a(b)(2)(A)(i). Under the FFDCA, "safe" means a "reasonable certainty that no harm will result from aggregate exposure" to pesticide chemical residues, including "all anticipated dietary exposures and all other exposures for which there is reliable information" (for example, drinking water). *Id.* § 346a(b)(2)(A)(ii). Additionally, EPA must assess the risk of the pesticide residues to infants and children utilizing a presumptive tenfold margin of safety for threshold effects unless a lower margin will be safe. 21 U.S.C. § 346a(b)(2)(C).

2. The Federal Insecticide, Fungicide, and Rodenticide Act

EPA also regulates pesticides under FIFRA. FIFRA requires EPA approval of pesticides prior to distribution or sale and establishes a registration regime for regulating their use. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). In contrast to the FFDCA's risk-only safety standard, FIFRA's "unreasonable adverse effects" standard means "any unreasonable risk to man or the environment," taking into consideration both risks and benefits of the pesticide. *Id.* § 136(bb).

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years. *Id.* § 136a(g)(1)(A). During "registration review," EPA must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account new scientific information and changes to risk-assessment procedures, methods, and data requirements. 40 C.F.R. §§ 155.40(a)(1), 155.53(a); 7 U.S.C. § 136a(g). EPA may propose measures to mitigate identified risks, such as label or registration changes. *See* 40 C.F.R. § 155.58(b).

Where EPA determines that a pesticide does not meet the requirements for registration, EPA can request that registrants submit requests to voluntarily cancel

their pesticides or certain uses under 7 U.S.C. § 136d(f), or initiate cancellation proceedings under § 136d(b).

B. Factual background

1. Prior Ninth Circuit litigation

In 2007, public interest groups petitioned EPA to revoke all chlorpyrifos tolerances. EPA failed to issue a formal response to the petition, and the U.S. Court of Appeals for the Ninth Circuit ordered EPA to respond to the petition by October 31, 2015. *In re Pesticide Action Network N. Am. v. EPA,* 798 F.3d 809, 815 (9th Cir. 2015). EPA published for comment a proposed rule revoking all chlorpyrifos tolerances. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (Nov. 6, 2015). The Ninth Circuit then ordered EPA to complete its final action on the petition by March 31, 2017. *In re Pesticide Action Network N. Am. v. EPA,* 840 F.3d 1014, 1015 (9th Cir. 2016). EPA denied the petition, departing from its proposal and leaving the tolerances in effect. 82 Fed. Reg. 16581 (Apr. 5, 2017). In response to another Ninth Circuit order, EPA issued a final order denying all objections. 84 Fed. Reg. 35555 (July 24, 2019); *League of United Latin Am. Citizens v. EPA*, 922 F.3d 443 (9th Cir. 2019) (en banc) (*"LULAC"*).

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the original petition and objections and concluded that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not

safe within the meaning of the FFDCA." *LULAC v. Regan*, 996 F.3d 673, 700 (9th Cir. 2021) (*"LULAC II"*). The Ninth Circuit chided EPA for taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition," which was an "egregious delay [that] exposed a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 703. The Ninth Circuit expressly precluded EPA from additional fact finding, as "further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." *Id.* at 702; *see also id.* at 678 (denying petition based on ongoing registration review was a "total abdication of the EPA's statutory duty under the FFDCA").

The Ninth Circuit instructed EPA to publish a final response to the 2007 petition within 60 days after the issuance of its mandate, without notice and comment, "that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703.

2. The Proposed Interim Decision under Registration Review

On a separate regulatory track, in December 2020, prior to the *LULAC II* decision, EPA released the Proposed Registration Review Interim Decision for Chlorpyrifos ("PID") (Long Decl. Ex. B). The PID concluded that aggregate exposure (including exposures in food, drinking water, and residential settings) from all currently-registered uses of chlorpyrifos was unsafe. *Id.* at 19. To reduce

aggregate exposures to safe levels, EPA proposed that chlorpyrifos applications be limited to eleven "high-benefit" uses, and further restricted with respect to geographic areas and application rates. *Id.* at 40-41. EPA proposed cancelling all other existing uses under FIFRA. *Id.* at 40. Multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses. *See* Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222, 11246 (Feb. 28, 2022) (the "Denial Order") (Long Decl. Ex. FF). Carrying out the modifications proposed in the PID would require use cancellations and label amendments. *Id.* at 11244. No registrants submitted voluntary cancellation requests or label amendments for their registrations. *Id.* at 11246. EPA has not yet issued a final interim decision for chlorpyrifos. *Id.* at 11233.

3. EPA's revocation of all chlorpyrifos tolerances

In response to *LULAC II*, on August 30, 2021, EPA published a Final Rule revoking all tolerances for chlorpyrifos. 86 Fed. Reg. 48315 (Long Decl. Ex. A). EPA set an expiration date of February 28, 2022 for the tolerances. *See id.* On February 28, 2022, EPA published the Denial Order in the Federal Register, responding to objections to the revocation. 87 Fed. Reg. 11222.

As EPA explained in the Final Rule, chlorpyrifos affects the nervous system by inhibiting acetylcholinesterase ("AChE"), an enzyme necessary for the proper

functioning of the nervous system. *Id.* at 11231. EPA's decision relied on the effect of AChE inhibition for assessing risks from chlorpyrifos and retention of the 10X safety factor to account for scientific uncertainties around the potential for adverse neurodevelopmental outcomes in infants and children. *Id.* at 11237. EPA considered aggregate exposures that would occur in food, drinking water, and residential settings due to currently registered uses. *Id.* at 11237-38. EPA's analysis of registered uses demonstrated that concentrations of chlorpyrifos and its drinking water metabolite in certain sources of drinking water would exceed the maximum safe levels for residues in drinking water, leading to unsafe aggregate exposures. *Id.* Because aggregate exposures to chlorpyrifos exceeded safe levels, EPA revoked all chlorpyrifos tolerances. *Id.* at 11238.

EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not submitted. Decl. of Timothy Kiely ¶ 26. Those proceedings will address existing stocks.[1] *Id.*

[1] Existing stocks are stocks of a registered pesticide product that were in the United States and packaged, labeled, and released for shipment prior to the effective date of the product's cancellation. *See* Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362 (June 26, 1991).

ARGUMENT

To obtain a stay, movants must establish their likelihood of success on the merits, the likelihood of irreparable harm without a stay, that the balance of equities tips in their favor, and that a stay is in the public interest. *Nken v. Holder*, 556 U.S. 418, 426, 434 (2009). Petitioners fail to meet this standard.

I. Petitioners are not likely to succeed on the merits.

To begin with, the Court still does not have before it a proper petition. *See* Resps.' Mot. to Dismiss. Parties can only seek judicial review of a final order under § 346(g)(2)(C) and regulations subject to that order. Because EPA's Denial Order issues on March 14, 2022, 40 C.F.R. § 23.10, the Court lacks jurisdiction unless a proper petition is filed on or after that date. Even if the Court had jurisdiction, a stay is not warranted.

A. EPA cannot conclude that chlorpyrifos is safe.

EPA's *sole* statutory criteria for establishing or revoking a tolerance is whether the residue is "safe." 21 U.S.C. § 346a(b)(2)(A)(i); *see also LULAC II*, 996 F.3d at 696 (amendments to the FFDCA "explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns."). After an exhaustive assessment of a multitude of studies, EPA determined that it cannot conclude that chlorpyrifos is safe, particularly for infants and children, because aggregate exposures to chlorpyrifos exceeded safe levels.

Exposure to chlorpyrifos can lead to neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. 87 Fed. Reg. at 11231. A large body of evidence shows an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* Laboratory animal studies, epidemiology data, and mechanistic studies all show evidence of a negative effect on the developing brain, including cognitive, anxiety and emotion, social interactions, and neuromotor functions. *Id.*

Petitioners attempt to undercut these findings by importing FIFRA's "unreasonable adverse effects" standard—which considers economic and social costs and benefits—into the FFDCA's safety standard. *See* Mot. at 20-21 (arguing that EPA's safety decision should have considered the "interests" of growers and Gharda in the continued use of chlorpyrifos). This fails because Congress treated pesticides used on food differently. The FFDCA imposes "an uncompromisable limitation: the pesticide must be determined to be safe for human beings." *LULAC II*, 996 F.3d at 678. Petitioners cannot rewrite statutes to include considerations Congress precluded.

B. EPA reasonably assessed "aggregate" exposure from "all anticipated" exposures under the FFDCA.

Petitioners argue that EPA erred by evaluating all registered uses of chlorpyrifos and that, instead, EPA was required to devise a subset of registrations that could be safe under the FFDCA, based on the subset of 11 geographically and

rate-restricted uses identified in a *proposed* determination (the PID) prepared for EPA's registration review under FIFRA. Mot. at 15-16. Petitioners are wrong.

First, EPA was not required to make a "tolerance-by-tolerance examination." Petitioners' contrary contention (at 15-16) ignores the FFDCA's direction to EPA to assess "*aggregate* exposure to the pesticide chemical residue" based on "*all* anticipated dietary exposures and *all* other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added); *see also LULAC II*, 996 F.3d at 703. Evaluating exposures from the uses associated with only one tolerance at a time would disregard exposures from other uses, contrary to the FFDCA.

Second, the FFDCA requires EPA to assess *all anticipated exposures* in making its safety determination. 21 U.S.C. § 346a(a)(2)(A)(ii). It is reasonable for EPA to consider all registered uses when determining which exposures are "anticipated." *See* General Principles For Performing Aggregate Exposure and Risk Assessments (Nov. 28, 2001) (Ex. A) at 45 ("The starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide."). There are currently 25 chlorpyrifos registrants and 76 total chlorpyrifos registrations. Kiely Decl. ¶ 5. *None* of the registrants, including Gharda, have submitted a request to voluntarily cancel their registrations. *Id.* ¶¶ 22-24; 87 Fed.

Reg. at 11245-46, 11267. Thus, at the time of the Final Rule, EPA could not reasonably conclude that there would be no anticipated exposures associated with those registered products. *Id.* at 11246.

Third, Petitioners' argument that EPA was obligated to conduct a tolerance-by-tolerance analysis imports FIFRA's standard for registering pesticides into the FFDCA. FIFRA and the FFDCA are different statutes with separate requirements. Registration review under FIFRA assesses all registrations of a particular pesticide. 7 U.S.C. § 136a(g). As it did in the PID, EPA may propose label modifications and cancellations in order to meet FIFRA's unreasonable adverse effects standard. 40 C.F.R. § 155.56. When registrants comply with EPA's proposed mitigation by voluntarily cancelling registrations or adopting use restrictions on product labels, then EPA's finding that a pesticide meets the FIFRA registration standard is based on the uses that remain and no longer includes the uses that are cancelled or amended. But, in assessing the safety of a tolerance under the FFDCA, EPA must consider whether anticipated exposures from proposed and registered uses are safe, not whether there are changes that could be made to registrations under FIFRA to make the uses safe.

Fourth, Petitioners' claim that EPA's prior practice has been to conduct a tolerance-by-tolerance analysis is wrong. Mot. at 16 (citing Seethapathi Decl. Ex. 4, Reiss Decl. ¶ 17). Petitioners base this assertion on the Agency's approach to

registering a new product under FIFRA—not the separate and distinct process for making a safety determination under the FFDCA. *See* Reiss Decl. ¶ 17 ("[T]he Agency routinely conducts assessments that presume what the use pattern will be upon a *registration decision*. This is fundamental to the Agency *registration process*.") (emphasis added). EPA has previously explained its position that the FFDCA "does not compel EPA to determine the appropriate subset [of tolerances] that would meet the safety standard." Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59608, 59675 (Nov. 18, 2009). Indeed, EPA's "general policy" when more than one tolerance is unsafe is *not* to independently select the subset of uses that meets the safety standard. *Id.*

Fifth, the PID was a *proposed* determination as part of a registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim (at 1), a final "finding that EPA's Designated Safe Uses are safe for everyone." *See supra* at 7; 87 Fed. Reg. at 11246. Some commenters, including cranberry and banana growers, argued that their crops should be included among the 11 considered uses; others, including advocacy and environmental groups, argued that a safety determination supporting even those limited 11 uses would contravene the available science. *Id.* at 11246, 11249. EPA has not yet fully considered these comments and will not issue a final interim decision until later this year. Kiely Decl. ¶ 9; *see also LULAC II*, 996 F.3d at 678. Contrary to Petitioners' claim (at 2,

11, 17), EPA did not make a final safety finding in the Final Rule or Denial Order for the subset of 11 uses. *See* 86 Fed. Reg. at 48333; 87 Fed. Reg. at 11241 ("[T]he Agency could support a safety determination for the very limited and specific subset of uses identified in the [PID]. The problem is that at the time of the final rule, the Agency did not have a basis for assuming that uses would be limited.").

Sixth, EPA could not have determined chlorpyrifos tolerances were safe based on the subset of 11 uses within the Ninth Circuit's 60-day deadline without, at a minimum, voluntary cancellation requests by all registrants of the other uses. 87 Fed. Reg. at 11246. The FFDCA does not provide an independent legal basis for EPA to selectively consider exposures associated with existing tolerances to ensure that "aggregate exposures" will be safe. Nor do Petitioners explain how the Court is to make a final safety finding for the 11 uses—which it must do to leave tolerances in place—when EPA has not done so. EPA did enter into good-faith negotiations with each of the technical registrants,[2] including Gharda, but none ever submitted a voluntary cancellation request under FIFRA to cancel other uses of chlorpyrifos. 87 Fed. Reg. at 11247-48. Nor did any registrants submit

[2] "Technical" or "manufacturing use products" are intended and labeled for formulation and repackaging into other pesticide products. *See* 40 C.F.R. § 158.300.

proposed revised labels that reflect cancelled uses, restrict remaining uses to certain geographic areas, and reduce application rates. *Id.* at 11246.

Instead, Gharda repeatedly sought unreasonable cancellation terms that could not be reconciled with EPA's obligations under the FFDCA. In its first post-*LULAC II* letter, Gharda stated that it was "willing to negotiate and execute an agreement with EPA" containing at least nine separate terms, including allowing continued uses on several other crops; phasing out the production, sale, and distribution for chlorpyrifos products for certain uses through 2026; and obtaining existing stock orders for additional time for those phased-out uses. Seethapathi Decl. Ex. 3, Ex. B at 1-2. In its second post-*LULAC II* letter, Gharda "commit[ted] to voluntarily cancel all currently approved agricultural uses" besides the subset of 11 uses, subject to nine other conditions, including allowing use of chlorpyrifos on cotton in Texas (which was not proposed in the PID) and the import of all finished technical product in the United States and overseas to be processed and sold for all currently registered uses. *Id.*, Ex. C at 1-2. In its final letter, dated July 6, 2021, Gharda proposed allowing the formulation and distribution for all current uses through June 2022 and the use of existing stocks through June 2023, instead of EPA's proposals of February and August 2022. *Id.,* Ex. H at 2; Kiely Decl. ¶ 18. EPA had concerns about, and did not agree to, those proposed terms because it could not make a safety finding for chlorpyrifos. Kiely Decl. ¶¶ 16-18. Without

voluntary cancellation requests in-hand from *any* registrants and with the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision based upon an assessment of the registrations that actually existed. 87 Fed. Reg. at 11248. Petitioners' suggestion (at 16) that EPA should have simply "adjusted" all chlorpyrifos registrations outside the subset of 11 uses ignores that involuntary cancellation proceedings can last up to two years. Kiely Decl. ¶ 26.

Finally, Gharda's suggestion that EPA did not permit it to meaningfully participate in the revocation process rings hollow. Since the petition to revoke chlorpyrifos tolerances was filed nearly 15 years ago, EPA has solicited comments on revocation multiple times. After years of administrative process in response to the 2007 petition, in which registrants participated, and in light of the scientific record EPA developed indicating chlorpyrifos is unsafe at current exposures, the Ninth Circuit said enough is enough and directed EPA to modify or revoke the chlorpyrifos tolerances within 60 days and without notice and comment. *LULAC II*, 996 F.3d at 702. No additional notice of its decision to revoke tolerances was required. *See* 21 U.S.C. § 346a(d)(4)(A)(i) (authorizing EPA to issue a "final regulation" without notice and comment in response to a petition to revoke). Gharda is not without a remedy. Gharda and the other registrants may at any time request voluntary cancellation or modification of their registrations and petition

EPA to establish new tolerances. Instead, Gharda is unjustifiably pursuing a stay of the revocation of tolerances for *all* uses.

C. The FFDCA does not require EPA to cancel uses before revoking tolerances.

Although the bulk of Petitioners' merits arguments focus on the subset of 11 uses identified in the PID, they ask the Court to stay the revocation of *all* tolerances until EPA issues an "appropriate" existing stocks order. Mot. at 6, 14. Petitioners fail, however, to explain how the Court is to conclude, as a scientific matter, that *all* uses are safe under the FFDCA. Instead, Petitioners point to the FFDCA's direction that "the Administrator shall coordinate such action with any related necessary action under [FIFRA]." Mot. at 15-16 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1). Thus, contrary to Petitioners' contention (at 21), the FFDCA does not require EPA to cancel registrations or address existing stocks before revoking tolerances. Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use "in a timely fashion." *LULAC II*, 996 F.3d at 704.

EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not

submitted. Kiely Decl. ¶ 26. Those proceedings will address existing stocks. *Id.* Petitioners apparently assume that they are entitled to lengthy existing stocks periods, but FIFRA permits the continued sale or use of existing stocks periods only if they are "not inconsistent with the purposes of this [Act]," 7 U.S.C. § 136d(a)(1), which specify no "unreasonable risk to man." *See supra* p. 3. Given the potential impacts to infants and children, a lengthy existing stocks period may not be consistent with FIFRA.

In sum, Petitioners have not demonstrated likelihood of success on the merits.

II. Petitioners have not demonstrated irreparable harm.

A party seeking a stay must demonstrate that the irreparable harm claimed "is certain and great and of such imminence that there is a clear and present need for equitable relief" to prevent irreparable harm. *Iowa Utils. Bd. v. FCC,* 109 F.3d 418, 425 (8th Cir. 1996). Monetary loss alone is insufficient, unless the loss threatens the very existence of the movant's business. *Packard Elevator v. ICC*, 782 F.2d 112, 115 (8th Cir. 1986) ("[E]conomic loss does not, in and of itself, constitute irreparable harm"); *see also Wis. Gas. Co. v. Fed. Energy Regul. Comm'n*, 758 F.2d 669 (D.C. Cir. 1985) (same). Petitioners must "substantiate the claim that irreparable injury is 'likely' to occur." *Packard Elevator*, 782 F.2d at 115. Petitioners have failed to demonstrate irreparable harm.

A. Growers have not demonstrated irreparable harm.

While Petitioners argue that vast numbers of family farms will incur severe economic losses, they do not establish that those losses are certain or are of a magnitude sufficient to warrant a stay.

Petitioners estimate losses of around $82 million for sugarbeet grower members alone and that these losses threaten the viability of those businesses. Mot. at 23. That figure dramatically overstates possible costs to family farms. *See* Decl. of Neil Anderson ¶ 20. EPA's expert economists estimate that total likely losses across all sugarbeet growers—taking into account both additional costs of alternatives and reductions in yield—are around just *ten percent* of Petitioners' estimate. *Id.* (potential costs of $2.2 to $31.5 million, with likely costs of $8.6 million); EPA Revised Benefits of Agricultural Uses of Chlorpyrifos (Nov. 18, 2020) ("Benefits Document") (Long Decl. Ex. E) at 48-49. In support of their claim that the losses threaten the viability of their businesses, Petitioners point only to a paragraph in a declaration on behalf of the American Crystal Sugar Company ("ACSC") claiming that impacts to its sugarbeet processing business would threaten the Company's existence. Mot. at 23 (citing Pets.' Att. 2, Hastings Decl. ¶ 27). ACSC's claim is based on the incorrect assumption that 20% of Minnesota and 10% of North Dakota sugarbeet acreage could be "lost." *See* Benefits Document at 49 (explaining percentages as acres *severely affected* by sugarbeet

root maggot rather than a percentage of *all sugarbeet acreage* throughout each state). EPA did not conclude that acreage would be "lost"; rather, EPA's analysis modeled yield losses of 45% for such affected acres. *Id.*; Anderson Decl. ¶ 24. Even if that assertion were correct, ACSC fails to explain why those reductions in yield during the pendency of this litigation would put the Company out of business, particularly when it has withstood similar variations in past years. Anderson Decl. ¶ 26.

Total estimated likely losses from reduced yield or increased costs of alternatives across the entire subset of 11 uses is around $53 million—or *just under 0.1%* of those growers' expected revenue. *Id.* ¶¶ 15-16. In addition, an EPA analysis of the impacts of revoking the tolerance found that, on the vast majority of farms, including small farms, losses are likely to be less than one percent of gross annual revenue. *Id.* ¶ 17. EPA estimated that only around 1,900 small farms, or 0.13% of all small farms growing crops, will experience losses greater than 3% gross revenue per-acre. *Id.* Even that number likely is an overestimate because growers produce multiple crops, including some that are not susceptible to pests controlled by chlorpyrifos. *Id.* ¶ 19; *see, e.g.,* Pet. Att. 2, Ex. H at ¶ 5 (sugarbeets are 22.5% of total acreage). And, if growers experience significant yield losses due to inadequate pest control, Petitioners have failed to allege that they will not be compensated by federal crop insurance for the majority of those losses.

Petitioners' alleged losses therefore do not rise to the level of harm justifying a stay.

Further, growers typically do not experience large pest pressures every year, or on every acre of their farm. For example, borers are not currently a major pest for cherries. Anderson Decl. ¶ 31. And, even in heavily infested peach orchards in the southeastern United States, only about 20% of trees are affected by borers. *Id.* ¶ 30; Benefits Document at 24. Thus, even though adequate alternatives are not available for use on peaches and cherries, allegations of tremendous harm to those growers are speculative.

Petitioners point to a lack of alternatives to chlorpyrifos, but this too falls short. In most cases, there are suitable alternatives to chlorpyrifos. *See* Anderson Decl. ¶ 27. In any event, these anticipated regulatory compliance costs are not the type of harm that courts recognize as warranting a stay—otherwise irreparable injury would essentially be read out of the standard in regulatory cases. *See, e.g., Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980) ("[I]njury resulting from attempted compliance with government regulation ordinarily is not irreparable harm.").

B. Gharda has not demonstrated irreparable harm.

Because Gharda does not claim that EPA's revocation of chlorpyrifos tolerances threatens the existence of its business, it has not shown irreparable

harm. *See Packard Elevator*, 782 F.2d at 115. Moreover, Gharda has failed to minimize its alleged economic harms. Gharda took a calculated business risk by increasing production of chlorpyrifos products in 2021 when the future regulatory status of chlorpyrifos was uncertain. 87 Fed. Reg. at 11266. That its gamble did not pay off does not constitute the type of harm that can form the basis for a stay.

Gharda also claims that it will experience reputational harm due to the stigma attached to EPA's purportedly "unfounded" statement that the revocation of chlorpyrifos will help to ensure children and others "are protected from the potentially dangerous consequences of this pesticide." *See* Seethapathi Decl. ¶ 51. Gharda's claim lacks merit. Although EPA's scientific analysis of chlorpyrifos is complicated, its conclusion is not: "Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270; *see also supra* pp. 8-9 (discussing potential impacts of chlorpyrifos to infants and children). Moreover, Gharda cannot distinguish reputational harm from the revocation versus harm from the Ninth Circuit's conclusion that existing chlorpyrifos exposures were unsafe for infants and children. *See CTS Corp. v. EPA,* 759 F.3d 52, 58 (D.C. Cir. 2014).

For these reasons, Petitioners have not shown irreparable harm absent a stay.

III. A stay is not in the public interest.

The public interest and balance of harms also weigh strongly in favor of denying Petitioners' stay request. *See Nken*, 556 U.S. at 435 (stay factors "merge when the Government is the opposing party"). Congress determined that the public interest here is safety and instructed EPA to revoke tolerances unless it concludes that current uses are safe. *See* H.R. Rep. No. 104-669(II) (July 23, 1996) (Ex. B) at 40 (replacing FFDCA requirement to consider "the necessity for production of an adequate, wholesome, and economical food supply" and "the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture" with a pure safety standard). Petitioners now ask this Court to do what Congress forbade: leave all tolerances in place even though the expert agency cannot conclude that they are safe. What is more, excusing Petitioners from complying with the Final Rule pending judicial review could result in harm to those exposed to chlorpyrifos through its continued use on food crops. That exposure through food is not the sole source of exposure does not diminish these harms: the FFDCA seeks to address their collective contribution, which cannot be addressed without regulating pesticide uses on food.

Granting Petitioners' stay request would also undermine judicial process and comity among sister circuits. Specifically, a stay would stand in considerable

tension with the Ninth Circuit's order to modify tolerances only if EPA finds they are safe.

CONCLUSION

For the foregoing reasons, Petitioners' motion should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 5,194 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ *Laura Glickman*
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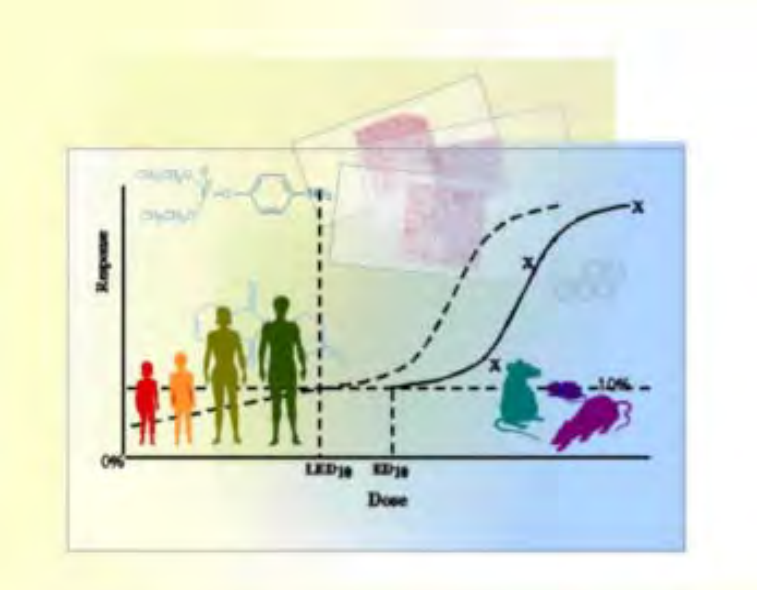
EXHIBIT A

Fax-On-Demand
Fax Number: (202) 401-0527
Item: 6043

General Principles For Performing Aggregate Exposure And Risk Assessments



Environmental Protection Agency
Office of Pesticide Programs

November 28, 2001

Table of Contents

ACRONYMS

ai	Active Ingredient
ARI	Aggregate Risk Index
CSFII	Continuing Surveys of Food Intakes by Individuals
DWLOC	Drinking Water Level of Comparison
FDA	U.S. Food and Drug Administration
FQPA	Food Quality Protection Act
FFDCA	Federal Food and Drug Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GIS	Geographic Information System
HED	Health Effects Division, Office of Pesticide Programs, USEPA
HHANES	Hispanic Health and Nutrition Examination Survey
LCO	Lawn Care Operator
MMPE	Milk, Meat, Poultry and Eggs
MRID	Master Record Identification
MOE	Margin of Exposure
NASS	National Agricultural Statistics Service
NHAPS	National Human Activity Pattern Survey
NHEXAS	National Human Exposure Assessment Survey
NHANES	National Health and Nutrition Examination Survey
NOAEL	No-Observed-Adverse-Effect Level
OPP	Office of Pesticide Programs, USEPA
ORD	Office of Research and Development, USEPA
PAD	Population-Adjusted Dose
PCO	Pest Control Operators
PDP	Pesticide Data Program
PHED	Pesticide Handlers' Exposure Database
RfC	Reference Concentrations
RfD	Reference Dose
RI	Risk Index
SAP	FIFRA Scientific Advisory Panel
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
UF	Uncertainty Factor
USDA	U.S. Department of Agriculture
USGS	U.S. Geological Survey

EXECUTIVE SUMMARY

EPA's Office of Pesticide Programs (OPP) is responsible for regulating pesticide residues in food under the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1996, Congress passed the Food Quality Protection Act (FQPA) which amended FFDCA. The FQPA amendments to the FFDCA directed OPP to consider "aggregate exposure" in its decision-making. Aggregate exposure and risk assessment involve the analysis of exposure to a single chemical by multiple pathways and routes of exposure. The pathways of exposure considered in this general principles document include the potential for pesticide residues in food and drinking water, as well as residues from pesticide use in residential, nonoccupational environments. The pathway of exposure refers to how human behavioral patterns potentially interact with pesticides in the environment. All potential, relevant routes of exposure are analyzed within an aggregate exposure assessment. These include the oral, dermal (absorption), and inhalation routes of exposure. Thus, OPP was required by the FQPA amendments to modify its exposure and risk assessment methods to consider that pesticide chemicals may enter the body through various pathways (through food, drinking water, and residential uses) and routes (ingestion, dermal, and inhalation).

In response to the FQPA mandates to consider aggregate exposure, OPP implemented "HED SOP 97.2 Interim Guidance for Conducting Aggregate Exposure and Risk Assessments (11/26/97)," which is commonly known as the Interim Guidance (USEPA, 1997e), in 1997 for assessing aggregate exposure and risk. This general principles document uses a mix of data as point estimates and data in a distributional form. According to the Interim Guidance, most frequently the "high-end" or "upper-bound" point estimates from the drinking water and residential exposure pathways are added to an estimate of food ingestion exposure from food (for acute exposures, generally the 99.9th percentile on the distribution of daily exposures). The Aggregate General Principles presented in this revised document support a different approach.

These general principles replace the Interim Guidance. They focus on describing principles to guide the way in which aggregate exposure and risk assessment may be performed when more extensive distributional data and more sophisticated exposure assessment, methods and tools are available. The current general principles document discusses the Interim Guidance methods, but emphasizes an expanded approach which looks beyond the Interim Guidance to encompass the use of distributional data for all pathways of exposure when data are available. A distributional data analysis (as opposed to a point estimate approach) is preferred because this tool allows an aggregate exposure assessor to more fully evaluate exposure and resulting risk across the entire population, not just the exposure of a single, high-end individual. The expanded general principles encourage assessment techniques which, using a combination of data, models, and reasonable judgements, represent each potentially exposed "individual" in the population over calendar time. This approach can generate reasonable estimates of risks across a population only if the exposure parameters

associated with each hypothetical individual are coherent, consistent, and logical. This means the hypothetical individual's temporal exposure characteristics, spatial exposure characteristics, and demographic and behavioral exposure characteristics should be consistent and reasonable for each type of individual, for each day in the assessment, over all days in the assessment. The use of distributional data sets which comprise the aggregate exposures to many individuals in the population of interest and the principle that the individual's aggregate exposure be consistent in temporal, spatial and demographic characteristics are two central components to this expanded aggregate exposure and risk general principles document. Using this approach OPP and others in the risk assessment community can move toward using a distribution of total aggregate exposures to many types of individuals potentially exposed in a population of interest.

A version of the Aggregate General Principles document was presented to the FIFRA Scientific Advisory Panel (SAP) in February of 1999. SAP member comments were incorporated into the general principles document where appropriate. On November 10, 1999 the availability of the draft "Guidance for Performing Aggregate Exposure and Risk Assessments" (commonly known as Aggregate Guidance) was published in the *Federal Register* (USEPA, 1999b; 64 FR 61343) and public comments were requested on the overall content of the document as well as seven specific questions. Based in part on the comments received, this science policy paper was revised and is now being issued in its revised format. In addition, OPP has prepared a separate Response-to-Comment document which specifically addresses comments received.

OPP anticipates that, as the scientific community conducts aggregate exposure and risk assessments following the principles in this document, new data sets and new models will be developed. It is important that quality and representativeness of any new data sets be evaluated, and that the details of any new models be transparent, including key assumptions. OPP intends to continue its practice of making its preliminary aggregate risk assessments for individual chemicals available for public review and comment and to seek external scientific peer review of significant changes in databases and assessment methodologies. Although this revised document is not being issued for another round of comment, OPP may revise and reissue this document periodically, as needed to update the document to reflect progress in improving aggregate risk assessment methodologies or changes made in response to peer review or public comment.

This revised document is organized to present an overview of aggregate exposure and risk assessment highlighting revised and expanded concepts. Section I describes the regulatory background of aggregate assessment, gives a brief introduction to the scope and organization of the document, and provides a review of some of the key terms and definitions in this document. Section II of the document provides a description of current practices and data sources utilized in conducting aggregate exposure analysis, including an explanation of the combination of probabilistic (food pathway only at this time) and deterministic types of exposure assessments. Section III provides a general framework and set of key concepts for the refinements put forth in the Aggregate General Principles. Pathway-specific considerations based upon the revised document are for performing aggregate exposure and risk assessment, expanding upon the Interim Guidance for Conducting Aggregate Exposure and Risk Assessment. Following this section, there are recommendations for future data and research needs (Section V) as well as an acknowledgment of the limitations in conducting aggregate exposure assessments (Section VI). The last section of the document, Section VII, describes approaches to model validation and verification, an important part of evaluating aggregate exposure and risk assessments, as assumptions embedded in any model and/or method and uncertainties and variability in the input data can be significant to the outcome of the assessment.

This general principles document for performing aggregate exposure and risk assessments is not meant to be comprehensive or to be interpreted as a prescriptive approach. Rather it articulates broad principles for consideration in the design of an aggregate risk assessment for a particular pesticide. Other factors, especially the exposure scenarios and the extent and quality of a variable data, will also influence significantly the specific approach. OPP will evaluate any and all methods or models developed to assess aggregate exposure.

The current document is one of a series of documents that OPP is issuing with specific emphasis on addressing new facets of the risk assessment process as required by FQPA. In particular, the current document relies heavily on the *Exposure Factors Handbook* (USEPA, 1997b); the draft "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" (commonly known as the Draft Residential SOP's); (USEPA, 1997a); the Interim Guidance (USEPA, 1997e); and "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs" (USEPA, 1998c). These earlier documents provide substantial background to the information provided. This science policy paper is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this document is not binding on either EPA or any outside parties. Although this document provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should

be abandoned. Finally, EPA expects to update this science policy paper in the future as necessary to reflect significant developments in the scientific approach or policy positions that affect how the Agency performs aggregate risk assessments.

I. Introduction

A. Legal Background

Pesticides are regulated in the U.S. under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetics Act (FFDCA). In 1996, Congress passed the Food Quality Protection Act (FQPA) which amended both FIFRA and FFDCA. Through these statutes, OPP evaluates risks posed by the use of each pesticide to make a determination of safety.

The FQPA amendments to the FFDCA directed OPP to consider "aggregate exposure" in its decision-making. "Aggregate exposure" refers to the combined exposures to a single chemical across multiple routes (oral, dermal, inhalation) and across multiple pathways (food, drinking water, residential). Prior to the FQPA amendments to FIFRA and FFDCA, OPP generally performed its risk assessments and established the safety of tolerances by examining each pathway separately, i.e., exposures to a pesticide through the food, drinking water, and residential pathways were each assessed independently and no concerted effort was made to evaluate potential exposures through all three pathways simultaneously. As amended by FQPA, Section 408(b)(2)(ii) of FFDCA requires OPP to make a finding for each tolerance or tolerance exemption "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." Section 408(b)(2)(C)(ii)(I) of FFDCA states that the Agency must find "there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues." Finally, Section 408(b)(2)(D)(vi) directs OPP, when making tolerance decisions, to consider "aggregate exposure levels...to the pesticide chemical residue...including dietary exposure and exposure from other non-occupational sources."

The FQPA-amended FIFRA also speaks to the requirement that OPP evaluate risks on an aggregate basis. Under FIFRA, OPP may register a pesticide for sale and distribution only if the use of the pesticide will not cause "unreasonable adverse effects on the environment." The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide; or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of FFDCA (21 U.S.C. 346a.). Thus, the standard for making decisions whether to register or continue registration of a pesticide for food-use must satisfy the standards in the FFDCA.

B. Scope and Organization of Document

Given the above-discussed statutory requirements imposed by FQPA and OPP's desire to better evaluate exposure and risks of pesticides to the population, OPP has developed the current general principles document for performing aggregate exposure and risk assessment. This document describes the overall framework and the general principles for performing an aggregate exposure and risk assessment. Aggregate exposure and risk assessment involve the analysis of exposure to a single chemical by multiple pathways (e.g., food, drinking water, and residential uses) and routes (ingestion, dermal, and inhalation).

In this general principles document, OPP proposes an approach to assessing aggregate exposure and risk for the total population. This approach relies on characterizing a large, representative group comprised of hypothetical, potentially exposed "individuals," where an "individual" is represented by a set of data or scientific judgements brought together from a variety of data sources. For example, an assessor may use currently available data sources such as the U.S. Census or the USDA's Continuing Survey of Food Intake of Individuals (CSFII) (USDA, 1992), which provide characteristics of each survey respondent, e.g., gender, geographic location, time of interview (consumption). This information on an "individual" can be used to match other exposure-related characteristics from other databases or data sources back to the individual, such as probability of application of a pesticide in the home or likelihood of being served by a community water system. As this process of identification and combination of data sources proceeds and is refined, assessors will be able to combine and connect data sets or other reasonable judgements together to represent coordinated descriptions of potentially exposed hypothetical "individuals."

There are a number of acknowledged limitations to this approach. For example, there is currently a limited amount of data and information concerning

residential exposures or standard methodologies for matching characteristics to ensure the assembly of a reasonably-representative population, or collection of "individuals." The Aggregate General Principles do not fully investigate the data needed to describe the interdependencies and linkages between and among pathways of possible exposure. OPP realizes that the investigation is on-going and that further work in this area will improve and refine aggregate exposure analyses.

It is also important to note that risk assessment and risk management are considered separate activities. Risk assessment involves the determination of the hazard potential, dose-response relationship, exposure potential of pesticides in the environment, and quantitative or qualitative characterization of risk. Risk management relates to the ways in which those risks may be mitigated or eliminated and includes such tools as tolerance revocation, changes to the agricultural or residential use pattern, or the application of requirements that those who apply the pesticide are trained in risk-reducing procedures. The revised and expanded Aggregate General Principles apply only to the risk assessment process, and not to the risk management process. It is important to note, too, that the approach discussed in this document does not support the use of any one particular percentile of exposure in regulatory decision-making, e.g., 95th percentile of exposure. This is considered to be a risk management issue that is informed but not determined by the level of refinement and the quality of the data used in the risk assessment. In any case, OPP will review all data included in an aggregate exposure and risk assessment and determine, on a case-by-case basis, the percentile of exposure to be used in making regulatory decisions for a particular chemical.

OPP acknowledges that exposures to pesticides may also occur from nonpesticidal uses of chemicals, e.g., in household products such as soaps, toothpaste, or paints. However, at this time the tools and methods available to estimate such exposure are extremely limited. OPP will work to develop science policy detailing the way in which aggregate exposure assessment may be performed for -pesticidal uses of a the data needed to make the assessment. At this time, data are limited for exposure estimation, and, therefore, risk assessment for nonpesticidal uses of pesticide chemicals is conducted on a case-by-case basis. Although this paper does not directly address the aggregate assessment of nonpesticidal uses of pesticide chemicals, OPP sees no intrinsic limitations which would prevent the described methodology from being adapted to include exposure from nonpesticidal chemicals in an aggregate exposure assessment.

This document is organized to present an overview of aggregate exposure and risk assessment highlighting revised and expanded concepts. The current section (Section I) describes the legal background of aggregate assessment, gives a brief introduction to the scope and organization of the document. The document also provides a description of current practices and data sources

utilized in conducting aggregate exposure analysis (Section II), including an explanation of the combination of probabilistic (food pathway only at this time) and deterministic types of analysis. This section includes a pathway-specific set of comments on important points concerning the current methods for performing aggregate exposure and risk assessment. Section III provides a general framework and set of key concepts for the refinements to aggregate exposure and risk assessment put forth in this general principles document. Pathway-specific considerations based upon these revised general principles are also examined in this section. Section IV presents a standard procedure for performing aggregate exposure and risk assessment, expanding upon the Interim Guidance. Following this section, there are recommendations for future data and research needs (Section V), as well as an acknowledgment of the limitations in conducting aggregate exposure assessments (Section VI). The last section of the document, Section VII, describes approaches to model validation and verification, part of evaluating aggregate exposure risk assessments, as assumptions, uncertainties and variabilities embedded in any model and/or method can be significant to the outcome of the assessment.

This document explains the definition and implementation of aggregate exposure analysis at OPP and expands upon the Interim Approach Paper for the March 1997 FIFRA Scientific Advisory Panel (SAP) (USEPA, 1997c). The pursuit of information, methods, and results of aggregate exposure assessment described in this paper allows OPP to realistically evaluate the potential exposure of individuals and the population to pesticides in the environment. OPP strongly believes that these methods, expanding upon the Interim Guidance for assessing the aggregate exposure will substantially improve the protection of public health, especially infants and children. Nonetheless, this concept document for performing aggregate exposure and risk assessments is not meant to be comprehensive or to be interpreted as a prescriptive approach. OPP will evaluate any and all methods or models developed to assess aggregate exposure. However, the framework, principles, and contents of the steps presented in this document should be considered in any aggregate exposure and risk assessment.

II. Data Inputs for Aggregate Exposure Assessment and Methods of Aggregation

Prior to the enactment of FQPA, when performing risk assessments, OPP has treated exposures to pesticides from different pathways as independent events i.e., OPP only analyzed each individual's exposure to one pesticide via a single pathway. In reality, however, exposures to pesticides do not occur as single, isolated events, but rather as a series of sequential or concurrent events that may overlap or be linked in time and space. By directing OPP to perform aggregate assessment (single chemical, multiple pathway/routes), Congress intended that OPP's exposure and risk assessments would move closer to describing the pattern of exposure actually encountered by individuals in the real world.

Since 1996, OPP has taken a number of steps to enhance its risk assessment capacity to respond to the FQPA mandate to consider aggregate exposure and risk in making decisions about the safety of tolerances. In 1997, OPP issued "HED SOP 97.2 Interim Guidance for Conducting Aggregate Exposure and Risk Assessments (11/26/97)," commonly known as the Interim Guidance (USEPA, 1997e). Since then OPP has worked to develop more sophisticated methods of estimating the combined exposure to pesticides by different routes and pathways. This paper explains OPP's current approach to aggregate risk assessment.

OPP will determine its approach to the assessment of each pesticide's aggregate exposure and risk on a case-by-case basis. OPP will always start with estimates of exposure by each relevant pathway–food, drinking water, and residential. As necessary to determine whether potential exposures are acceptable, OPP may perform multiple aggregate exposure assessments to refine exposure estimates. To the extent data permit, there are two basic ways to refine an assessment: employ improved data on exposure or conduct more sophisticated analysis of the data.

The initial aggregate risk assessment uses available data (which may be limited in scope), together with assumptions designed to be protective of public health and standard analytical methods, to produce a separate estimate of exposure to a pesticide, for a highly exposed subgroup of the general population, for each potential pathway and route of exposure. Then, as described more fully in the Interim Guidance, OPP calculates potential aggregate exposure and risk by combining point estimates that reflect an upper-bound or high end of exposure for each route / pathway. The assumption implicit in this approach is that individuals could encounter the high end exposures from different pathways at the same time and place. OPP believes, however, that the co-occurrence of high end food, drinking water and residential exposure scenarios will often be impossible or, at best, highly unlikely. For example, infants typically experience higher food and water exposures, while adults applying residential use pesticides account for many of the high end residential exposures. Although temporal and geographic co-occurrence of high food and water residues with

residential use patterns involving high exposure is theoretically possible, OPP thinks it is demographically unlikely because infants do not apply pesticides and adults do not have the same food and water consumption patterns as children. In other words, there will be very few, if any people who actually experience the high levels of exposure estimated by simply adding the high end values for each pathway. Thus, using this methodology, OPP is confident that the combined point estimates will overstate, sometimes significantly, the potential exposure that the vast majority of the general population group actually receives. The degree of overestimation decreases, however, as the refinement of the individual pathway exposure estimates improve. The primary advantage of a highly conservative, deterministic assessments is that they require relatively fewer data and analytical resources, and less time to conduct. Often, an aggregate risk assessment of this type is sufficient to demonstrate that proposed and approved pesticide uses are acceptable.

If the initial aggregate exposure assessment suggests that the proposed and approved uses of the pesticide may have unacceptable risks, it may be possible to refine the initial aggregate risk assessment. In the past, OPP's approach was to refine the estimates of the exposure by one or more of the different pathways; such refinements typically require considerable additional data. For example, OPP might use a point estimate from a Tier3 Food analysis in place of a value taken from a Tier 2 Food assessment. Or, OPP might develop residential exposure estimates using appropriately representative biomonitoring data instead of the values generated by using the Draft Residential SOP's. In effect, the refinements allow OPP to provide a more accurate aggregate exposure assessment, and the refinements may show that estimated exposure would be acceptable.

Alternatively, OPP could analyze the available data in a different manner, i.e., by using probabilistic techniques to combine exposures by different pathways. In order to combine exposure estimates across pathways using probabilistic techniques, OPP would need the capability of portraying exposure via each pathway as a distribution of potential exposures in the population. This is possible only when OPP has a representative distribution of data for one or more of the critical input values in the pathway exposure assessment, e.g., a database showing the distribution of pesticide residues in surface water or information on the application rate and frequency of use of a residential pesticide.

The following subsections present an overview of the methods used to assess exposure to pesticides by different pathways–in food, in drinking water, and from residential use. The ideas presented can be considered to apply to any aggregate exposure and risk assessment, regardless of the level of sophistication of the method of aggregation. Relevant points from the toxicological endpoint selection process are also described since pathways and routes are only aggregated when they share a common toxic effect. This information is presented since it is important to first fully understand the data sources, model capabilities and limitations, and robustness of data available for each of the three pathways of exposure upon which the revised approach expands. As the level of sophistication of aggregation increases, data input types and methods may also be augmented in quality and quantity.

A. Deterministic vs. Probabilistic Treatment of Data in Aggregate Exposure Assessments

Before considering the ways in which aggregate exposure and risk are currently assessed and data inputs are derived, it is important to understand deterministic and probabilistic treatment of data. A deterministic approach uses a point estimate from a data set, e.g., a single maximum value or an average value, to represent an input variable in the exposure model. This approach does not consider the range of potential exposures incurred by members of a population and does not describe the potential or probability of exposure to individuals within a population. Rather, the deterministic approach produces an output value that represents the potential exposure or risk of a group; depending on how the estimate was generated, the output value may reflect a “central tendency,” a “high-end,” or an “upper-bound.” In contrast, a probabilistic approach uses the full range of the data and produces a distribution of values as an output.

Currently, there are three possible combinations of data types in performing an aggregate exposure and risk assessment. First, an assessment could be entirely deterministic, i.e., the level of exposure for each pathway is estimated using the available data to produce point estimates. Second, the three pathways considered in aggregate exposure assessment may include both probabilistic and deterministic assessments of exposure, the former describing exposure as a distribution for a given population, and the latter utilizing point estimates to calculate a single estimate of exposure. Typically, the food exposure pathway for a single day is estimated on a population basis using probabilistic techniques based on distributions of residue and consumption data for specific food items, while exposure by the residential and drinking water pathways are presented as point estimates. Third, all three pathways might be described using probabilistic techniques. Clearly, because all pathways are more fully described, the latter approach provides the assessor with a better sense of the sources of variability and uncertainty in the assessment. In this way, too, an

assessor can gain a clearer picture of where additional data would be most useful in further refining risk estimates. On the other hand, the first two approaches generally require fewer data and involve less analytical resources, with the result that assessments may be completed more quickly. Section IV below describes considerations that may be helpful in guiding the choice of the type of analysis of aggregate exposure.

B. Aggregate Exposure and Risk Assessment: Current Practice

In 1997, OPP began conducting its aggregate exposure and risk assessments using procedures outlined in the Interim Guidance (USEPA, 1997e). The Interim Guidance was developed from material presented to the SAP in March 1997. This document described factors to consider when aggregating exposures or risks and methods for using toxicity endpoints in the aggregate risk assessment, among other things. The Interim Guidance is briefly summarized here; however, specific steps are not provided.

The Interim Guidance described five general durations of exposure used for the different pathways under consideration. They were:

- acute (relevant for one-day exposure scenarios specific to the food and water pathways, and reflects distribution of daily food consumption and daily water residue values);
- short-term (relevant for one- to 30-day exposure scenarios, which assumes average food and average water exposure and combines this with exposures specific to short-term residential pathway);
- intermediate-term (relevant for 30- to 180-day exposure scenarios, which assumes average food and average water exposure and combines this with exposures specific to intermediate-term residential pathway);
- chronic/long-term (average food and average water exposures combined with relevant residential exposures for aggregate exposures for greater than six months in duration); and
- cancer (average food and average water and residential exposures relevant for lifetime assessment) using the Q_1* approach.

OPP's current approach to assessing aggregate risk is in transition, contains many elements of the approach described in section II of this document. The methodology currently used for aggregate risk assessment varies with each

specific chemical and depends on the types of use patterns for the pesticide, the extent and quality of data available, and the level of refinement needed for the assessment. In general, OPP's aggregate assessments incorporate exposures by all pathways–food, water and residential–and consider, as appropriate, multiple time-frames. In addition, to the extent possible, OPP combines the available exposure information using probabilistic techniques.

Under current practice, exposure scenarios which result in negligible exposure may be considered for elimination from the assessment. However, this should be done cautiously because the final exposure which is analyzed in the assessment may be the accumulation of many small exposures from many pathways. Resources might be saved by excluding unimportant exposure scenarios or pathways (e.g., those that do not contribute appreciably to the total exposure) from full probabilistic analyses or from further analyses altogether. This concept is not meant to be used to minimize potential exposures but to conserve resources to investigate those potentially most significant. Unimportant parameters may be excluded from full probabilistic treatment, and for important parameters, empirical distributions or parametric distributions may be used. In all cases however, OPP believes that numerical experiments should be conducted to determine the sensitivity of the output to different parameters and assumptions.

C. Toxicological Endpoint Selection: Current Practice

The proper selection of the hazard endpoint for each route of exposure is essential to the accurate performance of aggregate exposure assessment. In general, an aggregate risk assessment should match the anticipated route of exposure with appropriate toxicity studies performed by the same route. When assessing exposures from food and drinking water, the oral route is of concern and, therefore, an oral toxicity study is appropriate for use in defining the hazard endpoint. When reviewing exposure potential from the residential (nonoccupational) use of a pesticide, exposure may occur by the oral, dermal, or inhalation routes, or by some combination of the three routes. Toxicity studies by these routes would be optimal. Where route-specific data are not available, route-to-route extrapolation may be necessary.

In addition to the selection of an appropriate hazard endpoint for each route of exposure (e.g., oral, dermal, inhalation), an aggregate risk assessment should attempt to match the anticipated frequency and duration of exposure with toxicity studies that reflect comparable timing of exposure. For example, if an effect occurs only after several days of chemical dosing (of animals), it would be inappropriate to compare the estimated exposure over a single day with the exposure associated with an effect which requires multiple days to develop. Rather, a sustained period of continued exposure, among other things, would be necessary to indicate that there is a potential for an adverse effect in humans. Similarly, a toxic effect that is established following a single dose or one day's exposure may prescribe that exposure be evaluated over the time period of a single day. As appropriate the matching of hazard endpoints and exposure patterns will include consideration of available data on pharmacokinetics and internal dose. OPP anticipates that multiple aggregate exposure and risk assessments may be performed per chemical under review based upon different toxicological endpoints evaluated.

D. Food Exposure Assessments: Current Practice

The primary source of food consumption data used in dietary risk assessments is the CSFII. The CSFII is particularly well suited to the conduct of national level dietary risk assessments because it is statistically designed to sample individuals of all ages and major ethnic subgroups to permit a reflection of the appropriate demographics. It is also balanced so that the national estimate of consumption is not biased by seasons of the year or regions of the country. As subsequent surveys are translated into foods as eaten for use in risk assessment, they will be used to update the dietary risk assessment process. OPP's assessments will incorporate the latest CSFII data (1994-1996) and the Children's Supplemental survey of 1998 beginning in 2001.

Data on the residues of pesticides in foods are obtained from a variety of sources. Traditionally, the primary source of residue data in foods has been field trial data which must be submitted in support of the registration and reregistration of a pesticide. These data overestimate the residues that are likely to occur in food as actually consumed because they reflect the maximum application rate and shortest preharvest interval allowed by the label. Data that are more reflective of residues on foods as consumed are often available from monitoring data in which food samples are obtained closer to the dinner table in the chain of commerce. These data may come from federally-conducted surveys such as the Pesticide Data Program (PDP) conducted by the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) Surveillance Monitoring data or from market basket studies that are typically performed by registrants. These data generally provide a better characterization of pesticide residues in or on foods consumed by the U.S. population.

Food exposure scenarios are typically evaluated for multiple time-frames: acute (one-day), chronic (several months to several years), and, in the event a pesticide has carcinogenic potential, lifetime exposure. When estimating exposure for both acute and chronic time-frames, OPP uses a series of refinements to reduce conservatism and to better reflect the actual exposure. Advancing through the refinement process requires additional use-related, and other data concerning each commodity. In most cases, refinements may be possible for some proportion of the commodities undergoing evaluation, but not for others. In such cases, deterministic estimates may be made for some food commodities in the assessment and more refined probabilistic assessments using distributional data sets may be used for other commodities and combined with the point estimates from deterministic assessments.

The approach to refining an acute dietary (food only) risk assessments is outlined in a previously released policy document–"Interim Office Policy for Performing Acute Dietary Risk Assessment" (USEPA, 1996). OPP defines Tiers 1 and 2 as using pesticide residue data on foods as point estimates in a deterministic assessment and Tiers 3 and 4 using distributions of pesticide residue data in a probabilistic assessment. A Tier 1 or initial range of refinement for food exposure assessment uses a single, high-end point residue estimate (tolerance) and a distribution of consumption data to provide a single, upper-bound (worst-case) point estimate of acute exposure. Tier 2 is the same as Tier 1, except that it uses a single, average residue data point (point estimate) for commodities which are typically mixed or blended. It provides a more realistic estimation of exposure than Tier 1 by considering average anticipated residues for food forms that are typically widely mixed or blended prior to consumption (e.g., corn oil from field corn). Tier 3 uses a distribution of residue data points (adjusted to include true zero values to reflect the percent of crop which is not treated) as well as a distribution of consumption data points. Tier 4 requires even more extensive data than Tier 3 (e.g., single-serving market basket surveys, cooking studies, etc.), but provides the most representative exposure picture (USEPA, 1996).

Chronic food exposure and risk assessments may also be refined to produce better estimates. All Tiers of the chronic assessment produce estimates of dietary (food only) risk which are based on average consumption of foods (which may be categorized by population and age and other subgroups) and average residue concentrations in specific foods. Chronic assessments currently conducted by OPP are deterministic. Tier 1 of a chronic food exposure and risk assessment uses tolerance level estimates of the magnitude of the residue and assumes that 100% of the crop is treated. Tier 2 is the same as a Tier 1 chronic food assessment, but data on the national percent of the crop treated is incorporated into the assessment. Tier 3 uses average residues from field trials or monitoring data, incorporates the percent of the crop which is treated, incorporates commercial processing factors, and uses refined livestock burden and milk, meat, poultry and eggs (MMPE) residue values. A Tier 4 food exposure and risk assessment may use any combination of market basket survey data (as average residue values) and incorporate cooking, residue decline, and residue degradation information, if available.

E. Drinking Water Exposure Assessments: Current Practice

To estimate aggregate exposure to pesticide residues in drinking water, OPP uses the general policy outlined in the "HED SOP 99.5 Updated Interim Guidance for Incorporating Drinking Water Exposure into Aggregate Risk Assessments" (USEPA, 1999a) and updated in the document "Standard Operating Procedure (SOP) for Incorporating Screening-Level Estimates of Drinking Water Exposure into Aggregate Risk Assessments;" draft document (USEPA, 2000a). The registered uses and the potential for a pesticide to contaminate surface and groundwaters are considered initially. If the use pattern and potential to contaminate water resources are such that there is no reasonable likelihood of transport to or contact with surface or groundwaters, OPP concludes the pesticide will not impact drinking water residues, and exposure and risk to the pesticide in water are not included in the aggregate assessment. For example, this would be the case for pesticides exclusively registered as baits or seed treatments and pesticides with import tolerances only.

If a pesticide has any potential to contaminate water resources based on use patterns, OPP uses water quality models to estimate the concentration of the pesticide that could run off into surface water or leach into shallow groundwater. The concentration estimates generated from the models are considered to be upper-bounds on pesticide concentrations in drinking water obtained from surface and groundwater sources. OPP then calculates a DWLOC (Drinking Water Level of Comparison) which is the highest concentration of a pesticide in drinking water that would be acceptable (i.e., produce total exposure equal to the population-adjusted dose or PAD) considering the estimated exposure to that pesticide from other sources (i.e., food and residential use). Separate DWLOCs

are calculated for different exposure durations and age groups where warranted, e.g., for acute (one-day), or for chronic (long-term) exposures. OPP compares the model-generated concentration estimates for a pesticide in ground- and surface water to the DWLOC. If the model-estimated concentrations in ground- and surface waters are less than the DWLOC, OPP concludes with reasonable certainty that residues of the pesticide in drinking water from present uses do not contribute towards an aggregate level of exposure that exceeds a risk level of concern.

If the model estimates are greater than OPP's levels of comparison for drinking water (DWLOC), OPP refines its model estimates using more realistic information/assumptions and compares the refined estimates to levels of comparison for drinking water again (USEPA, 2000a). If the model estimates still exceed OPP's levels of comparison (DWLOC) for the pesticide in drinking water, OPP may obtain available water quality monitoring data for the pesticide, and conduct an in-depth review of the data to determine if they are acceptable and reliable for use in quantitative drinking water exposure and risk assessment. Some of the data sources reviewed include: (1) prospective monitoring studies designed to track a pesticide's movement into surface or groundwater from the point of application; (2) retrospective monitoring studies designed to provide information on general pesticides occurrence (examples include U.S. Geological Service (USGS), National Water Quality Assessment Program (NAWQA) database on ambient surface water and some groundwater), data collected under the Safe Drinking Water Act (SDWA) for approximately 25 pesticides in finished drinking water, data collected under the EPA National Well Survey (1990); and (3) pesticide specific data as collected by registrants (examples include the Acetochlor Registration Partnership, and surveys for atrazine in drinking water).

If the monitoring data are suitable, they may be used to calculate aggregate exposure for use in a human health risk assessment. Average annual and maximum (peak) or high end concentration values (point estimates) from localized monitoring data for the pesticide may be used in deterministic chronic and acute exposure assessments, as appropriate, i.e., usually average values are used in assessments concerned with exposures greater than one day, and maximum or high end values are used in exposure assessments of one day's duration.

If the available water quality models' estimates are equal to or exceed OPP's DWLOC, and no appropriate monitoring data are available, OPP considers the entire risk picture for the pesticide and determines the appropriate action. That is, if exposure to the pesticide is above levels of concern from food and residential exposures, and drinking water impacts are indicated to be potentially significant by the model estimates, a risk management decision may include a requirement for monitoring data to assess the pesticide's presence in drinking water, or various other risk management options. Also, for those pesticides that fail the screening Tiers and require detailed risk assessments, the preferred approach to the dietary (food + drinking water) portion of an aggregate exposure assessment is to combine a probabilistic drinking water exposure assessment with a probabilistic food exposure assessment.

F. Residential Exposure Assessments: Current Practice

Currently, OPP uses the draft "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" (commonly known as the Draft Residential SOP's) (USEPA, 1997a) as guidance for conducting estimates of residential exposure. These SOP's identify common (approximately 13) pesticide use patterns/use sites (e.g., treatment of residential lawns, garden plants, etc.) that result in residential exposures. Each of these residential activities/use sites is further divided into handler and postapplication categories. ("Handler" exposures may occur when individuals mix, load, or apply a pesticide; individuals could incur "postapplication" exposure either as bystanders affected by the application of a pesticide or when they enter a treated site.) These are further divided by age group (e.g., adult, toddler, etc.), route (oral, inhalation, dermal), and specific activity (e.g., incidental ingestion of soil, incidental ingestion from hand-to-mouth transfer). As an example, the left-hand side of Figure 1 illustrates these pathways and routes for residential lawns. These SOP's produce a point estimate of exposure for each assessed scenario.

The basic steps in performing a residential assessment are as follows:

- identify formulations, application rates, and sites of application (from labels);
- identify method of application;
- determine magnitude of exposure by route for the applicator;
- identify postapplication exposure scenarios;
- determine magnitude of postapplication exposures (accounting for overall residues and dissipation);

- determine duration of exposure (short-term, intermediate-term, and long-term).

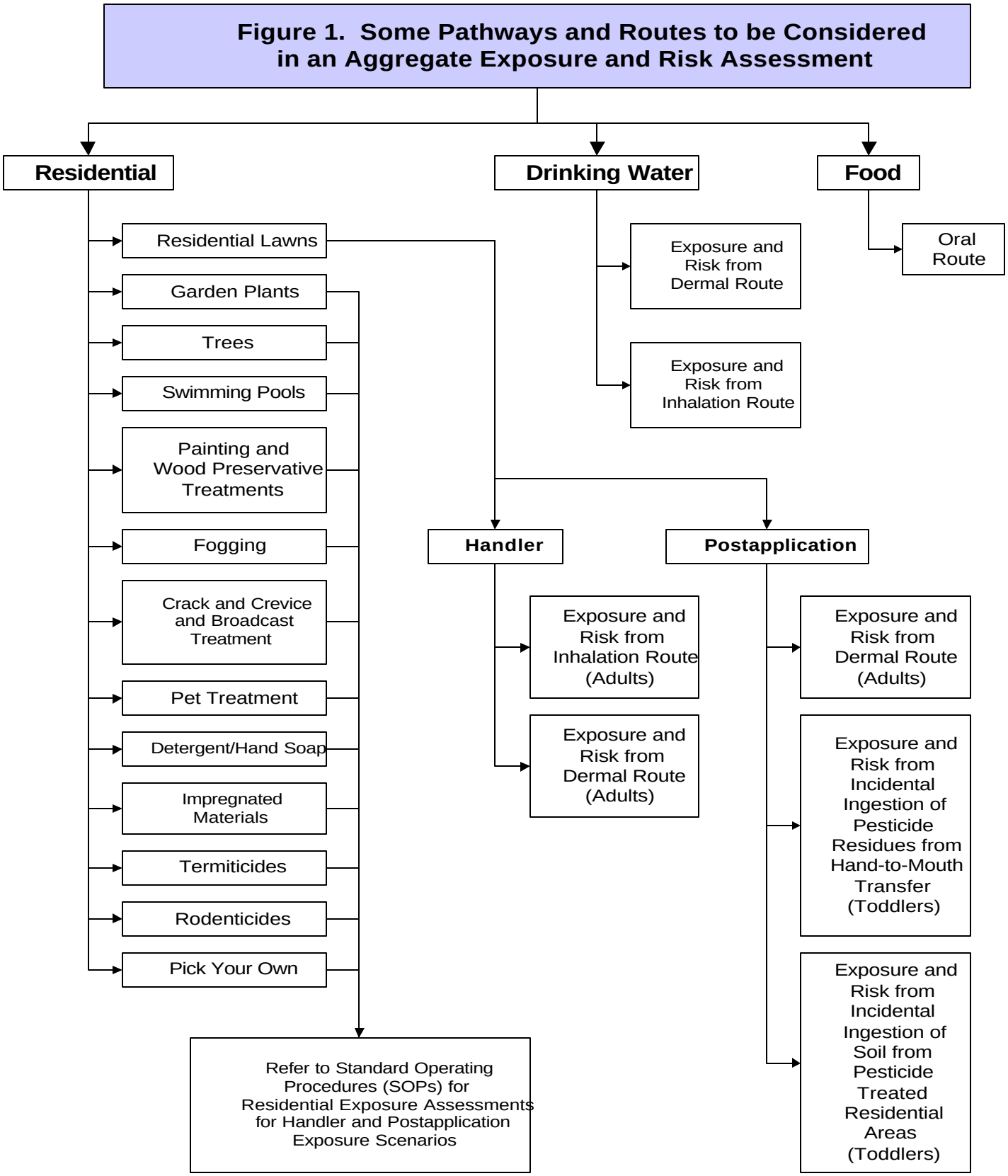
Additional details on the residential analytical methods, assumptions, and default values are described in the Draft Residential SOP's (1997a). Note that the SOP's are undergoing revision and will be released in an updated form.

Useful data for residential assessments are available from several sources. Data addressing nondietary exposure have traditionally been required (under the Series 875 Occupational and Residential Exposure Test Guidelines Group A–Applicator Exposure Monitoring Test Guidelines and draft Group B–Post Application Exposure Guidelines) (USEPA, 1998a; USEPA, 1987) when certain toxicity and exposure criteria are met. Acutely toxic compounds in Acute Dermal Toxicity Category I and Acute Toxicity Category II, are triggers for applicator exposure and postapplication exposure monitoring data requirements, respectively. Other adverse effects such as developmental or neurotoxicity are also considered, if results of those studies show adverse effects.

Other sources include proprietary data submitted to the Agency to support residential uses of pesticides, and in a few cases published studies. However, for most nondietary exposure assessments, surrogate data and screening-level (Tier I) assessments presented in the Draft Residential SOP's (USEPA, 1997a) will be used.

If the estimates of residential exposure in combination with estimates of food exposure exceed the PAD or RfD, OPP determines the appropriate regulatory action. That is, if food and residential exposures are above the level of concern for a pesticide, a risk management decision may include a requirement for additional data and/or various other risk management options to reduce risk to acceptable levels.

Figure 1. Some Pathways and Routes to be Considered in an Aggregate Exposure and Risk Assessment



III. Framework for Expanded Aggregate Exposure and Risk Assessment

The previous section provided a brief overview of the Interim Aggregate Guidance and illustrated some of the concepts which apply to both the interim and expanded approaches to aggregate risk assessment. This Section III details some of the specific characteristics of the revised (expanded) general principles. This document is meant to provide a framework for future aggregate exposure and risk assessment. Future assessments should be based on assessing exposure to an individual in the population and then assessing exposure to the population (or subpopulation) as a whole. This section describes the key concepts and definitions that are important to understanding the expanded approach to aggregate exposure and risk assessment.

Since pesticides are used in a wide variety of ways in numerous locations, there is no simple approach to describing which exposure scenarios should comprise a group of individual aggregate exposure estimates nor any universal standard for the types and quality of data required for any set of given exposure scenarios. Therefore, exposure analysts are expected to take into appropriate consideration many case-specific pieces of information and employ suitable judgement concerning the use of data in the development of aggregate exposure and risk assessments. Consequently, a specific step-by-step set of instructions is not presented.

While current and revised practices for performing aggregate exposure and risk assessment use the same data sources and inputs, the same data quality standards, and the same pathways of aggregation (food, drinking water, and residential), these general principles describe new ways to frame the data and to combine data from existing sources. Generally, OPP envisions that the aggregate exposure assessment process begins with the identification of the toxicological endpoint(s) of concern for a particular chemical assessment; proceeds toward the identification of possible exposure scenarios (e.g., based upon label use patterns) and assigns certain toxicological endpoints for each route of exposure of concern in the aggregate assessment; and, finally, defines a series of hypothetical, potentially exposed “individuals” by bringing together data sets or a series of professional judgements relating to the aggregate exposure assessment under consideration (toxicological endpoint, duration of exposure, exposure scenario). This is done by appropriately combining information about a potentially exposed “individual’s” demographic (e.g., age, gender, and racial/ethnic background), temporal (season), and spatial (region of the country) characteristics throughout the analysis in a manner which maintains the consistency of the individual. In this way, the analysis is not limited to individuals with only certain predefined characteristics, but rather utilizes data representing the entire distribution of possibly exposed “individuals” to develop not only the “average”or the “high-end” exposure value (“individual” as a point in time and space), but the entire distribution for evaluation. It is important to note that neither the current, interim practices for performing aggregate

exposure and risk assessment, nor the revised and expanded approach discussed in this document suggest the use of any one particular percentile of aggregate exposure for use in regulatory decision-making, e.g., 95th percentile of exposure. OPP will review all data included in an aggregate exposure and risk assessment and determine, on a case-by-case basis, the percentile of exposure to be used in making regulatory decisions for a particular chemical.

A. Expanded Method of Aggregation and Key Concepts of Revised Approach

The revised approach to aggregate exposure and risk assessment focuses on the potential exposure to a single chemical by multiple routes to individuals in a population. A fundamental difference between the current and revised approach to aggregate exposure assessment is the principle that exposure occurs to each individual in the population, individual by individual, and that significant variation or differences among individuals based on exposure-related characteristics such as age, gender, and geographic location should be captured in an aggregate assessment. The expanded approach will consider consistent spatial, temporal, and demographic/behavioral factors as well as linkages among product uses and overlapping exposures in developing a population-based distribution of individual exposures. By probabilistically considering these exposures on an individual-by-individual basis, combining these exposures into a population-based distribution, and examining exposures to individuals on a collective basis, the risk assessor is able to provide the risk manager with more realistic information on the distribution of exposures in the total population and the characteristics of and reasons behind any high-end exposure estimates.

Under this new, expanded approach, aggregate exposure assessment is performed by identifying a series of scenarios which are defined in part by a series of characteristics of time, space, activity pattern that also describe a subgroup of the general population who will experience exposure to a pesticide. These exposure scenarios should correspond to the exposure durations deemed to be of significance in light of the toxicity data available for the pesticide. The identification of realistic individual-focused exposure scenarios helps prospectively to define populations of concern, and provide critical windows within time-frames and routes of exposure that will be linked to toxicity endpoints. By focusing on the individual and then the population (or subpopulation) of individuals, an assessor builds the aggregate analysis which considers jointly the multitude of temporal-spatial, demographic, and other factors that, together, determine the exposure profiles of individuals, both singly and collectively.

1. Exposure to the Individual

The basic concept underlying aggregate exposure assessments is that exposure occurs on an individual-by-individual basis. Since an individual may only be in one place at a time and engage in only one series of behaviors at a time, the revised approach recognizes that estimates of an individual's exposure should reflect consistent spatial, temporal, and behavioral and demographic characteristics. As such, the revised approach should better ensure that exposures agree in temporal, spatial and demographic characteristics, and should avoid creating an exposure situation which makes little logical or practical sense. The revised approach recognizes that exposures to an individual in a population: (1) may occur by more than one route (i.e., oral, dermal and/or inhalation); (2) may originate from more than one source and/or pathway (i.e., food, drinking water, and residential); (3) may occur within a time- frame that corresponds to the period of exposure required in an appropriately designed toxicity study to elicit an adverse toxicological effect; (4) should occur at a spatially relevant set of locations that correspond to an individual's potential exposure; and (5) should be consistent with the individual's demographic and behavioral attributes.

It is important that the consistency of the data concerning the hypothetically exposed individual be maintained throughout the aggregate exposure assessment within the limitations deemed necessary by the risk assessor. The aggregate intake values should reflect, to the extent useful to characterize significant variability, the food, drinking water, and residential exposure estimates for the same hypothetical individual at the same time, in the same place, and using the same demographic and behavioral characteristics. The exposures assigned to an individual should be internally consistent and appropriately reflect the dependencies and linkages that are inherent under different temporal and spatial exposure scenarios. In other words, when useful to characterize significant differences in potential exposure, the aggregation should be simultaneously temporally, spatially, and demographically specific, i.e., characteristics of the hypothetical individual should agree in time, place, and demographic and behavior factors (ILSI, 1998a). By "individual" OPP is referring to a consistent set of characteristics, based in data and realistic judgements which reflect potential aggregate exposure for each type of person, over time. This concept is illustrated in the matrix in Figure 2 which shows examples of various dimensions which should be considered in developing a hypothetical individual for aggregate exposure modeling purposes.

In assessing aggregate exposure, each of the individual "sub-assessments" should be linked back to the same hypothetical individual. In other words, each of the "sub-assessments" investigating the food, drinking water and residential pathways of exposure must apply to the

same “individual” and it is these individual-based “sub-assessments” which are subsequently aggregated into a population-based aggregate exposure assessment. As such, aggregate exposure estimates should provide a description of the distributional exposures received by individuals across the U.S. population from all potential pathways.

It is important to note the “individuals” are not selected or chosen using some criteria or scheme under this new, expanded approach, but rather the “individual” is seen as the modeling basis from which to begin the aggregate exposure assessment. Thus, when using the phrase “calculated on an ‘individual-by-individual’ basis” when referring to exposures, OPP does not mean to perform calculations for specific, identified, real individuals. Rather, OPP means to develop estimates of exposure for “hypothetical individuals” each of whom represent a realistic member of the U.S. population. The attributes of hypothetical individuals that are considered in the revised document are summarized in Figure 2. OPP generally does not support selecting only certain subsets of individuals, either the most highly exposed or the average individual, but instead seeks to utilize all available data to assess aggregate exposure to the total population. By combining data sources and using reasonable professional judgement, OPP intends to prepare enough individual assessments that the collective group, in total, will provide a reasonably accurate characterization of the distribution of exposure across the entire exposed population.

Figure 2. Exposure to an Individual in the Population

Example(s) of Individual Characteristics	Dimension	Correlation for an Individual in the Population
<Person's Age <Season of the Year	Temporal	<Age correlates with body weight/height, consumption pattern (record), inhalation rate <drinking water consumption and residential pesticide application pattern consistent with season of year
<Location and type of home (urban area, region of country)	Spatial	<drinking water estimates consistent with region of country (rural or municipal water supply) < residential pesticide usage likely for region of country
<Gender	Demographic	<reproductive status consistent with age <personal preferences, behaviors, and characteristics consistent with data on home pesticide usage and type of home
Individual Example. A hypothetical individual who is part of a population of concern in an aggregate exposure and risk assessment might be a one-year old female, in New England, during the winter, in a rural location without municipal water (on rural well water), whose food consumption is selected from the range of records for the age one-year old, and who encounters residential pesticide use (exposure) consistent with a rural, New England location in the winter. She does not apply home pesticides, but may come in contact with pesticides by crawling on the floor. Body weight, height, surface area, inhalation and other biological determinants are consistent for a one-year old.		

2. Calendar-Based Approach, Exposure Interval, and Event Correlation

In developing a detailed exposure assessment to individuals in a population for a single chemical with a variety of use patterns, the assessment ideally should estimate the daily exposure of an individual to the exposure from each source on any given day. A calendar-based approach provides the ability to estimate daily exposures over time (and from multiple sources) to an individual on an individual by individual basis and is in keeping with a basic tenet of aggregate risk assessment that exposures, when aggregated, be consistent and realistic. Importantly, this approach permits the inclusion of exposures due to the presence of residual pesticides from applications on previous days. Carryover is particularly important in the evaluation of pesticides used in and around residences and similar sites. Residential application of a pesticide may occur on a single day, but exposures may continue for several days following application as the product degrades in the residential environment. Each succeeding day following application is anticipated to result in a decreased exposure until the level returns to pretreatment event levels. Multi-day exposures of this type can be reflected in a calendar-

based model in the form of decay curves which model the decline in pesticides residues on the initial day over the next several days of the modeled year. For example, if a homeowner uses an indoor fogger on one day to treat a roach problem, the inhabitants may also receive exposures on subsequent days as the pesticide is distributed in the house. As the pesticide decays with time, subsequent exposures (on subsequent days) from this application would decline as well, but a calender-based approach does not preclude a second or subsequent applications from subsequently occurring and "adding to" exposures from previous applications.

In addition, an adequate calendar-based assessment should appropriately incorporate linkages or correlations/associations (which can be either positive or negative) between exposure scenarios. For example, in some cases the use of one product may affect the likelihood of using another product. This might be true with respect to products used for flea control: an indoor fogger, lawn care product, and a flea product for a pet might be more likely to be used simultaneously by a homeowner performing an integrated treatment for fleas. In other cases, the products may serve essentially the same purpose, such that the use of one will almost certainly preclude the use of the other. In the same vein, if a homeowner uses an indoor fogger on one day, he or she is unlikely to use a fogger on the following day.

In addition to linkages in time, linkages can be extended to spatial aspects as well. For example, places of residence can be linked or otherwise correlated to a type of water source. It is much more likely, for example, that a residence located in a rural site in the Midwest will have a private well as a source of the household water supply than a residence in an urban location in the Northeast. In this case, the location of the residence can be linked through the use of existing data with the source of the water supply to appropriately incorporate real-world situations and ensure that unrealistic or unlikely combinations are appropriately discounted.

Finally, a calender based approach can allow the risk assessment to correlate exposure with a toxicologically relevant period of the exposed individual's life span. Occasionally, toxicology studies may identify a toxic effect that uniquely affects one gender or people in a specific age range. The calendar-based system allows the risk assessor to focus and evaluate on the differences in exposures that occur at any critical life stages. Various computer software programs have been or are being developed which incorporates a calender based approach to estimating aggregate exposures including Calendex™ , LifeLine™, and CARES™. The developers of the first two programs have presented their programs for review by the SAP (USEPA, 2000f; USEPA, 2001). These models use a variety of data including generic data, chemical specific information, and default assumptions as necessary.

3. Relevant Toxicological Information

One critical concept which is described in both the Interim Aggregate Guidance and this revised document is the relationship between the scope of an aggregate exposure assessment and the toxicity profile of a pesticide. First, it is important that an individual's exposure be matched with relevant toxicological doses in terms of route, duration, and effect. Moreover, it is appropriate to combine exposures occurring by different pathways/routes only when the toxicological endpoints for the pathways/routes are related with respect to target organ and nature of adverse effect.

Toxicological endpoints must be matched with an appropriate exposure duration to perform an aggregate risk analysis. Exposure scenarios without associated, measured toxicological endpoints can be included in an aggregate assessment through use of extrapolation methods which have been reviewed and approved by the Agency (i.e., route-to-route extrapolation). The mode of action of the toxicological effect must be the same across routes of exposure for this to be legitimately performed. In some cases, however, the toxic effects are markedly different by one route and duration from those produced by a different route and duration. To produce an aggregate risk estimate in situations in which it is NOT appropriate to aggregate exposures due to differing toxicological effects, risk measures should be calculated separately for each route and duration for a given toxic effect for each hypothetical "individual," and then combined to characterize the distribution of exposure for the total population. In these situations, multiple aggregate assessments may be performed for a single chemical of interest if the relevant toxicological endpoints for all routes/pathways are not the same. When that is the case, a separate aggregate assessment is then performed for each toxic effect of concern.

4. Rolling Time Window of Exposure

The calendar-based approach discussed in III.B.2. provides new avenues for incorporation of toxicological data by permitting the use of "rolling time-frames" of varying length to examine the entire spectrum of likely exposures for periods of exposure that exceed the safe level for the appropriate toxicity endpoint. The "rolling time-frame" of exposure refers to a technique for calculating a series of sequential calendar-based averages which attempts to better reflect the dosing regimes used to determine the toxicological estimates. For example, if the toxicologically relevant duration of exposure is a week, the initial value for a seven-day rolling average would include exposure values from January 1 through January 7, and the 2nd set of values would include exposure values for January 2nd through January 8th, etc. Each of the 365-available rolling seven-day periods for the year would be examined by moving the start date by one day on each pass. A calendar-based rolling average provides OPP with a much more realistic representation of exposure over time and with greater flexibility in matching the human exposure duration with a toxicological effects from animal studies. For example, in the case of a toxicity study that measures effects following a seven-day dosing period, it could be appropriate to consider exposure expressed on a "seven-day rolling time-frame" basis.

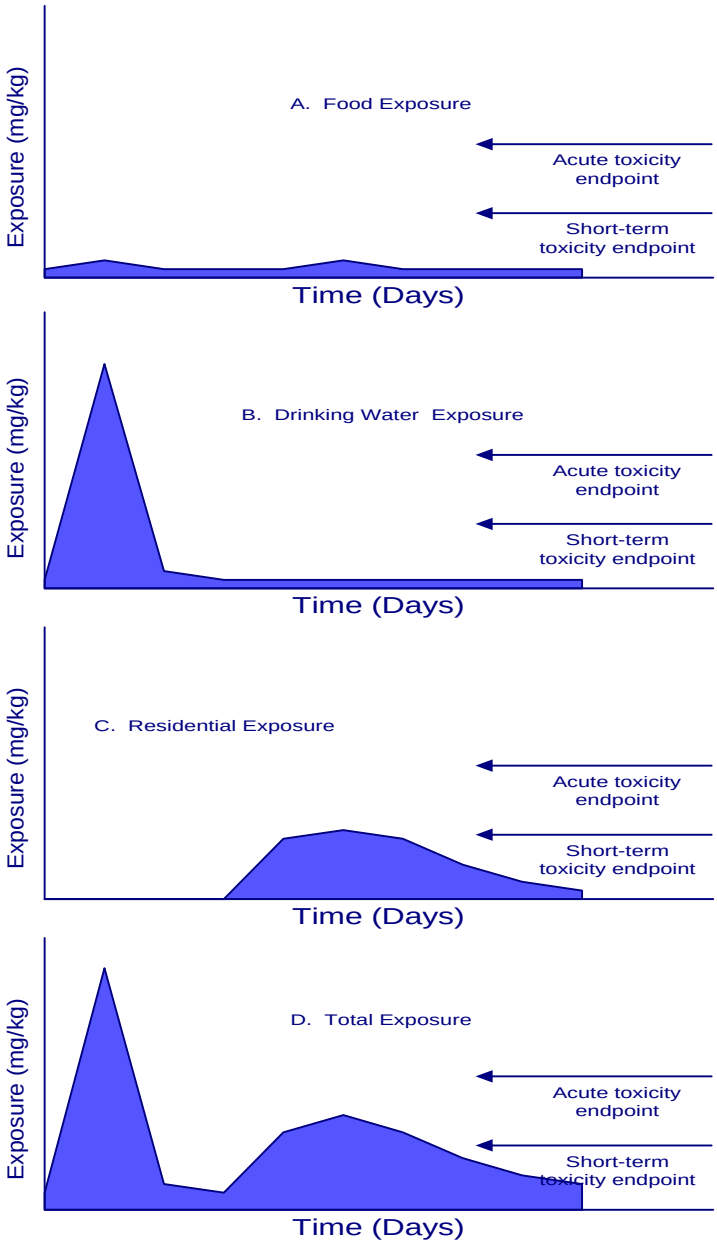
The use of a rolling time-frame approach will allow for more detailed use of toxicological data than today's methods and better incorporates the time-frame associated with the dosing which produces a toxic effect. OPP currently selects multiple toxicological endpoints for pesticides to reflect a variety of time-frames (acute and chronic for the food pathway and short- term, intermediate-term, and long-term for the residential pathway) and routes of exposure (oral, dermal, and inhalation). The use of a rolling time-frame approach is expected to make it less necessary for the time-frames of the exposure assessments to be "force-fit" into the time-frames associated with the dosing during the toxicological studies on which the risk assessments are based. With the advent of the new, revised aggregate exposure and risk assessment methods described in the Aggregate General Principles, a series of short-term exposures could be matched with a developmental or reproductive effect which may occur only during critical periods because aggregate exposure and risk assessment includes use of a rolling time window of exposure.

When an aggregate assessment is conducted using a calendar-based approach, the results of the assessment can be considered in a manner similar to Figure 3 which demonstrates the relationship between duration of exposure and toxicology endpoint for three pathway-specific exposure distributions (food, drinking water, and residential) and the total

exposure distribution when an acute endpoint is selected. Here, the magnitude of daily exposures indicated on the y-axis and time is plotted on the x-axis. In these examples, the potential for an exposure value which exceeds the PAD is determined by comparing the magnitude of daily exposure to a toxicological endpoint such as an acute or short-term PAD, depending upon the toxicological data available for a chemical. Determination of which endpoint should be used for comparison is based upon the duration and route of the exposure.

Investigating these exposure profiles in detail, the noticeable "spike" in the second and fourth graph can reflect a change in drinking water exposure. In these graphs, there is an increased exposure to the compound of interest, but the increase persists for only one or two days. The appropriate comparison would be to the acute PAD which is exceeded in both the second and fourth graphs in Figure 3. Comparison to the short-term endpoint would be inappropriate because the duration of the increased exposure relative to background exposure is of insufficient duration according to the definition of short-term exposure. The opposite case occurs in the Residential Exposure example, the third graph in Figure 3. Here, the increased exposure occurs for several days in a row, during which time the short-term PAD is exceeded. Comparison to the acute PAD would be not be appropriate in this case according to the definition of acute exposure which is one day or less. The final graph is an illustration of the possible results from an aggregate assessment combining all three pathways of exposure. Here, the proximate relationship between the two episodic exposures and the overlayering of the background food exposure means that a number of time-based toxicological criteria (e.g., acute PAD, short-term margin of exposure or MOE) can be calculated. In this case, a potential concern for acute exposure exists from drinking water exposure (during which time the acute PAD is clearly exceeded). The concern for the short-term exposure from the residential scenario also remains.

Figure 3. Pathway-specific and Combined Exposure



However, an added complexity is introduced in this example of aggregate scenarios because a constant exposure to the compound continues in the time interval between the two episodic exposures. This intervening exposure represents the combination of the background food and water exposures and is roughly half the short-term PAD. The short- term PAD is clearly exceeded during the period of elevated drinking water exposure. If the short-term effect of concern is not clearly reversible within the one day between the drinking water exposure and the introduction of the residential exposure, this entire series of exposures would be treated as a single, continuous exposure for the purposes of risk assessment. If the effect of concern is reversible within the one-day time-frame, the exposures can be treated as discrete events. Through aggregate exposure assessment techniques, an assessor may be able to examine in more detail the relationship between the duration of exposure to an individual in a population and the toxicologically significant exposure duration in which an adverse effect may occur. This helps to create a more realistic sense of exposure to individuals in a population.

B. Pathway-Specific Considerations Before Aggregation

This section describes pathway-specific issues and issues for consideration when performing aggregate exposure and risk assessment for individuals in a total population. There are a number of specific issues to consider when performing the pathway-specific analysis prior to aggregation which are described in additional detail below.

1. Food Pathway and Aggregation

Aggregate exposure scenarios often are developed beginning with the food exposure pathway. Aggregate analysis should be performed on an individual basis in order to maintain the linkages and associations between consumption data and demographic data. Food consumption data files provide very extensive demographic information including region of residence, season, and socioeconomic status of the consumption survey respondents. This information assures that, by starting with the survey respondents in the CSFII, the risk assessor has a hypothetical population that is representative of the U.S. population. In addition, the demographic data may also be useful in defining likely related residential and drinking water exposure scenarios. Similarly, pesticide use and usage data may be characteristic of or otherwise related to region of residence, and knowledge of characteristic differences related to region may permit development of more refined and focused individual-based aggregate risk assessments. Regional factors will also be important in selecting the appropriate drinking water data for use in the assessment. Finally, OPP notes that starting with the food pathway in developing an aggregate to assessment does not mean that it is the most significant

contributor to overall risk. Therefore it is important to consider other pathways–water and residential–that may be more significant.

2. Drinking Water Pathway and Aggregation

Specific issues in aggregating potential exposure to pesticides through drinking water also include spatial, temporal, and treatment-related considerations. The concentration of pesticides in drinking water, and thus exposure, is usually a local or regional phenomenon driven by pesticide use patterns and local hydrologic and climatological conditions. Accordingly, it cannot be assumed that exposure to a pesticide in one location of the country will be the same for other locations, and drinking water exposures to pesticides to individuals in a population should be incorporated into aggregate exposure assessments on a localized basis. This step can be accomplished using distinct data sets collected in light of specific pesticide use patterns, when available. However, local data sets are applicable only for that locale, i.e., drinking water concentrations of products used in the corn belt would not be assumed for all individuals across the entire country, but only for individuals who may potentially be exposed in that locale. Also, pesticide impacts on drinking water are often seasonal in nature and are driven by time of application and the weather conditions present shortly after application. Therefore, temporal variation in pesticide concentrations in drinking water should be considered in any individual-based, aggregate exposure assessment for drinking water. The impact of treatment in whatever form (sedimentation, flocculation, chlorination, filtering through granular or powdered activated carbon, etc.) should be considered in any drinking water exposure assessment, where data are available. Municipal drinking water facilities across the nation use a variety of treatment processes in delivering tap water to the public. OPP will publish a policy document discussing the effects of treatment on water concentrations of pesticides in fall of 2001. Drinking water obtained from private wells can be assumed to be mostly untreated.

Exposures of individuals to pesticide residues in drinking water should be incorporated into exposure assessments on a local or regional basis. Factoring drinking water exposure into the framework already contemplated for food-related exposures means developing a "person-by-person" approach to estimating drinking water exposure to pesticides over time. Because exposure to pesticides in drinking water is a local or a regional concern, and additionally, because the food portion of the dietary exposure assessment is being done on an individual basis, each hypothetical person included in an aggregate risk assessment should be assigned to a location and a drinking water source consistent with that location.

Once an individual has been associated with a representative drinking water source, the available data should be examined for the occurrence of pesticides in the drinking water source over time. Geographic Information System (GIS) tools, cropping and pesticide use information, fate and transport data, modeling results, monitoring data, and information on the effects of blending and treatment should be used to determine the pesticides most likely to occur in that water source, and potential pesticide concentrations over time. Initially, OPP expects to assume that a person would be exposed only to those pesticides that are used in the recharge area above an aquifer for groundwater, or in the watershed of the drinking water source for surface water. As a guide to determining likely regions upon which to focus risk assessment scrutiny, OPP will consider using information such as the National Agricultural Statistics Service (NASS) database or data from Doane's Marketing Service. Alternatively, an analysis of cropping patterns and pest pressure may be explored to identify likely areas for concentration of effort.

OPP will continue to move forward in refining the screening-level approach. OPP plans to move beyond the screening-level assessment by using distributional data for the drinking water pathways. OPP is investigating the incorporation of the full range of data from models such as PRZM/EXAMS as a distribution to permit expression of the full range of predicted values in exposure estimates. OPP is also currently investigating the use of linear regression techniques as applied across occurrence data for pesticides in surface water. A draft guidance document will be issued in winter of 2002 describing a tiered approach to estimating drinking water concentrations, with distributional analysis reflecting variability in concentration due to seasonal use patterns as the highest tier. The technique is intended to provide a distribution of pesticide concentrations at drinking water intakes prior to treatment that may be used in a probabilistic analysis for drinking water exposure. In this and other ways, OPP is moving beyond a screening-level aggregate assessment to incorporate more realistic, quantitative estimates of exposure to pesticides from drinking water.

3. Residential Pathway and Aggregation

Assessing potential aggregate exposure to pesticides resulting from applications made in and around the home and public places such as playgrounds and playing fields, is also influenced by temporal, spatial, and demographic considerations. In addition, an individual's age and gender attributes may play a significant role when addressing an individual's residential exposure in an aggregate exposure assessment.

In general, a decision to use a pesticide depends on a perceived need for control of a certain pest or group of pests. For example, those desiring a weed free lawn are inclined to use an herbicide at different times of the year based on when weed seeds are germinating or shortly after they have emerged. An individual may make a decision to self-treat a lawn or to hire a professional lawn care operator (LCO). Urban houses may be more likely to receive pesticide treatment for chronic pests such as cockroaches on a routine basis. Exposure of young children in any of these environments may be higher than adults because of their unique behavior (nondietary ingestion, i.e., hand-to-mouth), increased activity, or greater contact with the surfaces where pesticide applications may have been made. An assessor should attempt to bring together these residential pesticide use scenarios in the form of a representative group of hypothetical individuals, based in data.

Temporal considerations can be identified by focusing on the pest to be treated and whether the application has been made by the resident himself or a professional applicator. Weed control on lawns using broadcast applications is typically performed in the spring to control germinating or newly emerging weeds. Insects such as billbugs or sod webworms appear in lawns as the growing season progresses. Summer weed control tends to be accomplished by the use of spot applications either made by the resident using a hand held sprayer of specific weeds or along patio borders. Professional applicators normally treat weeds during the summer on an "as needed" basis while making routine fertilizer treatments. Most LCO's have an additional trigger on their spray wands to activate the herbicide spray when they run into a weedy spot during the fertilizer treatment. Residents typically have poor knowledge of turf diseases and thus are less likely to use fungicides while professional lawn services are more likely to anticipate disease conditions and make appropriate treatments. Temporal consideration regarding the use of LCO's and the time of the week of application may need to be considered. Typically, treatments are likely to be made by a professional during the work week and by the resident on the weekend. Based in available data, an assessor should link the probability of professional or self-applied

residential pesticide use with a hypothetical individual in an aggregate assessment.

Spatial (geographic) considerations can also be identified by focusing on the site/pest considerations such as fire ants on lawns in the South. The use of a pesticide may be limited to cool season grasses which are primarily grown in the North and Midwest. Home gardens in the humid Southeast may require more fungicide treatments than gardens in California. For example, the periodic cicada is a problem in the Northeast, yet does not occur in the Pacific Northwest. Spatial considerations can be made for the characteristics (e.g., location of residence) for each individual in the population.

Applications of pesticides made in and around homes, schools, offices, and other public areas may result in potential exposure via the oral, dermal, and inhalation routes. Consideration of linkage of uses where appropriate is particularly important for residential uses. Linked uses are those in which two products are or may be used in combination, such as dipping a pet and treating the carpet of a flea-infested home, or used in such a way that using one product substantially increases the probability of using a second product. The recognition and maintenance of these potential linkages will be critical in developing realistic estimates of exposures to a hypothetical individual with defined demographic characteristics. At this time, the understanding of patterns of use is limited, although the Agency is aware of efforts to conduct surveys describing the pesticide use practices of the U.S. public. Exposure assessments for residential and other nonoccupational sources will focus on those use scenarios outlined in the Draft Residential SOP's (USEPA, 1997a). The patterns of use for pesticides in residential, nonoccupational, and institutional settings are highly dependent upon location, season, dwelling type, and a myriad of other factors that impact the behavior of a potential pesticide user. Where appropriate, an assessor should link residential pesticide use preferences with particular classes or categories of individual, based on data, when performing aggregate exposure assessments. Where data are limited in quantity or are of poor quality, the Draft Residential SOP's should serve as the basis for initial estimates of exposure.

Age/gender/pathway considerations play a role in aggregate assessments related to the behavior of individuals. Young children may be exposed to more pesticide residues for a variety of reasons. For example, young children engage in more hand-to-mouth activity (nondietary ingestion) than do adults. Some national surveys of home and garden pesticide usage suggest that more males than females treat lawns, whereas females are more likely to treat the interior of the house. Consideration of data of this type will aid in developing reasonable and realistic aggregate exposure and risk assessment scenarios.

To the extent possible, the assessment of residential, nonoccupational, and institutional use patterns should characterize seasonal and geographic variations, and associated pest pressures. Residential uses cannot necessarily be assumed to be consistent with or coincide with the large national or broad regional breakouts currently used in the food exposure assessment arena. For instance, a food exposure assessment might cover the entire Pacific Northwest region of the United States. However, the coastal regions of Washington and Oregon are more humid and have milder temperatures than would be found in Idaho. Thus, residential uses of pesticides would likely differ considerably between these two areas because of differences in pest pressure, even though they are within the same "region." Aggregate risk assessments should reflect use patterns and practices on a scale sufficient to capture the variability in pesticide use , but not so large as to inappropriately dilute real and significant differences.

Demographic considerations may be important for characterization of individuals in the population. For example, urban poor and rural poor may have different pesticide usage patterns based on a greater likelihood of having a vegetable garden or increased likelihood of living in a multifamily dwelling in an urban area. Low income residents in suburban areas may be less likely to hire lawn services than other suburbanites. Those who own homes may be more likely to hire lawn services than those who rent. These demographic considerations can also be considered for each individual in the population.

IV. Questions To Consider When Conducting Aggregate Exposure Assessment

These general principles for performing aggregate exposure and risk assessments are not meant to be comprehensive or to be interpreted as a prescriptive approach. OPP will evaluate any and all methods or models developed to assess aggregate exposure. However, the framework, principles, and contents of the steps presented in this document should be considered in aggregate exposure and risk assessments.

The appropriate means of combining probabilistic exposure estimates from food, drinking water, and residential exposure in the expanded approach involves combining exposures for a single chemical from all pathways for each individual (separately) in the population. In other words, aggregate exposure estimates are combined by considering exposures of collections of hypothetical individuals in the population. In this way, the aggregate exposures in a population of individuals (e.g., U.S. population or children ages one to six years old) is a collection (distribution) of exposures of all the individuals in the population. Each individual's aggregate exposure distribution is defined by applying the key concepts presented in Section III.

For example, it is not appropriate to derive separate, unlinked, independent distributions of exposed individuals for each pathway of potential exposure, and to then merely sum exposure from each pathway to derive a distribution of aggregate exposure for a population of individuals. The assessor should identify linked individual-specific pathway exposure scenarios that are reasonable and supported by data. In essence, the incorrect approach would place three sets of individuals (or three different populations), which are not connected through logical correlations and linkages of potential exposure, into one population aggregate exposure distribution. In this case, each "individual" would represent a series of illogical and incoherent set of exposures which would not occur in reality. Therefore, it is critical to honor as much as possible the temporal, spatial and demographic data available for each type of hypothetical individual in the population when developing an aggregate exposure assessment of population, and ensure that logically inconsistent combinations are not generated. The distinction between the current, Interim practices and the expanded approach should be considered when reviewing Section IV.

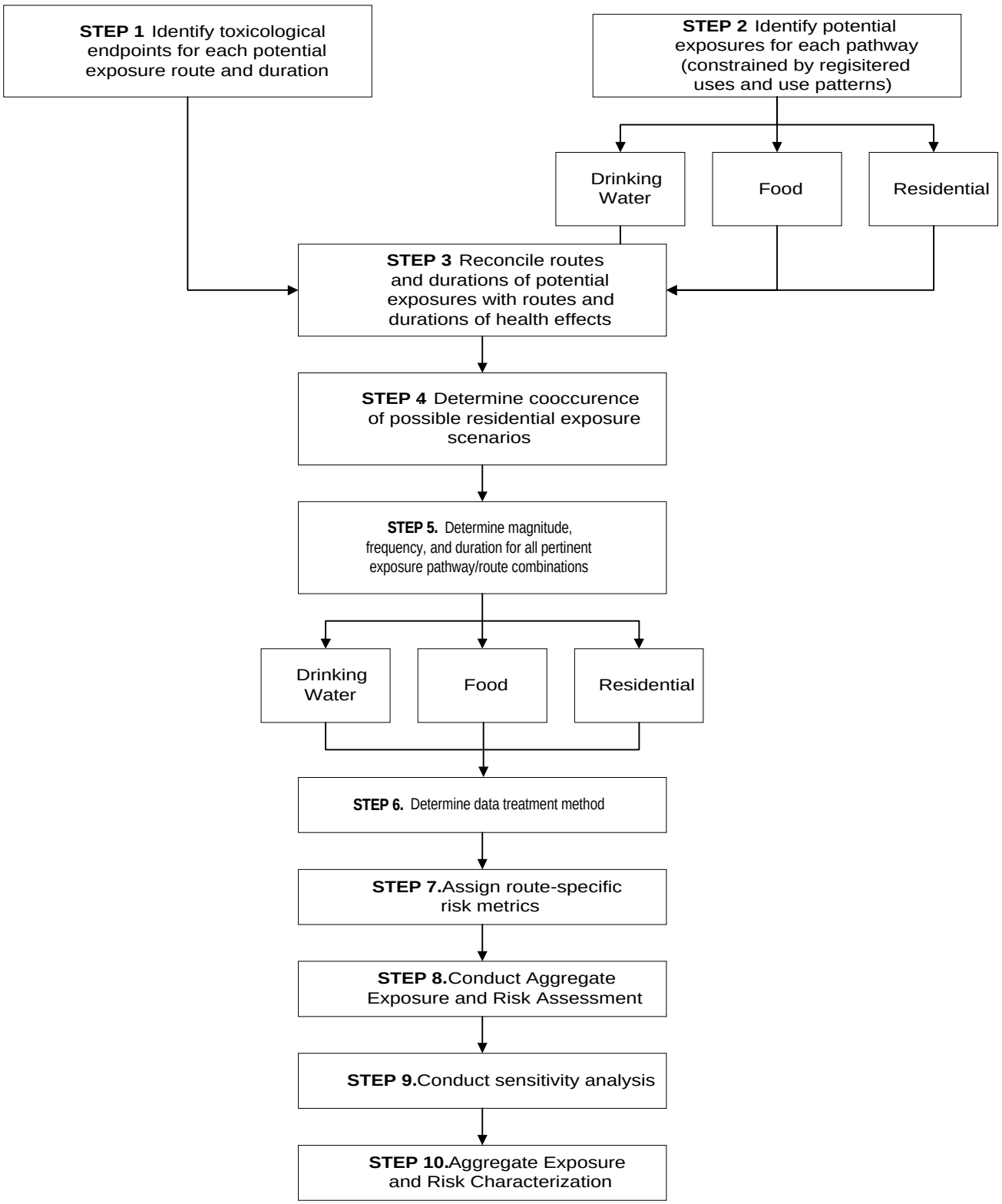
Section IV describes OPP's practices and proposed principles which it intends to use in conducting aggregate exposure and risk assessments under FFDCA. These practices expand upon the Interim Aggregate Exposure and Risk Assessment Guidance. These principles and practices are illustrated in the form of "Ten Steps." While OPP is not prescribing that these specific steps be implemented in strict accordance with the discussion offered here, OPP does expect any aggregate assessment to take the Ten Steps into consideration and explain any deviations from the ideas and principles discussed herein. See Figure 4 for an overview of the sequence of steps to consider in an aggregate exposure and risk assessment.

A. Questions and Issues to Consider when Employing the Expanded Method of Aggregation

1. Identify Toxicological Parameters *(i.e., effect, dose, and duration of dosing), each potential exposure route (i.e., oral, dermal, inhalation), and exposure duration (i.e., acute (one-day), short-term, intermediate-term, and long-term) of interest. The appropriate exposure duration would be selected and identified by consideration of the duration of the health effect (i.e., the reversibility of the effect) and the time to onset of the health effect.*

An initial step in performing an aggregate risk assessment is to review all available toxicity data to identify the toxicological endpoints of concern for a particular pesticide active ingredient (ai) and their associated parameters (e.g., dose, duration, route, etc.). Generally for a pesticide, these data include the results of the tests species in 40 CFR Part 158, as well as other data. The results of this hazard identification step should influence the subsequent identification of appropriate exposure scenarios which will be impacted by the toxicity profile of the pesticide, especially factors relating to the time to onset of effects and duration of effects or period of reversibility. The toxicity endpoint should match the temporal characteristics of the exposure scenarios identified for inclusion in the assessment. These factors should be evaluated in a coordinated manner to ensure that all appropriate scenarios are accounted for and that all toxicity endpoints of concern are addressed.

Figure 4. Ten Steps in Performing Aggregate Exposure and Risk Assessme



If toxicological endpoints are the same, toxicological effects which occur at different dose levels via different routes of exposure should be combined within an aggregate exposure and risk assessment. For example, cholinesterase inhibition may occur from either oral or dermal exposures but at different dose levels. In these situations, conversion to a common risk metric may be needed, in order to combine the routes of exposure (here, oral and dermal). Additional details and steps for combining pathways of exposure and issues to consider while developing route-specific exposure scenarios, and combining exposure scenarios, are provided in “Step 7" of this section.

Frequently, there may be more than one toxicological endpoint for a single chemical. If the toxicological effects via different routes of exposure are not the same, then those exposure scenarios should NOT be combined. For example, if dermal exposure to a pesticide results in cholinesterase inhibition but inhalation exposure causes liver damage, then dermal exposure and inhalation exposure should NOT be combined in an aggregate assessment since the toxicological effects are different. Here, for example, more than one aggregate exposure and risk assessment can be performed for a single active ingredient, if necessary, in which each endpoint (e.g., cholinesterase inhibition and liver damage) is evaluated separately. Similarly, if a particular pesticide active ingredient elicits a specific toxic effect only following oral administration, and no effects are seen via the inhalation or dermal routes, only those exposure scenarios which reflect the oral route of exposure would be included in the analysis of this toxicological endpoint. Specifically, in this latter example, only the food pathway, any oral pathway residential exposure scenarios listed in the Draft Residential SOP’s, and the drinking water exposure scenarios would be evaluated in the assessment of aggregate exposure and risk.

In addition, routes should only be combined when the duration of exposure and toxic effect of the chemical exposure correspond. For example, it would not be appropriate to combine an exposure by the oral route in which a liver enzyme is inhibited following a one-day exposure with an exposure by the dermal route in which that same enzyme is destroyed following only a long-term exposure. Similarly, if there is no effect seen at the acute dose level, but there is an effect in the long-term (one-year dog study), only the long-term exposure scenario would be evaluated. The time period of exposure needed to produce a toxic effect is determined through critical analysis of the toxicological literature for the chemical of interest. Factors to be considered in evaluating a toxicological endpoint include the type of effect, the dose level, the duration of the exposure, the reversibility of the effect, and the time to onset of the effect.

All these considerations will be included in the identification of appropriate exposure scenarios via all pathways (i.e., food, drinking water, and residential) in the analysis of aggregate exposure and risk.

An additional factor to be considered when determining the toxicological endpoints of concern for a particular pesticide active ingredient is the potential difference in the toxicity of a pesticide resulting from different routes of exposure. The differences may result from pharmacokinetic factors including rate and degree of absorption, distribution, and potential differences in metabolism. Materials absorbed through the skin may be partially metabolized as they enter the skin. Alternatively, some pesticides may require activation by the liver. The liver may be bypassed when chemicals are absorbed through the lung and skin and therefore exposure via these routes may not result in first-pass bioactivation in the liver. Although both lung and skin each have the capability to metabolize xenobiotics themselves, they also have the capacity to initiate the bioactivation process for metabolism by other organs. The toxicity endpoint may also vary in treatment in the risk assessment depending upon the assumptions made about its interaction with the body. For instance, considerations of threshold may be important for noncancer endpoints. Although low-dose linearity is typically assumed for cancer, mechanistic research is increasingly providing support for nonlinear dose-response for certain cancer effects (e.g., thyroid carcinogenicity via perturbation of thyroid-pituitary axis).

The importance of the duration of exposure on toxicological effect in the evaluation of aggregate exposure is illustrated in Figure 3 above. A single pathway-specific exposure scenario for an individual or group of individuals in the population may not result in a duration of exposure which equals or surpasses the exposure duration which may cause an effect from a specific chemical. However, a combination of exposure scenarios (or, more precisely, their aggregation) for an individual or group of individuals in the population may exceed the exposure duration in which the effect may occur. As illustrated in Figure 3, none of the individual pathways (food, drinking water, or residential), taken separately, exceed the short-term toxicity endpoint for significantly longer than one day, but, when these separate pathways are combined or aggregated (as in the bottom panel of Figure 3) the short-term toxicity endpoint is exceeded for a period of greater than one day and would potentially trigger a concern for short-term exposure.

2. Identify the Potential Exposures Scenarios *(including duration and route) for each pathway for each hypothetical individual in the identified population. The universe of potential exposure scenarios should be constructed by first characterizing all proposed and*

registered use patterns for the chemical. Using bounding estimates and the results of less refined aggregate assessments, identify exposure scenarios, routes, and/or pathways that would be excluded from the refined assessment because the contribution to aggregate exposure is negligible. Document such decisions.

The starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide. The aggregate assessment should identify all potential pathways and routes by which individuals in any identifiable subpopulation might be exposed to the pesticide. OPP is not prescribing any particular methodology to perform aggregate exposure and risk assessment, nor is OPP prescribing any specific number of potential exposure scenarios or individuals to include in the assessment. Depending on the proposed and approved uses and use patterns for the chemical, separate scenarios considered may range from a single scenario to dozens of scenarios.

The initial identification of potential exposure scenarios may result in a seemingly limitless number of combinations, and performing an aggregate exposure assessment to address all of them could prove extremely difficult or impossible. If so, it may be appropriate to limit the scope of the assessment. The first step in narrowing an aggregate exposure assessment would be to consider the relative contribution to aggregate exposure of whether the scope of the assessment may be limited by excluding specific routes of exposure within an exposure scenario, specific exposure scenarios, and entire pathways. If (as discussed below) such routes, exposure scenarios, or pathways make only negligible contributions to aggregate exposure, the assessment could exclude them from further quantitative analysis. In addition, it may also be appropriate to limit a refined aggregate exposure assessment to a focus on a specific duration of exposure, e.g., one day or lifetime, because earlier, less refined aggregate exposure assessments have shown that other exposure durations present no risk concerns.

In addition to considering the toxicological effect, dose level and duration and timing of effect, the analyst should also consider all proposed or approved uses and use patterns of the pesticide active ingredient in developing realistic aggregate exposure scenarios via all relevant routes of exposure. Evaluating all proposed or approved use patterns will enable the analyst to determine for the food pathway, for example, which crops and crop groups should be considered in the analysis; for the residential pathway, which uses are registered for the chemical and, therefore, which residential application scenarios should be included in the analysis; for the drinking water pathway whether drinking water contamination should be evaluated, and if so, the degree to which localized drinking water assessments, should or can be performed. Of the seemingly limitless combinations of food, drinking water, and residential pathway scenarios which could be developed in an aggregate exposure assessment, a review of the toxicologically appropriate constraints (e.g., the duration of effect) and the proposed or approved uses and use patterns would likely significantly limit the number of aggregate exposure scenarios to be evaluated.

Because of the complexity introduced into the risk assessment process by the multitude of potential exposure scenarios, the identification of the potential aggregate exposure scenarios to be included in the assessment should be preceded by conducting a bounding estimate of all exposure scenarios. This is an important step in determining the scope of the assessment. The bounding process will greatly simplify the data preparation and calculation phases, but will also make the risk characterization process more transparent and useful by permitting the attention of the risk manager to be focused on the more important aspects of the assessment. A first step in the bounding process is the evaluation of the relative contribution/importance of the various routes and pathways that may be of concern in the final risk estimate. Generally, OPP would ordinarily consider as negligible a particular pathway that contributes less than 1.0% of the total PAD in the most refined assessment performed, and OPP would recommend that such use not be included in a quantitative, refined analysis. Similarly, where a specific exposure scenario contributes less than 0.1% of the PAD, OPP would ordinarily consider such exposure scenario as negligible. No more than 10% of the PAD should be excluded in this manner. The decision to exclude a pathway or exposure scenario should be made only if the criteria appear to be met for all identifiable subgroups who are potentially exposed. Each such decision should be identified and it should be noted in the risk assessment as extant but not included in the quantitative risk assessment. Similarly, if specific uses make negligible contributions to the risk assessment, or the toxicity by a particular route is low, the uses or routes should be noted in the risk assessment, but not included in the quantitative risk assessment. The

rationale for exclusion from the quantitative risk assessment should be explained in each case. At the conclusion of the process, the risk assessment should be transparent regarding what pathways, exposures scenarios, or uses have been excluded from the quantitative analysis and there should be a qualitative analysis of how these exclusions affect the quantitative analysis.

A negligible contribution from a pathway or route can be demonstrated by conducting a bounding estimate for a given pathway. A bounding estimate is one in which several conservative assumptions are combined to provide an estimate of exposure unlikely to be exceeded in actual practice. An example of a bounding estimate for food exposure is a Tier 1 or 2 acute dietary assessment in which the entire crop is assumed to be treated and residues are assumed to be present at tolerance or field trial levels. The actual exposure in the diet is unlikely to exceed this level and in most cases is anticipated to be much lower. For residential exposure assessments, there are no "bounding estimates" per se, but use of the equations defined in the Draft Residential SOP's (USEPA, 1997a) with upper-end and mean values inserted for each of the parameters may provide a reasonable, health protective estimate. The use of surface and groundwater concentrations generated by water quality models as currently used by OPP (GENEEC, PRZM/EXAMS, and SCI-GROW) would provide a bounding estimate for comparison to at DWLOC for the drinking water portion of the assessment.

3. Reconcile the Routes and Duration of Potential Exposures *with the routes and durations of the health effects. Match exposures (by route and duration) with the toxicological endpoints (by route and duration) and then conduct an aggregate risk assessment on the matches only when the integrity of the individual relationship between the endpoint, route, and duration is maintained.*

Determining which routes (i.e., ingestion, inhalation, and dermal) and pathways (i.e., food, drinking water, and residential) are to be aggregated is a key decision in the development of an aggregate exposure assessment. Two general factors control this decision process–the toxicologically relevant dose and the potential exposure pattern of the active ingredient. The exposed individual's dose should be matched against a relevant toxicological dose in terms of route, duration, and effect.

The careful evaluation of all route-specific exposure scenarios based on timing of effect and other toxicologically relevant characteristics as well as the registered uses and use patterns, and then the matching of

those scenarios based on data that support the combinations further assures the integrity of the aggregate exposure scenarios.

4. Determine Which of the Possible Residential Exposure Scenarios Are Likely to Occur Together *(i.e., co-occur within a given time-frame) and which occur independently.*

Within the residential exposure pathway there may be multiple possible scenarios, potentially involving exposure via all routes of exposure. Some of those exposure scenarios might be linked or correlated such that the occurrence of one affects the likelihood of the occurrence of another. For example, the use of one product may generally preclude the use of another and a homeowner is unlikely to use more than one type of roach spray to treat a given roach infestation problem. On the other hand, the use of one home pesticide product may indicate the likelihood of another. For example, it is not unusual for a person performing conventional treatment of flea-infestation to concomitantly treat the pet with a type of dog dip and to spray for the fleas in the home, so as to completely eliminate the problem and lessen the chance for reoccurrence. These types of codependencies and interrelationships should be evaluated so as to properly discount unlikely and unrealistic combinations of residential exposure scenarios while at the same time appropriately accounting for correlated or linked uses. Marketing data may be available to aid in evaluating these dependencies.

5. Determine Magnitude (i.e., Exposure Concentration), Frequency, and Duration of Exposure *(i.e., contact) for all pertinent exposure combinations.*

To bring together exposure pathways (food, drinking water, and residential) to chemicals used as pesticides, the magnitude of exposure and risk needs to be calculated for each pathway/route separately, then brought together as a total risk value. The pathways/routes to be considered in an aggregate assessment are food/oral; drinking water/oral; and residential/oral, dermal, inhalation. In bringing these pathways together, particular consideration should be given to temporal and spatial issues with regard to the likely overlapping of exposure events from a pesticide through multiple sources of exposure.

Temporal issues include those relating to seasonal variation within an exposure scenario. For example, certain types of behaviors (e.g., lawn care) are unlikely to occur in the cold winter months in the northern part of the country: data may be available to evaluate the application of a lawn treatment in December in Maine, but such a scenario defies reasonable logic. No such application is likely to take place and, thus, does not merit

inclusion in the risk assessment. Similarly, contamination of water by a rapidly metabolized corn herbicide is most likely to occur in the spring and is less likely to occur in the winter months. Thus, aggregation scenarios in which drinking water exposures were involved would likely focus on other exposure scenarios which occur in the spring.

Another temporal aspect which should be considered is the frequency of and time interval between, exposure events. If a home owner fumigates a house today, it is unlikely that fumigation would be repeated tomorrow. However, residual exposure may continue for the next several days following fumigation although at a reduced level. Spatial considerations include the region of the country and climatic differences that may be anticipated. These differences include allowances for the seasonal differences in temperature that occur depending upon the region. In this example, the impact of a region coincides with temporal considerations. For example, impacts of winter on use patterns for pesticides might be very different in Maine as compared to Florida.

In addition to temporal issues, spatial issues should also be considered. For example, it might be important in evaluating certain exposure scenarios to distinguish between rural versus urban settings. A rural setting is more likely to be associated with a private well as a drinking water source than an urban setting. Similarly, data may show that regional production of fresh market produce is limited to distribution in that region and this may impact the need for a regional dietary assessment especially during peak harvest season requiring that an assessment with a regional focus be performed.

To further illustrate the principle that temporal and spatial issues are relevant and need to be considered within an aggregate exposure assessment, consider two hypothetical individuals–a man living in a single family home in rural central Florida and a woman living in an apartment in Chicago. The individual in Florida would be more likely to depend on a private well for drinking water, perform his own lawn care throughout much of the year, treat his home several times a year for roaches, have a private swimming pool, and eat locally produced food for nine months a year. The individual in Chicago depends on municipal drinking water, does not have a private lawn or swimming pool, and lives in an apartment with monthly scheduled pest control service. Based solely on time, place, and demographics it is likely that these two individuals have significantly different potential exposures to a given pesticide. After defining the toxicological endpoint (effect) and route of concern, the assessor should decide upon the appropriate set of residential, food and drinking water exposure assumptions for combining these risk scenarios. The decisions concerning which residential scenarios should be considered in aggregate

risk assessments should be made using the scenarios in the Draft Residential SOP's as a basis for primary selection.

6. Determine Most Appropriate Technique *(deterministic or probabilistic) for incorporating data into exposure algorithms.*

Once input data are collected for exposure variables of interest, several techniques are available for representing these variables. OPP has traditionally used a deterministic approach to generate a single estimate of exposure and risk based on expressing all input variables in the exposure algorithm as single values (point estimates). Alternatively, one can use probabilistic techniques to more fully incorporate available information taking into account the range of possible values that an input variable could take, and weighting these values by their probability of occurrence. Probabilistic techniques acceptable to OPP are discussed in another guidance (USEPA, 1997d). Isn't this just the little plain english paper?] OPP anticipates that a probabilistic approach to exposure assessment via all pathways will be possible in the future.

The choice of distributions to include as inputs into the aggregate exposure and risk model should always be based on all relevant information (both qualitative and quantitative) available for input. The selection of a distributional form (probabilistic or deterministic) should consider the quality and quantity of the information in the database, and should address broad questions such as the mechanistic basis for choosing a distributional form, the discrete or continuous nature of the variable, and whether the variable is bounded or unbounded. In all cases, input values expressed as a distribution should be fully described (USEPA, 1998c).

Not all input values need, or necessarily should, be expressed as a mathematically-modeled distribution, and probabilistic techniques should be used only on those pathways and exposure patterns which significantly influence the final risk estimate. If an input variable does not significantly affect an exposure estimate regardless of its distribution, then its use in a probability distribution represents marginal value added (USEPA, 1998c). Given this, using both deterministic and distributional data in the aggregate assessment process is acceptable. From a computational standpoint, a probabilistic analysis can include a mix of point estimates and distributions for the input parameters to the exposure model. However, when doing so the risk assessor and risk manager should continually review the basis for "fixing" certain parameters as point values to avoid the perception that these are indeed constants that are not subject to change.

7. Determine the Appropriate Risk Metric *to be used in analysis and calculating aggregate exposure and risk.*

There are several methods of measuring and aggregating risk for single chemical, multi-route, multi-source assessments. Two aggregation methods were developed by OPP–the Total MOE and the Aggregate Risk Index (ARI) (USEPA, 1998e). Arithmetically, the two approaches are the same when the uncertainty factors (UF) are the same for all routes of exposure. When the UF's differ by route, however, the ARI is preferred. OPP will continue to employ either the total MOE or the ARI in its aggregate exposure and risk assessments.

Currently, risk assessments in OPP are based on the MOE concept. The MOE is calculated by dividing the No-Observed-Adverse-Effect Level (NOAEL) from a toxicity study by an appropriate estimate of the level of anticipated exposure. Thus, as a rule, risk increases as the MOE decreases. Each MOE is compared against a composite UF which serves as a standard when ascertaining whether a given hazard is acceptable.

Total MOE (MOE_T) Method:

The following aggregation equation has been used since April 1996 to aggregate "unitless" MOEs into a Total MOE (MOE_T). This concept was presented to, and endorsed by, FIFRA's Science Advisory Panel (FIFRA SAP, 1997):

Equation 1

$$MOE_T = \frac{1}{\frac{1}{MOE_1} + \frac{1}{MOE_2} + \ldots + \frac{1}{MOE_n}}$$

where MOE1, MOE2,...MOEn represent route-specific (e.g., oral, dermal, inhalation) MOEs. To use this equation, all MOEs must have associated with them the same numerical UF (typically 100 for interspecies extrapolation and intraspecies variability), as in this example:

Oral:	MOE = 100	UF = 100
Dermal:	MOE = 200	UF = 100
Inhalation:	MOE = 70	UF = 100

The MOE_T is always lower than the lowest MOE. The MOE_T decreases with each additional MOE in the equation because each additional exposure increases the hazard. The lowest MOE (the inhalation MOE of 70 in this example) has the most influence on the MOE_T. The MOE_T of 34.1 would be a concern because it is less than the acceptable UF of 100. A major deficiency of this method is that it cannot accommodate dissimilar UF's for different pathways and routes.

Equation 2

$$MOE_T = \frac{1}{\frac{1}{100_O} + \frac{1}{200_D} + \frac{1}{70_I}} = 34.1$$

Ideally, route-specific MOEs for each route of exposure should be aggregated. When limitations on the available toxicity data make this approach impossible, data from another route can be substituted although this introduces some degree of error. For example, an inhalation MOE can be calculated by using an oral

NOAEL that has been extrapolated to an “equivalent” inhalation NOAEL. Uncertainty could result from using an extrapolation method that does not account for pharmacokinetic differences between the routes, and from assuming that the route with no data will have the same toxic signs as the well characterized route.

Aggregate Risk Index (ARI) Method:

The ARI was devised as a way to aggregate MOEs that have dissimilar UF’s. MOEs for each route of concern are compared against UF’s which reflect the nature, source, and quality of the data, and the FQPA mandate to protect susceptible infants and children. This can result in a variety of UF’s such as these:

	Oral	**Dermal**	**Inhalation**
MOE:	300	100	1000
	---	---	---
UF:	1000	100	300

MOE’s can only be combined if they have a common UF. If the MOE/UF ratios for each route are treated as fractions (as shown above), they can be adjusted to a common denominator of 1. This is accomplished by dividing each MOE by its UF to yield a Risk Index (RI):

	Oral	**Dermal**	**Inhalation**
RI:	0.30	1.0	3.3

The RIs can then be combined to yield an ARI:

Equation 3

$$ARI = \frac{1}{\frac{1}{RI_1} + \frac{1}{RI_2} + \ldots + \frac{1}{RI_n}}$$

Equation 4

$$ARI = \frac{1}{\frac{1}{0.30_O} + \frac{1}{1.0_D} + \frac{1}{3.3_I}} = 0.22$$

RI's and ARI's are always compared against 1. This allows for direct comparisons between routes and between chemicals. As a general rule, an RI or ARI greater than or equal to 1 is of little concern, but an RI or ARI less than 1 suggests a risk of concern. In this example, the ARI (0.22) suggests a risk of concern because it is less than 1. The oral exposure has the lowest RI (0.30), so it is the major route of concern.

The ARI is an extension of the MOE concept. As with the MOE, risk increases as the RI or ARI decreases. The ARI method automatically considers each route's potency when route-specific NOAELs are used. The following equation is a simplified way of calculating a chemical's ARI in a single step:

Equation 5

$$ARI = \frac{1}{\frac{UF_1}{MOE_1} + \frac{UF_2}{MOE_2} + \ldots + \frac{UF_n}{MOE_n}}$$

Oral hazards are usually expressed as the "Percent of RfD" rather than as an MOE. Because the UF for the oral route is used to define the oral RfD, the percent of RfD (expressed as a decimal) can be put directly into the equation (assume oral exposure is 330% of the RfD, i.e., 3.3:

Equation 6

$$ARI = \frac{1}{RfD_O + \frac{UF_D}{MOE_D} + \frac{UF_I}{MOE_I}}$$

Equation 7

$$ARI = \frac{1}{3.3_O + \frac{100_D}{100_D} + \frac{300_I}{1000_I}} = 0.22$$

Percentages of reference doses (RfDs) and reference concentrations (RfCs) for all routes may also be aggregated:

Equation 8

$$ARI = \frac{1}{RfD_O + RfD_D + RfC_I}$$

8. Conduct Analysis to Determine the Magnitude of Exposure and Risk for Each Pertinent Exposure Pathway. *Aggregate, as appropriate, exposure and risk and sum risk. Then aggregate risk for each pathway from all pathways to each individual in the population. Several aggregate exposure and risk assessments may be required for a single active ingredient.*

In this step, the aggregate assessment is conducted from information generated in Steps 1 to 7 with the appropriate temporal, spatial, and demographic exposure factors correctly assigned and consistently maintained throughout the analysis. In accordance with Steps 1 through 7, specific considerations in this "bringing together" include:

- Time (duration, frequency, and seasonality of exposure; seasonally-based pesticide residues in food; frequency of residential pest control which reflects housing location and type);

- Place (location and type of home); watershed (size of drinking water facility) or aquifer characteristics (confined or unconfined); region (regionally specific drinking water concentrations of the pesticide being considered); and

- Demographics (age; gender; gender- and age-specific body weights; reproductive status; ethnicity; personal preferences, behaviors, and characteristics).

All "linkages" of time, space and demographic characteristics should be made using supporting data. Aggregate exposure and risk assessment are first completed for individuals, who are then combined to develop distributions of aggregate exposure and risk to subpopulations and populations.

9. Conduct Sensitivity Analysis *to identify the "driver" or source(s) of risk for each route. Identify scenario(s) of concern, such as highly exposed subpopulations by sources.*

After performing an aggregate exposure and risk assessment, it may be helpful to also conduct sensitivity analysis to ascertain the pathway, commodity, exposure scenario, route, or other element of the analysis, which contributes the highest amount to total exposure and risk. Those routes and pathways with the lowest RI pose the greatest risk, and are potential candidates for risk mitigation. Sensitivity analyses can also be performed to learn how changes to input assumptions would change

the result. Sensitivity analysis in aggregate exposure and risk assessment is performed by examining characteristics defining high exposure and examining and investigating the differences in total exposure and risk with those exposure contributors of interest modified or eliminated.

A sensitivity analysis can be used to examine the relative contribution of particular routes of exposure or exposure pathways or other exposure scenarios within a pathway. For example, the sensitivity analysis might focus upon which route of exposure contributes the largest portion of the total exposure, which residential scenario of the many that were included in the aggregate analysis is the greatest contributor to exposure, or for the food exposure pathway, which commodity or commodities are the greatest contributors to the total food exposure value. For example, in food exposure assessment, commodities with extensive use, greater consumption reported, and higher concentration of pesticide residue are likely to contribute the largest overall exposure for the food pathway. The inclusion/exclusion of such commodities from the analysis could provide valuable information as to the relative importance of use of this commodity to total exposure and risk.

With this knowledge, an aggregate exposure and risk assessor may be able to: (1) state for risk management purposes the pathway of exposure which accounts for the greatest proportion of the total estimated risk; (2) recommend where future data gathering efforts might be focused; or (3) suggest ways in which total exposure and risk could be reduced. Sensitivity analyses are particularly useful in deciding whether or not to elevate a pathway-specific analysis to the next level of data refinement (increasing sophistication of exposure and toxicological data) and therefore consume more resources.

10. Aggregate Exposure and Risk Characterization

The risk characterization process includes an integrative analysis followed by a risk characterization summary detailing the major results of the risk assessment. The integrative analysis brings together the assessments of hazard, dose-response, and exposure to make risk estimates for the exposure scenarios of interest. The integrative analysis typically identifies the elements of the aggregate analysis which most affect the exposure and risk conclusion for use in decision-making. It is an appraisal of the science that supports the risk manager in making regulatory decisions. Risk characterization reports also indicate where the greatest opportunities for data or methodological improvements may exist.

Risk characterization routinely includes the following points capturing the important items covered in hazard, dose-response, and exposure characterization:

- primary conclusions about hazard, dose-response, and exposure, including other plausible alternatives,
- nature of key supporting information and analytical methods,
- risk estimates and their attendant uncertainties, including use of key assumptions when data are missing or uncertain,
- statement of the extent of extrapolation of risk estimates from observed data to exposure levels of interest (i.e., MOE) and its implications for certainty or uncertainty in quantifying risk,
- significant strengths and limitations of the data and analyses, including any major peer reviewers' issues, and
- if appropriate, comparison with similar risk analyses or common risks with which people may be familiar.

The risk characterization should identify all exposure scenarios that are not quantified in the aggregate risk assessment, and discuss qualitatively the possible impact of such exposure scenarios on the results of the risk assessment. Among other scenarios, the characterization should address potential exposures through breast milk and inhalation exposures from pesticide residue in water used for bathing and nonpesticidal uses of the chemical, unless sufficient data support inclusion of the scenario in the quantitative assessment.

Whenever assessing aggregate exposure from different pathways, it is important to characterize potential differences in the uncertainty of each pathway. Estimates of exposure by different pathways are calculated using different inputs: exposure data, assumptions, survey for pathways populations. Therefore the resulting estimates for pathways may differ in their level of accuracy and representativeness. The risk characterization should consider and discuss, as appropriate, how the inputs relating to populations, exposure data, and default assumptions may influence the relative accuracy of the pathway estimates. Further the risk characterization should discuss the potential differences in susceptibility of major identifiable subgroups and life stages.

The risk characterization is a valuable part of generating any Agency report on aggregate risk, whether the report is preliminary to support allocation of resources toward further study, or comprehensive to support regulatory decisions. In the former case, the detail and sophistication of the characterization are appropriately small in scale; in the latter case, appropriately extensive. Also, on the continuum from simple to more sophisticated assessments, default assumptions are used at almost every stage because the database is almost never complete. The use of defaults is predominant at screening stages and is used less as more data are gathered and incorporated. The risk characterization should carefully delineate which issues in a particular assessment are most important.

Transparency in environmental decision-making, clarity in communication, consistency in core assumptions and science policies from case to case, and reasonableness are important elements of risk characterization. While it is appropriate to err on the side of protection of health and the environment in the face of scientific uncertainty, common sense and reasonable application of assumptions and policies are important to avoid unrealistic estimates of risk (USEPA, 1995). Both integrative analyses and the risk characterization summary present an integrated and balanced picture of the analysis of the hazard, dose-response, and exposure. The risk characterization should summarize the evidence and results, and describe the quality of available data and the degree of confidence to be placed in the risk estimates. Important features include the constraints of available data and the state of knowledge, significant scientific issues, and significant science and science policy choices that were made when alternative interpretations of data existed (USEPA, 1995). Choices made about using default assumptions or data in the assessment are explicitly discussed in the course of analysis, and if a choice is a significant issue, it is highlighted in the summary.

B. Aggregate Assessment Reporting Guidance

For OPP to evaluate aggregate risk assessments submitted for consideration, sufficient information must be provided such that the assessment can be reproduced for confirmation of the procedures and results reported. This position is consistent with OPP's policy for single pathway assessments. Similarly, aggregate risk assessments prepared by OPP should provide adequate information to permit confirmation of the outcome by the public. The format for an aggregate risk assessment report should fully describe and document the ten steps for conducting an aggregate risk assessment as detailed in this document (Section IV.A.1-10). In addition, information should be provided on: purpose and scope; inputs and assumptions; data sources; exposure algorithms and scenarios; and, definitions of defaults.

The purpose and scope of the assessment should be clearly stated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined and supported. In addition, key inputs and assumptions for exposure and hazard portion of the assessment should be listed. Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimate of interest (e.g., mean, median, high end percentiles). The selection of distributions and whether distributions used for input parameters reflect resampling of empirical distribution functions or imputations should be explained and justified.

The sources for data used in an assessment should be clearly identified. Where these are studies that have previously been submitted, and/or reviewed by the Agency, identifying information such as petition number, reregistration submission, document number (MRID), or Agency review number should be provided, so the data points can be readily confirmed. Where data points have been excluded from the probabilistic analysis, the exclusion should be identified and justified. Studies from which data are obtained should contain sufficient quality assurance/quality control of data to assure sample integrity during treatment, collection, transportation, storage, and analysis.

A discussion of the exposure algorithm(s) and their appropriateness for the scenario and population under study is recommended. Names of models and software used to generate the analysis should be identified. Routes of exposure should be clearly defined. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced. Moreover, the analyst should identify all assumptions used and explain why they are reasonable. Assumptions that have a significant impact upon the results are to be documented and explained.

V. Future Data and Research Needs

Although the development of probabilistic aggregate risk assessment tools has greatly expanded the level of detail with which risk assessment can evaluate the variability and impact of pesticide use patterns on estimated risk, OPP does not anticipate initiating any new data call-ins or data requirements with the finalization of the Aggregate General Principles.

EPA's Office of Research and Development (ORD) is conducting research on aggregate exposure and risk in support of OPP's mandate to improve its capabilities to perform aggregate risk assessment. For example, there is a major population-based field study underway that focuses on children's aggregate exposure to pesticides in homes, daycare centers, and schools. This study is scheduled for completion in FY 2004, with major products delivered in FY 2005. The results will be used to evaluate and refine a protocol that can be used by the pesticide industry and others to develop exposure data to refine residential assessments. This research will also verify pathways and activities that represent the highest exposures to children. In FY 2003, ORD will refine the current aggregate SHEDS-Pesticides exposure model to estimate exposures and absorbed dose to environmental contaminants by children and adults. ORD is also analyzing data that focuses on aggregate exposure and risk from multiple chemicals through multiple pathways, particularly for children. Data sources include NHEXAS (National Human Exposure Assessment Survey), NHANES (National Health and Nutrition Examination Survey) and ORD's STAR grants.

A. Food Ingestion Pathway

The importance of the rate of application of pesticides to agricultural commodities and the use patterns associated with pesticides have been recognized as a potential area for refinement in estimating food exposure which has not always been included in the assessment process. This issue is discussed in the "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management" (USEPA, 2000e). The "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs" (USEPA, 1998c) includes a discussion of how use-related information can be better included in the risk assessment. That document also describes acceptable sources of data and how the data will be used. Other documents which are available include "Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment" (USEPA, 2000c) and "Available Information on Assessing Exposures from Pesticide in Food: A Users Guide" (USEPA, 2000d). Other possible modifications to food assessments might include adjustment for residue levels in foods based upon differences in use patterns on fresh market and processed commodities or information concerning domestic vs. foreign production and treatment practices during different seasons. OPP is confident that this revised

document can substantially be followed using current data sources, judgements or other methods.

In the area of food consumption, few data are available describing intraindividual variation in daily consumption patterns over long periods of time. Existing cross sectional consumption data define interindividual variation, but give little insight into intraindividual behavior over time. Longitudinal data exist for a few groups of individuals in highly localized areas across the United States. More small surveys for a greater variety of subpopulations or a systematic subset nationwide would provide information needed to estimate the likely exposure of an individual to food borne pesticides over an extended period of time.

B. Drinking Water Pathway

For drinking water, in the short-term, OPP is working to improve the current screening-level models used to estimate the concentration of pesticides in drinking water, particularly for surface water. Several approaches have recently been completed and incorporated into OPP's standard practices: (1) use of a "cropped area" factor to take into account that 100 percent of a basin supporting a drinking water facility may not be cropped; and (2) modification of the pond scenario currently incorporated into OPP's screening-level water quality models to simulate a small reservoir that is large enough to support a drinking water facility. OPP is currently working on development of a more refined screening model for groundwater. There is consensus among the water quality modeling community that a basin scale water quality model linked to a GIS to estimate concentrations of pesticides in drinking water with a moderate to high level of confidence, although not currently available, would improve the ability to predict concentrations of pesticides in drinking water. In addition, research to estimate of the extent to which various kinds of drinking water treatment remove pesticides from tap water would improve model estimates of pesticide concentrations in drinking water.

It is often useful to collect available data on pesticides in drinking water from state agencies for public health, environmental protection, water resources, etc., as well as to generate data on pesticides in drinking water from statistically based surveys. For pesticides that are not found to have acceptable residue levels in screening-level models, available monitoring data and refined model estimates representing either drinking or nondrinking water supplies will be used to develop pesticide concentration distributions in drinking water for use in probabilistic aggregate exposure and risk assessments. Focused, targeted monitoring stratified across a variety of drinking water sources (vulnerable & typical) with known pesticide use for relevant pesticides is one possible source of such information. Data sets from most vulnerable drinking water sources (smaller facilities serving small populations) could be used with high confidence to bound the upper-end of the distribution of pesticide concentrations in drinking water. Data sets from more typical drinking water sources (larger systems serving large populations) could be used with high confidence to evaluate the "middle" or central tendency of the distribution of pesticide concentrations in drinking water. For incorporating drinking water into acute and chronic aggregate exposure and risk assessments these are the most critical portions of the pesticide concentration distribution.

C. Residential Pathway

In the residential exposure pathway, the ability to assess the likelihood of coincidental dietary and nondietary exposure improves with detailed use-related information. Use-related information includes details regarding the amount of pesticide applied per use, the frequency and timing of use events, and an estimate of the numbers and kinds of people making these applications. In addition, exposure assessors should be aware of applications made by consumers themselves and applications made by professional for hire services such as, pest control operators (PCO's) and professional LCO's. Usage information sources include inferences from pesticide product labels and information provided by proprietary market research service firms or government agencies. States such as California have databases of usage information and associations representing professional for hire services may also have usage information.

Frequency of use information, on a national scale, is available in the Agency's National Home and Garden Pesticide Usage Survey (NHGPUS). However, this survey is 10 years old and focuses only on major use pesticides. In addition, this survey provides very little information about postapplication activities.

Increasingly, as pesticide registrants form data generating Task Forces in response to the FQPA, longitudinal surveys are being considered for use in residential exposure scenarios. These surveys are being designed to address

usage, frequency of use, and other key information needed in an aggregate assessments such as demographic, geographic and seasonal variation.

OPP recognizes that refinements to risk assessment are always possible and that future research will lead to improved methodologies. As new data and research become available, OPP will review this document to determine whether it should be updated.

VI. Limitations in Aggregate Exposure and Risk Assessments

Aggregate exposure and risk assessments have a number of limitations depending upon whether the analysis uses deterministic or probabilistic treatment of data. Deterministic data used in an aggregate exposure and risk assessment can provide a conservative, “worst case” estimate if the estimates themselves represent the high end or upper-bound. However, as described by Cullen and Frey, because of the variability and uncertainty about exposure, the degree and direction of the conservatism associated with deterministic inputs and outputs is unknowable without detailed description of the specific exposure scenario. Deterministic estimates based on conservative inputs provide no indication of the magnitude of uncertainty surrounding the quantities estimated and lend no insight into the key sources of underlying uncertainty. Analysts should be aware of the limitations surrounding the use of deterministic data sets and make these limitations known to the risk manager (Cullen and Frey, p. 7).

The use of distributional data in a probabilistic aggregate exposure assessment also has limitations. Probabilistic analysis enables an expanded characterization of the uncertainty and variability in the data set providing information about the range and likelihood of potential exposure. However, assigning an incorrect distribution or an unrepresentative data set to an input variable with a sparse data produces an inaccurate assessment with unquantifiable uncertainty. Thus, there are cases for which probabilistic analysis is not the most appropriate choice. In particular, this may be the case when data limitations make a screening-level assessment the reasonable stopping point in the analysis, or when exposures are found to be negligible (See Table 1).

Table 1. Where Probabilistic Analysis May and May Not Be Useful

Cases in Which Probabilistic Analysis May Be Useful	Cases in Which Probabilistic Analysis May Not Be Useful
When the consequences of poor or biased exposure estimates are unacceptably high	When a screening-level deterministic calculation indicates that exposures are negligible
When a screening-level, deterministic calculation indicates exposures of potential concern, but carries a level of uncertainty that does not warrant immediate expenditures on remediation	When the cost of averting the exposure is smaller than the cost of probabilistic analysis
When there is interest in the value of collecting additional information, such as when time and resources permit additional sampling, but questions remain about whether this will impact the quality of the decision to be made	When safety is an immediate and urgent concern
When uncertain information stems from multiple sources	When the distribution of the input variables is so uncertain and/or indeterminate that detailed probabilistic analysis is inappropriate
When significant equity issues are raised by sources of variability, such as when subpopulations face unusual exposures relative to those of the general population	When there is little variability or uncertainty in the analysis
When assessing the potential benefits of targeting resources for various interventions, for example, when more than one strategy for remediation is available, but one would reduce exposure via the food chain while another would improve air quality	
When ranking or prioritizing exposures, exposure pathways, sites, or contaminants in important	
When the cost of remedial or intervention activity is high	

Cullen and Frey, p.8

OPP believes that as long as: (1) assumptions are well-explained, reasonable, and transparent; (2) sensitivity analyses are performed to determine if any assumptions are "driving" the risk or control the resulting risk estimate; and (3) the resulting risk estimate is properly characterized and incorporates the results of the sensitivity analyses, then the risk estimates are an adequate basis for regulatory decision. Furthermore, the "Guiding Principles for Monte Carlo Analysis" (USEPA, 1997d) suggests that when data for an important pathway/parameter are limited, it may be useful to define plausible alternative scenarios to examine the impact of a possible range of values for important parameters on the overall assessment. In doing this, the risk assessor should select the range of values for important parameters consistent with the knowledge of the variability of the parameter and test the sensitivity of the

assessment to the input parameter range. Where parameters are entered as distributions, the assessor should assess the impact of assumptions about the shape of the distribution on the risk assessment. These evaluations should be included in the risk characterization and considered during the interpretation of results.

A. Food Ingestion Pathway: Limitations

The techniques for assessing exposure occurring by each of the exposure pathways described in this document have inherent uncertainties. However, the food exposure pathway is perhaps the most highly investigated pathway included in the aggregate exposure and risk assessments. While there are uncertainties in the food exposure analysis, the uncertainty decreases as higher Tiers in food exposure analysis are reached. Uncertainties present in the food exposure and risk pathway may include the use of residue data from maximum application scenario instead of "typical" pesticide use rate, estimates of the percent of crop treated, and the use of monitoring data from past years which may not reflect current geographical distributions of pesticide uses or use practices. Although percent of crop treated information collected nationally are highly refined, more accurate data may be available in the form of the individual company marketing information or data from growers or producers. Additionally, regional residue data and longitudinal consumption data are limitations at this time. These uncertainties should be considered as the food exposure pathway is investigated within an aggregate exposure and risk assessment.

B. Drinking Water Pathway: Limitations

In the drinking water pathway, there are various sources of uncertainties associated with incorporating data on exposure to pesticides in drinking water into an aggregate exposure and risk assessment whether using models to estimate pesticide concentrations in drinking water or the available monitoring data on water quality. OPP understands that the results provided by the computer simulation models currently used at the first and second Tier of analysis for pesticide concentrations in surface water do not characterize either the effects of dilution, distribution and/or potential treatment at a drinking water facility. However, model refinements to provide improved estimates are in progress. Therefore, the models' limitations increase the uncertainty in the semiquantitative exposure assessment upon which the results are based. OPP has developed and implemented in early 2000 a model scenario that more accurately reflects pesticide concentrations in reservoirs that are large enough to be used as a drinking water facility including the output of time-dependent distributions of residues that reflect actual weather data. The SCI-GROW groundwater screening model provides concentration estimates for a pesticide that consistently bound greater than 99% of concentrations for that pesticide in drinking water wells in use areas (USEPA, 1999c).

The highest degree of confidence and lowest uncertainty would be associated with extensive monitoring data representing finished drinking water sampled over several years for specific pesticides known to be highly to moderately used in areas surrounding the drinking water facility. A range of drinking water facilities stratified across those considered to be most vulnerable to contamination to those considered to be more typical would be included in a data set associated with a high level of confidence. For surface water, these vulnerable areas are represented by small- to medium-sized watersheds in agricultural areas that are heavily cropped. For groundwater, agricultural areas with shallow depths to potable groundwater, coarse or sandy soils, and high recharge rates are considered vulnerable to contamination from pesticides.

C. Residential Pathway: Limitations

In the residential exposure pathway, reconciling environmental measurements, human activity patterns that contribute to potential exposure, and the biological factors that ultimately lead to absorbed dose presents unique challenges for exposure assessors attempting to estimate nondietary, residential exposure. Many of the current estimates (postapplication in particular) are made in the absence of formal guidance by the Agency beyond the screening-level SOP's. ORD is conducting and designing studies to support postapplication and residential model development, and the results of those studies will become available over the next several years. Similar exposure studies to be generated by industry task forces are also in the design phase. All of this information will be reviewed and used as it is made public.

The current, postapplication residential exposure models addressing reentry onto treated lawns and carpets are simple algorithms. Estimates (e.g., Guranathan et al., 1998) need to be viewed in the context of available health surveillance data and studies in which biological monitoring was performed following structured activities. Biological monitoring studies such as those of young children living in the immediate vicinity of pesticide treated orchards (Loewenherz et al., 1997; Simcox et al., 1995) can also provide insight regarding the magnitude of residential exposure. While the models discussed above often predicted up to thousands of micrograms of pesticide per kilogram body weight, the available biological monitoring data and health surveillance data suggest much less per kilogram body weight. The Agency is currently evaluating the default assumptions in the available model/algorithms which may account for the apparent discrepancy in exposure estimates from these sources.

Estimating residential exposure of the pesticide applicator is more straightforward. To estimate residential handler exposure, Agency exposure assessors use data available in the Pesticide Handlers' Exposure Database (PHED) and from studies on individual pesticides. These data are based on guideline studies and other published data concerning methods and quantity of

pesticide application. While the data may contain many nondetects, they do address activities that are reasonably well defined. When a specific application scenario does not exist in PHED or other available databases, exposure assessors estimate the quantity of pesticides that residents use to treat their homes, lawns and gardens, and how often are those applications made using surrogate data and professional judgement. Some of the questions surrounding an application scenario without data specifically targeted to that use pattern can be answered through the use of indirect data available though marketing services, company data, or well designed surveys. To the extent that data are not available for use in estimating a home pesticide applicator's exposure, and estimates based on surrogate use data are used, different types of uncertainty exist.

Postapplication exposure following treatment of vegetables is also based on activities that are fairly well defined and based on models designed to estimate farm worker exposure. Often, levels of available residues can be estimated. However, chemical dissipation rates are often unavailable, thus allowing only high-end residue estimates. Postapplication inhalation exposure can be addressed using survey data from the National Human Activity Pattern Survey (NHAPS) and well defined ventilation rates available in the Agency's *Exposure Factors Handbook* (USEPA, 1997b). Surveys such as NHAPS can assign "individuals" to a place for a period of time while conducting a certain activity, e.g., reading a book. Exposure is estimated by comparing an activity, a time duration as reported in NHAPS, and an appropriate (age/weight/gender) ventilation rate from the *Exposure Factors Handbook* to a residue estimate. But, what is often unknown is airborne concentrations of pesticides following applications and their subsequent dissipation.

VII. Validation and Verification of Aggregate Assessment

A. Model Evaluation and Enhancement

In any computer-based simulation/modeling effort, it is important that the analyst determine that a model is valid, i.e., that the model-predicted result corresponds reasonably well to results obtained in the "real world." Specifically, this suggests that a model be both verified and validated. Model verification attempts to confirm that the computer simulation is performing as intended and check the translation of the conceptual simulation model into the appropriate computer code. Model validation, on the other hand, concerns itself with determining whether the conceptual model is an appropriate simulation of reality and an accurate representation of the system under study (Law and Kelton, 1991).

Given the complexity of the models under consideration for conducting aggregate assessments, and the state of the available data, rigorous validation and verification of any model is probably undoable. Any model used to assess aggregate exposure should undergo a rigorous evaluation phase (including peer review) to establish the credibility of the model and determine that the model output (i.e., the model predictions) are adequately representative of reality (ILSI, 2001). This stage of model evaluation should also include identification of the model's strengths and limitations as well as the most critical parameters and assumptions used by the model. The validity and credibility of any aggregate exposure model can be investigated by comparing model predictions (in terms, for example, of the distribution of daily exposures, expressed in mg pesticide/kg body weight) with the exposure distributions as predicted by a variety of completed studies such as the Hispanic Health and Nutrition Examination Survey (HHANES) and NHANES, various OPP and academic institution data, industry task force studies, and (if available) proprietary data from industry or trade groups. Data to support such investigations are limited for many pesticides and therefore validation may not always be possible.

B. Biomonitoring

Biological monitoring, or biomonitoring, provides a basis for estimating an internal dose by measuring a pesticide and/or its metabolite concentrations in selected body tissues or fluids. Biomonitoring studies of selected chemicals measure exposures that have already incurred. Also, biomonitoring involves sampling only (e.g., blood sample) with no additional health or other consequences likely to occur from the sampling procedures. When done quantitatively, the internal dose determined from biomonitoring reflects exposures (i.e., absorbed doses) from all possible routes. Since the internal dose calculated from biomonitoring represents exposures from all pathways by all routes, biomonitoring may provide a method of validation for aggregate exposure assessments. It should, however, be supplemented with information on when and how exposure occurred, how the sample was collected, and data describing the absorption, metabolism and excretion for the compounds in question.

Biomonitoring studies should not be confused with using humans as test subjects. The government has in place very stringent standards that apply to federally funded research to ensure the protection of human subjects. OPP believes that the protection of public health from adverse effects of pesticides can be achieved through reliance on animal testing and use of the highest ethical standards. Biomonitoring studies investigate the biological consequences of pesticide exposure during the normal cycle of product use, and not the intentional dosing of human subjects.

The most appropriate methods for biological monitoring should be chosen based on a thorough knowledge and understanding of the pharmacokinetics of the specific pesticide in humans. Detailed guidance for the design and execution of biological monitoring studies is presented elsewhere (USEPA, 1998a and references therein). For certain pesticides, biological monitoring may not be an appropriate validation technique. Consider a particular pesticide that is extensively metabolized to a large number of minor metabolites. Each minor metabolite may be subject to interindividual variability. The following example illustrates the degree of potential inaccuracy in predicting absorbed doses from minor metabolites. A minor metabolite may represent an average of two percent of the absorbed dose with reported values ranging from 0.5 percent to 5.0 percent in human volunteers. Using the average value would require the use of a 50-fold correction factor to calculate an absorbed dose. Conversely, if the five percent value is representative, a correction factor of 20-fold would be recommended. It is recommended that a suitable biological monitoring marker metabolite would represent at least 30 percent of the administered dose, with a range of values not exceeding a factor of three in human volunteer studies.

GLOSSARY

Absorbed Dose. The amount of a substance penetrating across the absorption barriers (or the exchange barriers) of an organism, via either physical or biological processes. Synonymous with internal dose (USEPA, 1992).

Active Ingredient (ai). The chemical component of a pesticide formulation or end-use product that is intended to act as a pest deterrent. The biologically-active chemical agent in a pesticide product (USEPA, 1997a).

Aggregate Dose. The amount of a single substance available for interaction with metabolic processes or biologically significant receptors from multiple routes of exposure.

Aggregate Exposure. The amount of a chemical available at the biological exchange boundaries (e.g., respiratory tract, gastrointestinal tract, skin) for all routes of exposure.

Aggregate Exposure Assessment. A process for developing an estimate of the extent of a defined population to a given chemical by all relevant routes and from all relevant sources (ILSI, 1998a, p. A-2).

Aggregate Risk. The likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to a single substance.

Biomonitoring. Measurement of a pesticide or its metabolites in body fluids of exposed persons and conversion to an equivalent absorbed dose of the pesticide based on a knowledge of its human metabolism and pharmacokinetics.

Cumulative Risk. The likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to a group of substance sharing a common mechanism of toxicity.

Dislodgeable Residue. The portion of a pesticide (which may or may not include its metabolites) that is available for transfer from a pesticide treated surface (USEPA, 1997a).

Dose. The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism (USEPA, 1992).

Dose Rate. Dose per unit time (e.g., mg/day). Also called dosage. Dose rates are often expressed on a per-unit-body-weight basis (mg/kg/day). Dose rates may also be expressed as an average over a time period (i.e., lifetime) (USEPA, 1992).

Exposure. Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of that contact (USEPA, 1992).

Exposure Assessment. The qualitative or quantitative determination or estimation of the magnitude, frequency, duration, and rate of exposure of an individual or population to a chemical.

Exposure Scenario. A combination of facts, assumptions, and inferences that define a discrete situation or activity where potential exposures may occur (USEPA, 1997a). OPP uses this term as a synonym for "source."

High End Exposure. A plausible estimate of individual exposure or dose for those persons at the upper-end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure.

Intake. The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation. (See also potential dose) (USEPA, 1992).

Level of Comparison. Also known as Drinking Water Level of Comparison. A drinking water level of comparison is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses.

Lowest-Observed-Adverse-Effect Level (LOAEL). The lowest dose in a toxicity study at which an adverse effect is observed.

No-Observed-Adverse-Effect-Level (NOAEL). The highest dose in a toxicity study at which no adverse toxic effect is observed.

Pathway. The physical course a chemical or pollutant takes from the source to the organism exposed. Also called exposure pathway (USEPA, 1992).

Population Adjusted Dose (PAD). The reference dose adjusted by the FQPA safety factor.

Potential Dose. The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin (USEPA, 1992).

Reference Concentration (RfC). NOAEL (inhalation)/uncertainty factor (UF).

Reference Dose (RfD). NOAEL/uncertainty factor (UF).

Route. The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption. Also called exposure route (USEPA, 1992).

Source. A term defined in EPA's "Guidance of Cumulative Risk Assessment Part 1, Planning and Scoping" as an entity or action that releases to the environment or imposes on the environment chemical, biological, or physical stressor or stressors. See http://www.epa.gov/ORD/spc/cumrisk2.htm. When OPP discusses the different ways in which use of a pesticide may lead to exposure, OPP uses the term "exposure scenario." These terms are synonyms.

Surrogate Data. Substitute data or measurements on one substance (or population) used to estimate analogous or corresponding values for another substance (or population).

Transfer Coefficient. Residue transfer rate to humans during the completion of specific activities (e.g., cm^2 per hour), calculated using concurrently collected environmental residue data (USEPA, 1998a).

Uncertainty. Lack of knowledge about specific factors, parameters, or models.

Uncertainty Factor (UF). Factors used to account for inter- and intraspecies differences in relation to toxic effects, and uncertainties associated with the data.

Unit Exposure. The amount of a pesticide residues to which individuals are exposed, normalized by the amount of active ingredient used.

Uptake. The process by which a substance crosses and absorption barrier and is absorbed into the body (USEPA, 1992).

Variability. Differences attributed to true heterogeneity or diversity in a population or exposure parameter.

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EXHIBIT B

104TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 104–669
Part 2

FOOD QUALITY PROTECTION ACT OF 1996

JULY 23, 1996.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 1627]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 1627) to amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:

Page 50, strike line 5 and all that follows through page 91, line 16, and insert the following:

26–049

TITLE IV—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 401. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This title may be cited as the "Food Quality Protection Act of 1996 ".

(b) REFERENCE.—Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 402. DEFINITIONS.

(a) SECTION 201(q).—Section 201(q) (21 U.S.C. 321(q)) is amended to read as follows:

"(q)(1) The term 'pesticide chemical' means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.

"(2) The term 'pesticide chemical residue' means a residue in or on raw agricultural commodity or processed food of—

"(A) a pesticide chemical; or

"(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

"(3) Notwithstanding paragraphs (1) and (2), the Administrator may by regulation except a substance from the definition of 'pesticide chemical' or 'pesticide chemical residue' if—

"(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

"(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.".

(b) SECTION 201(s).—Paragraphs (1) and (2) of section 201(s) (21 U.S.C. 321(s)) are amended to read as follows:

"(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

"(2) a pesticide chemical; or".

(c) SECTION 201.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(gg) The term 'processed food' means any food other than a raw agricultural commodity and includes any raw

agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

"(hh) The term 'Administrator' means the Administrator of the United States Environmental Protection Agency.".

SEC. 403. PROHIBITED ACTS.

Section 301(j) (21 U.S.C. 331(j)) is amended in the first sentence by inserting before the period the following: "; or the violating of section 408(i)(2) or any regulation issued under that section.".

SEC. 404. ADULTERATED FOOD.

Section 402(a) (21 U.S.C. 342(a)) is amended by striking "(2)(A) if it bears" and all that follows through "(3) if it consists" and inserting the following: "(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists".

SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES.

Section 408 (21 U.S.C. 346a) is amended to read as follows:

"TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

"SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

"(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

"(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

"(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term 'food', when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

"(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

"(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue

that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

"(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

"(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

"(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

"(B) either—

"(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

"(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

"(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

"(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

"(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

"(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

"(A) in response to a petition filed under subsection (d); or

"(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term 'modify' shall not mean expanding the tolerance to cover additional foods.

"(2) STANDARD.—

"(A) GENERAL RULE.—

"(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

"(ii) DETERMINATION OF SAFETY.—As used in this section, the term 'safe', with respect to a tolerance for a pesticide chemical residue', means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

"(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

"(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

"(i) DEFINITION.—As used in this subparagraph, the term 'eligible pesticide chemical residue' means a pesticide chemical residue as to which—

"(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a 'nonthreshold effect');

"(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

"(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a 'threshold effect'), the Administrator determines that the level of aggregate exposure is safe.

"(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

"(I) at least one of the conditions described in clause (iii) is met; and

"(II) both of the conditions described in clause (iv) are met.

"(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

"(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

"(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

"(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

"(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

"(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

"(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

"(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

"(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

"(i) shall assess the risk of the pesticide chemical residue based on—

"(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

"(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

"(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

"(ii) shall—

"(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

"(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

"(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

"(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

"(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

"(iii) available information concerning the relationship of the results of such studies to human risk;

"(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

"(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

"(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances

in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

"(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

"(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

"(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

"(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

"(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

"(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

"(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

"(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

"(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

"(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

"(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

"(3) DETECTION METHODS.—

"(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

"(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

"(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

"(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

"(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

"(A) in response to a petition filed under subsection (d); or

"(B) on the Administrator's initiative under subsection (e).

"(2) STANDARD.—

"(A) GENERAL RULE.—

"(i) STANDARD.—The Administrator may establish or leave in effect an exemption from

the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

"(ii) DETERMINATION OF SAFETY.—The term 'safe', with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

"(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

"(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

"(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

"(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

"(d) PETITION FOR TOLERANCE OR EXEMPTION.—

"(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

"(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

"(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

"(2) PETITION CONTENTS.—

"(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

"(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

"(II) a statement that the petitioner agrees that such summary or any information it con-

tains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

"(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

"(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

"(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

"(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

"(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

"(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

"(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

"(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

"(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

"(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

"(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

"(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be

accompanied by samples of the pesticide chemical with respect to which the petition is filed.

"(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

"(3) NOTICE.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

"(4) ACTIONS BY THE ADMINISTRATOR.—

"(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

"(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

"(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

"(iii) issue an order denying the petition.

"(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

"(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

"(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has

been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

"(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

"(e) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

"(1) GENERAL RULE.—The Administrator may issue a regulation—

"(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

"(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

"(C) establishing general procedures and requirements to implement this section.

"(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

"(f) SPECIAL DATA REQUIREMENTS.—

"(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

"(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

"(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

"(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

"(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

"(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

"(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

"(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

"(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

"(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

"(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

"(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with re-

spect to such regulation or order pursuant to paragraph (2).

"(2) FURTHER PROCEEDINGS.—

"(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

"(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of a reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

"(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

"(h) JUDICIAL REVIEW.—

"(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection

(e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

"(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

"(3) ADDITIONAL EVIDENCE.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

"(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

"(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be

the subject of judicial review under any other provision of law.

"(i) CONFIDENTIALITY AND USE OF DATA.—

"(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

"(2) EXCEPTIONS.—

"(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

"(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

"(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

"(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

"(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

"(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

"(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

"(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or

that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

"(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

"(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

"(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

"(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

"(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

"(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

"(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall

revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

"(A) the date by which each such cancellation of a registration has become effective; or

"(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

"(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

"(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

"(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

"(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a

tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

"(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

"(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

"(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

"(m) FEES.—

"(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be suf-

ficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

"(A) the acceptance for filing of a petition submitted under subsection (d);

"(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

"(C) the acceptance for filing of objections under subsection (g); or

"(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

"(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

"(n) NATIONAL UNIFORMITY OF TOLERANCES.—

"(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term 'qualifying pesticide chemical residue' means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

"(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

"(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

"(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term 'qualifying Federal determination' means a tolerance or exemption from

the requirement for a tolerance for a qualifying pesticide chemical residue that—

"(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

"(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

"(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

"(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

"(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

"(5) PETITION PROCEDURE.—

"(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

"(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

"(i) satisfy any requirements prescribed, by rule, by the Administrator; and

"(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing

the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

"(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

"(i) is justified by compelling local conditions; and

"(ii) would not cause any food to be a violation of Federal law.

"(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

"(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

"(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

"(7) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

"(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue

bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

"(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

"(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

"(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

"(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

"(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

"(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

"(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

"(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

"(A) shall provide for the testing of all pesticide chemicals; and

"(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

"(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

"(5) COLLECTION OF INFORMATION.—

"(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

"(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

"(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

"(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

"(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for

resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

"(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

"(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

"(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

"(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

"(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

"(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

"(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

"(q) SCHEDULE FOR REVIEW.—

"(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

"(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

"(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

"(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

"(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

"(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

"(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

"(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.".

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING.

For the fiscal years 1997 through 1999, there is authorized to be appropriated in the aggregate an additional $12,000,000 for increased monitoring by the Secretary of Health and Human Services of pesticide residues in imported and domestic food.

SEC. 407. ALTERNATIVE ENFORCEMENT.

Section 303(g) (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (2), (3), and (4) as paragraphs (3), (4), and (5), respectively,

(2) by inserting after paragraph (1) the following:

"(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

"(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

"(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.";

(3) in paragraph (3), as so redesignated, by striking "paragraph (1)" each place it occurs and inserting "paragraph (1) or (2)";

(4) in paragraph (4), as so redesignated, by striking "(2)(A)" and inserting "(3)(A)"; and

(5) in paragraph (5), as so redesignated, by striking "(3)" each place it occurs and inserting "(4)".

PURPOSE AND SUMMARY

The purpose of H.R. 1627, Title IV, is to amend the Federal Food, Drug, and Cosmetic Act to modernize the regulation of pesticides. This measure replaces the outdated Delaney Clause with a unified safety standard, institutes workable protections for infants and children, establishes parameters for comprehensive risk assessment, ensures uniformity of safety standards, and improves consumer access to dietary information, among other provisions.

BACKGROUND AND NEED FOR LEGISLATION

Pesticides are chemicals used to control pests (such as weeds, rodents, and insects) that hinder the production of an abundant, affordable, and varied food supply. Pesticide residues are small amounts of pesticide that remain in or on food after the crop has been harvested and processed. Over the years, a complex regulatory scheme has emerged to balance the agricultural and

consumer benefits that pesticides can provide against potential risks to human health and the environment.

This regulatory scheme is administered by three agencies: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). It is also based on two statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the House of Representatives, the regulation of pesticides for agricultural use under FIFRA historically has been within the jurisdiction of the Committee on Agriculture, with the Committee on Commerce exercising jurisdiction over FFDCA provisions relating to health effects of pesticide residues in or on food, as well as certain monitoring and enforcement activities.

THE REGULATORY FRAMEWORK FOR PESTICIDE RESIDUES IN FOOD

Pesticide residues in food are regulated under the FFDCA. Current law contains two standards: one for raw products and the other for processed food. This standard, known as the Delaney Clause, bars the establishment of tolerances for pesticide residues in processed foods if the pesticide is a carcinogen.

EPA is responsible, under FIFRA, for regulating pesticide use and, under FFDCA, for setting residue tolerances for pesticides used on food crops. A tolerance establishes the maximum level of residue that can remain on the food products. Any food containing excess residues is considered adulterated and can be withheld from the market by the FDA, which is responsible for enforcing the tolerances.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

FIFRA governs pesticide registration and licensing, including labeling that prescribes conditions under which pesticides may be used legally. Manufacturers must register pesticides and be granted a license before a pesticide can be sold. FIFRA requires the registration or pre-market approval (in essence, a license) of any pesticide distributed in the United States for each intended use. The sale or use of a pesticide in a manner inconsistent with the terms of its registration is unlawful.

The legal requirements for registration recognize that pesticides are both necessary and potentially harmful. EPA must register a pesticide if it will perform its intended function without posing "any unreasonable risk to man or the environment taking into account the economic, social, environmental costs and benefits" of the pesticide use. In sum, to register a pesticide, EPA must conclude that the benefits of such a product exceed its risks. EPA bases its decision on risk assessment which measures the probability and severity of adverse effects or harm to human and/or animal health. Assessments of dietary risks from pesticide residues depend on data from many sources: field studies that show what pesticides are used and the levels of residues that can be expected to occur; the estimates of food people eat; and toxicological data which assess the potential for adverse health effects from specific pesticides.

The burden of showing that a pesticide meets FIFRA standards rests with the registrant. Developing this health and environ-

mental data is costly and time-consuming. Currently, this process typically takes $8 million and 5 years to complete, excluding the time and expense of the basic research that leads to the discovery of a new pesticide or the cost of building new manufacturing facilities.

As a result of amendments to FIFRA, EPA is in the process of reregistering pesticides originally registered many years ago when tests for the safety of residues were less sophisticated. New data required for reregistration may lead to the conclusion that some existing uses should be canceled or changed because of risks to public health.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)

FFDCA governs "tolerances" for the maximum residue level legally allowed for a specific pesticide on a specific food. FFDCA prohibits the distribution of raw agricultural commodities and processed foods that contain levels of pesticide residues that are greater than permitted under Federally-approved "tolerances." FFDCA currently contains two different legal standards for tolerances, one for raw agricultural commodities and one for certain processed foods, which are described below.

In general, tolerances are calculated by measuring the amount of a pesticide that remains in or on a crop after it is treated with a pesticide at its proposed maximum allowable rate. Actual residues can vary as a result of weather and other factors. A tolerance is set at a level calculated to give 95 percent certainty that the remaining residue will not exceed the tolerance when the pesticide is applied at the maximum level and frequency.

Once EPA establishes the tolerances, FDA enforces these them by inspecting foods at various stages from the farm gate to the port of entry to retail stores. FDA and USDA also do studies that simulate the typical dietary intake of American consumers.

Products with residues exceeding tolerances are considered to be "adulterated" and subject to seizure. It is important to note that EPA will not register the use of a pesticide on a food crop under FIFRA until the Agency has established all necessary tolerances under FFDCA.

RAW AGRICULTURAL COMMODITIES

Under Section 408 of FFDCA, EPA sets tolerances that are "safe for use, to the extent necessary to protect the public health" for pesticide residues on raw agricultural commodities. In doing this, EPA must give appropriate consideration to "the necessity for the production of an adequate, wholesome, and economical food supply." Thus, Section 408 is similar to registration under FIFRA in that it allows both the risks and benefits of a pesticide to be considered in setting tolerances for residues on raw agricultural commodities.

PROCESSED FOODS

Section 409 of FFDCA controls the regulation of pesticide residues that concentrate in processed foods. In this instance, consideration of benefits is not permitted. Under Section 409, pesticide resi-

dues are subject to the zero-risk standard of the Delaney Clause which states that "no additive shall be deemed safe (and therefore no tolerance may be set), if it is found * * * to induce cancer in man or animal. * * *" The Delaney Clause sets a zero-risk standard for pesticides that induce cancer in test animals, even if the risk to humans is inconsequential.

A major problem with the existing statutory framework derives from the current law's emphasis on whether a pesticide residue concentrates in processed food. If a raw agricultural product has a processed form but its pesticide residues do not concentrate (i.e., the residue on the processed food is less than the residue on the raw product), the residue in the processed food is covered by the raw food tolerance under Section 402 (a), which is known as the "pass-through" provision of the statute. The pass-through provision allows pesticides that do not concentrate in processed foods to bypass the zero-risk standard of the Delaney Clause. However, if the pesticide residue concentrates in the processed food (i.e., the processed food residue is greater than the raw product tolerance), it will be denied a 409 tolerance because it falls under the standard of the Delaney Clause. This policy has been the subject of litigation, and EPA is required under a consent agreement to meet deadlines for making decisions on a number of pending residue matters.

CURRENT EPA POLICY

At the request of the EPA, the National Academy of Sciences (NAS) studied existing Delaney policy and issued a report entitled "Regulating Pesticides in Food: The Delaney Paradox." The NAS report recommends that pesticide residues in both raw and processed food be regulated on the basis of a unified safety standard. In response to the NAS study, EPA issued a new policy interpretation of the Delaney Clause in October 1988. Instead of applying the zero-risk standard of the Delaney Clause, EPA tried to set one standard of de minimis or negligible risk, which was defined as a hypothetical cancer risk of less than one in a million over a 70-year lifetime for food tolerances under Section 409 of FFDCA. However, EPA's de minimis interpretation of the Delaney Clause was subsequently challenged in court and ruled invalid.

Under the current court-imposed consent degree, EPA has agreed to a schedule for making tolerance revocation decisions on a number of section 408 and 409 tolerances, many of which EPA has acknowledged only pose a negligible risk. If the tolerances under which use of these pesticides is permitted are revoked, an estimated 100 crops—including numerous fruits and vegetables—will be affected. Disruption in the production of these crops could have serious dietary and cost consequences for consumers and serious adverse impacts on the economies of the nation's major agricultural States.

HEARINGS

The Subcommittee on Health and Environment held two days of hearings on H.R. 1627, the Food Quality Protection Act, on June 7, 1995, and June 29, 1995. (The June 29, 1995 hearing also considered H.R. 1771.)

Testifying before the Subcommittee on June 7, 1995 were: Dr. Lynn R. Goldman, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, Environmental Protection Agency; Mr. William B. Schultz, Deputy Commissioner for Policy, Food and Drug Administration; Mr. Lawrence Elworth, Special Assistant for Pesticide Policy, Department of Agriculture; Dr. Carl K. Winter, Director, FoodSafe Program, University of California; Mr. Leonard P. Gianessi, Senior Research Associate, National Center for Food and Agricultural Policy; Dr. George M. Gray, Deputy Director, Harvard Center for Risk Analysis, Harvard School of Public Health; Ms. Juanita Duggan, Executive Vice President, Government Affairs and Public Communications, National Food Processors Association; Mr. Dennis Stolte, American Farm Bureau Federation; Dr. Steven Ziller, Vice President for Science and Technical Affairs, Grocery Manufacturers Association of America; Mr. Jay J. Vroom, President, American Crop Protection Association; Mr. Erik Olson, Natural Resources Defense Council; Mr. Jay Feldman, Executive Director, National Coalition Against the Misuse of Pesticides; and Ms. Carolyn Brickey, Executive Director, National Campaign for Pesticide Policy Reform.

Testifying before the Subcommittee on June 29, 1995 were: Ms. Nancy Gould Chuda, Chair, The Colette Chuda Environmental Fund and Children's Health Environmental Coalition, accompanied by Mr. James Chuda, Vice-Chair; Mr. Robert Eichler; Dr. Philip J. Landrigan, Professor and Chair, Department of Community Medicine, Mount Sinai Medical Center; Dr. J. Routt Reigart, representing the American Academy of Pediatrics; Dr. Mary S. Wolff, Professor of Community Medicine, Environmental and Occupational Medicine, Mt. Sinai School of Medicine; Mr. Edward Hopkins, Environmental Policy Director, Citizen Action; and Ms. Caroline Smith-DeWaal, Director, Food Safety Program, Center for Science in the Public Interest.

COMMITTEE CONSIDERATION

On July 17, 1996, the Subcommittee on Health and Environment met in open markup session and approved H.R. 1627, the Food Quality Protection Act of 1996, for Full Committee consideration, as amended, by a voice vote. On July 17, 1996, the Full Committee met in open markup session and ordered H.R. 1627 reported to the House, as amended, by a roll call vote of 45 yeas to 0 nays, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. The following is the recorded vote on the motion to report H.R. 1627, as amended by the Subcommittee on Health and Environment, including the names of those Members voting for and against.

COMMITTEE ON COMMERCE—104TH CONGRESS, ROLLCALL VOTE NO. 150

Bill: H.R. 1627, Food Quality Protection Act of 1996.

Motion: Motion by Mr. Bliley to order H.R. 1627 reported to the House, as amended.

Disposition: Agreed to, by a rollcall vote of 45 yeas to 0 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley	X			Mr. Dingell	X		
Mr. Moorhead	X			Mr. Waxman	X		
Mr. Tauzin	X			Mr. Markey	X		
Mr. Fields	X			Mr. Collins			
Mr. Oxley	X			Mr. Hall	X		
Mr. Bilirakis	X			Mr. Richardson	X		
Mr. Schaefer	X			Mr. Bryant	X		
Mr. Barton	X			Mr. Boucher	X		
Mr. Hastert	X			Mr. Manton	X		
Mr. Upton	X			Mr. Towns	X		
Mr. Stearns	X			Mr. Studds			
Mr. Paxon	X			Mr. Pallone	X		
Mr. Gillmor	X			Mr. Brown	X		
Mr. Klug	X			Mrs. Lincoln			
Mr. Franks	X			Mr. Gordon	X		
Mr. Greenwood	X			Ms. Furse	X		
Mr. Crapo	X			Mr. Deutsch	X		
Mr. Cox	X			Mr. Rush			
Mr. Deal	X			Ms. Eshoo	X		
Mr. Burr	X			Mr. Klink	X		
Mr. Bilbray	X			Mr. Stupak	X		
Mr. Whitfield	X			Mr. Engel	X		
Mr. Ganske	X						
Mr. Frisa	X						
Mr. Norwood	X						
Mr. White	X						
Mr. Coburn	X						

Committee Oversight Findings

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee held legislative hearings and made findings that are reflected in this report.

Committee on Government Reform and Oversight

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

New Budget Authority and Tax Expenditures

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee states that H.R. 1627 would result in no new or increased budget authority or tax expenditures or revenues.

Committee Cost Estimate

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 23, 1996.

Hon. THOMAS J. BLILEY, Jr.,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for Title IV of H.R. 1627, the Food Quality Protection Act of 1996.

Enactment of Title IV of H.R. 1627 would affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: Title IV of H.R. 1627.
2. Bill title: Food Quality Protection Act of 1996.
3. Bill status: Title IV, as ordered reported by the House Committee on Commerce on July 17, 1996.
4. Bill purpose: Title IV of the bill would amend the Federal Food, Drug, and Cosmetic Act, and would authorize the appropriation of $12 million over the 1997–1999 period to the Department of Health and Human Services (HHS) to increase monitoring of pesticide residues in imported and domestic food. Title IV would change the standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food.
5. Estimated cost to the Federal Government: Assuming appropriation of estimated amounts authorized for discretionary programs conducted by EPA and HHS, enacting Title IV of H.R. 1627 would lead to fiscal year 1997 funding for food tolerance programs of about $26 million. CBO estimates that the bill would authorize appropriations totaling about $154 million over the 1997–2002 period.

In 1996, about $2 million in fees was collected and spent by EPA for establishing pesticide tolerances in food. Under Title IV of H.R. 1627, we assume sufficient fees would continue to be collected for food tolerance work, and that the agency would spend all of the fees collected. Hence, the income from the fees and the spending of that income would offset each other, and there would be no net impact on direct spending for each fiscal year.

SPENDING SUBJECT TO APPROPRIATION

[By fiscal year, in millions of dollars]

	1996	1997	1998	1999	2000	2001	2002
Spending under current law:							
Budget authority	22	.....	.....	.....	.....	.....	.....
Estimated outlays	22	7	.....	.....	.....	.....	.....
Proposed changes:							
Estimated authorization level	.....	26	27	27	24	25	26
Estimated outlays	.....	18	27	27	25	25	25
Spending under H.R. 1627, title IV	22	26	27	27	24	25	26
Estimated outlays	22	25	27	27	25	25	25

Note.—The 1996 level is the amount appropriated for that year.

The costs of this bill fall within budget functions 300 and 550.

6. Basis of estimate: For the purpose of this estimate, CBO assumes that the bill will be enacted before 1997 appropriations for EPA and HHS are provided and that all funds authorized by Title IV of H.R. 1627 will be appropriated.

The bill would specify an authorization of $12 million over the 1997–1999 period to HHS for increased monitoring of pesticide residues on imported and domestic food. For this estimate, we split the $12 million authorization into equal components of $4 million a year for fiscal years 1997 through 1999. In addition, CBO estimates the bill would authorize the appropriation of $45 million to continue food safety programs conducted by EPA and about $97 million to continue pesticide residue monitoring conducted by HHS over the next six years.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. CBO estimates that enacting Title IV of H.R. 1627 could affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill. We estimate the pesticide tolerance fee collected under current law could increase if EPA's resource needs grow as a result of enactment of this title. If the fees are increased, we estimate that direct spending would increase by the same amount, thus resulting in no net impact.

[By fiscal year, in millions of dollars]

	1996	1997	1998
Change in outlays	0	0	0
Change in receipts	(1)	(1)	(1)

[1] Not applicable.

8. Estimated impact on State, local, and tribal governments: Title IV of H.R. 1627 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) but this mandate would impose no significant costs on state, local, or tribal governments.

This title would prohibit state and local governments from establishing or enforcing regulatory limits on pesticide residues that differ from limits established by the federal government. The bill would establish a process under which states could petition EPA for an exception to this prohibition. We estimate that state and local governments would incur no significant costs as a result of this provision.

9. Estimated impact on the private sector: CBO has identified several private-sector mandates in the bill. Among these are provisions that would require large retail grocers to display information provided by EPA about pesticides, and that would require businesses that register, manufacture, or import certain products to screen for substances that may have an effect on humans that is similar to an effect produced by naturally occurring estrogen, or other endocrine effects as directed by EPA.

Although the mandates become effective at different dates, CBO, estimates that the aggregate direct costs of mandates in this bill would not likely exceed the $100 million threshold established in Public Law 104–4 in the first five years that the mandates become effective. Costs for estrogenic testing could exceed the threshold in subsequent years, if more expensive tests become required. The direct costs of the new mandates on the private sector could be at least partially offset by savings from changes the bill would make to the standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food.

10. Previous CBO estimate: On July 10, 1996, CBO prepared a cost estimate for H.R. 1627 (Titles I–V) as ordered reported by the House Committee on Agriculture, on June 19, 1996. The Commerce Committee version of Title IV is different from the Agriculture Committee version, and has a different budgetary impact.

11. Estimate prepared by: Federal Cost Estimate: Kim Cawley and Anne Hunt. Impact on State, Local, and Tribal Governments: Marjorie Miller. Impact on the Private Sector: Patrice Gordon.

12. Estimate approved by: Robert A. Sunshine, for Paul N. Van de Water, Assistant Director for Budget Analysis.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill would have no inflationary impact.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

SEC. 401. SHORT TITLE AND REFERENCE

Section 401(a) authorizes citations to refer to this title as the Food Quality Protection Act of 1996; all amendments refer to the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC 321 et seq.), according to Section 401(b).

SEC. 402. DEFINITIONS

Section 402(a) amends Section 201(q)(1) of the FFDCA (21 USC 321(q)(1)) to change the existing definition of "pesticide chemical" to include: any pesticide as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); any active ingredient of a pesticide; and any inert ingredient of a pesticide. (FIFRA definitions of these terms are at Section 2(a) (7 USC 136(a)), Section 2(u) (7

USC 136(u)), and Section 2(m) (7 USC 136(m)), respectively.) Section 402(a) also adds a new paragraph (2) at the end of Section 201(q) to define "pesticide chemical residue" as a residue, in or on either raw or processed food, of a pesticide chemical (as defined at (1)) or of any other added substance that is present primarily due to metabolism or degradation of a pesticide chemical. It allows the Administrator of the U.S. Environmental Protection Agency (EPA) to exempt a substance from these definitions if the occurrence of the residue in a food is due to natural causes or human activities unrelated to "a pesticidal purpose," and if the Administrator, after consulting with the Secretary of Health and Human Services (DHHS), determined that the substance should be regulated under a section of FFDCA other than Sections 402(a)(2)(B) and 408.

Section 402(b) amends the current definition of a "food additive" in FFDCA Section 201(s) to exclude (1) a pesticide chemical residue on raw or processed food, and (2) a pesticide chemical. Section 402(c) amends FFDCA Section 201 by adding definitions for "processed food" and "Administrator." New subsection (gg) defines "processed food" as any food other than a raw agricultural commodity, including any such commodity that has been subject to canning, freezing, cooking, dehydration, milling, or other processing. New subsection (hh) defines "Administrator" as the Administrator of the EPA.

SEC. 403. PROHIBITED ACTS

Section 403 amends FFDCA Section 301(j) (21 USC 331(j)), which prohibits disclosure of information about confidential methods or processes, except to employees of the DHHS, U.S. Department of Agriculture (USDA), certain committees of Congress, or to the courts when relevant to a proceeding. It adds FFDCA Section 408(i)(2) to the list of sections under which, if confidential information is gained, the prohibition applies.

SEC. 404. ADULTERATED FOOD

Section 404 amends FFDCA section 402(a)(2) (21 USC 342(a)(2)) so that all pesticide residues in all foods are regulated under Sections 408 and 402(a)(2), but not Section 406 or 409. Existing Section 402(a)(2) states that all food shall be deemed adulterated (A) if it "contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of Section 406," (B) "if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a)", or (C) "if it is, or if it bears or contains, any food additive which is unsafe within the meaning of Section 409." Under current law, therefore, pesticide residues on raw food are governed by Section 408, but pesticide residues on processed food are regulated under Section 409 if they concentrate during processing. Section 406 states that food containing added poisonous or deleterious substances is unsafe unless the substance cannot be avoided and does not exceed limits set by EPA to protect public health (i.e., tolerances). Section 404 of H.R. 1627 also removes the clause following "*Provided*" in FFDCA Section 402 (a)(2). The effect is to

retain the principle that food is considered adulterated or "unsafe" if a raw agricultural commodity contains a pesticide residue that is "unsafe" within the meaning of the new section 408, if a food contains any food additive that is unsafe within Section 409, if a food contains a new animal drug that is unsafe within the meaning of Section 512, or if a food contains any other added poisonous or deleterious substance that is unsafe within the meaning of Section 406. However, pesticide residues in processed food also would be excluded from coverage of Section 406 (and Section 409) and would fall instead under Section 408.

SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

Section 405 amends FFDCA Section 408 (21 USC 346a), currently pertaining to pesticide residue tolerances for raw food. The proposed amendments would establish a single regulatory framework for both raw and processed foods.[1]

Sec. 408(a). Requirement for Tolerance or Exemption

New Section 408(a)(1)—General Rule retains the current provisions of Section 408(a) which deem any pesticide residue on food unsafe (and therefore the food is adulterated under Section 402(a)(2)(B)), unless it has a tolerance and is within the limits of the tolerance, or has an exemption from a tolerance. For purposes of new Section 408, both raw agricultural commodities and processed food products are considered "food." A provision of the current law is moved by the bill; new subsection (k) exempts from tolerance requirements pesticides "generally recognized as safe" before enactment of H.R. 1627 (see below).

New Section 408(a)(2)—Processed Food writes into law the "pass-through" provision used currently by EPA. Presently, if a tolerance or exemption is in effect for a pesticide chemical in a raw food, the residue of that pesticide in that food, after it is processed, is not unsafe as long as the residue is below the raw food tolerance or is exempt from the requirement for a raw food tolerance. The new subsection permits all foods to be considered safe, and not adulterated under Section 402(a)(2)(B), if they contain pesticide residues that are within a tolerance, or are exempt from the requirement for a tolerance, and the residues have been removed to the extent possible.

New subsection 408(a)(3)—Residues of Degradation Products discusses products of precursor or parent pesticides. It requires EPA to apply the tolerances and exemptions established for residues of the parent pesticide to residues of the pesticide's breakdown products, as long as the tolerance did not expressly exclude breakdown products and EPA had not determined that the dietary exposure to the breakdown product posed a different or significantly greater potential health risk than the parent pesticide. The Committee understands that in making such a determination today, EPA does not include, in calculating the combined levels, degradation prod-

[1] FFDCA Section 409 is not amended by H.R. 1627. Instead, H.R. 1627, Section 402 redefines "food additive" and "pesticide chemical residue" so that pesticide residues always are covered by Section 408, as it would be amended. A key effect of this change is to make the Delaney Clause no longer applicable to pesticide residues concentrated in processed foods.

ucts that pose no health risk (such as GRAS substances). It is the Committee's intention that such degradation products not be included in any determination as to whether the combined residues of a pesticide and its degradation products meet the tolerance levels.

New Section 408(a)(4)—Effect of a Tolerance Or Exemption specifically prohibits considering a food adulterated within the meaning of Section 402(a)(1) because it contains a pesticide residue, if a tolerance or exemption were in effect for that pesticide on that food. This clarifies the principle that pesticide residues are regulated under Section 402(a)(2) only.

Sec. 408(b). Authority and Standard for Tolerance

Existing FFDCA Section 408(b) requires the EPA Administrator to promulgate regulations establishing tolerances for pesticides used on food "to the extent necessary to protect the public health." In setting tolerances, the Administrator is required to consider relevant factors including the necessity for production of an adequate, wholesome, and economical food supply; other ways in which the consumer may be affected by the same pesticide or by other related substances; and the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture. The Administrator is authorized to establish a tolerance at zero level if the scientific data do not justify establishing a greater tolerance.

New Section 408(b)(1)—Authority authorizes the Administrator to issue regulations establishing, modifying, or revoking tolerances for pesticide chemical residues in or on a food in response to a petition or on the Administrator's initiative.

New Section 408(b)(2)—Standard lays out the criterion by which tolerances would be set. New subsection 408(b)(2)(A)—General Rule would set the general rule for the standard. Under new subsection 408(b)(2)(A)(i)—Standard the Administrator may establish or leave in effect a tolerance for a pesticide residue in or on food only if the Administrator determines that the tolerance is safe. EPA must revoke or modify a tolerance if it is not safe.

New Section 408(b)(2)(A)—Determination of Safety defines "safe" as a determination that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all dietary exposures and all other exposures for which there is reliable information.

In new Section 408(b)(2)(A)(iii) a rule of construction clarifies that if a determination is made under subsection 408(b)(2)(A) the provisions of subsection of 408(b)(2)(B) do not apply.

Subsection (b)(2)(A) establishes the standard of "safe" for tolerances for pesticide chemical residues in or on food. For the purposes of this section, "safe" means there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. The Committee understands "aggregate exposure" to the pesticide chemical residue to include dietary exposures under all tolerances for the pesticide chemical residue, and exposure from other non-occupational sources as well.

The Committee has adopted the standard of "reasonable certainty of no harm" based on EPA's current application of the standard. The Committee understands that the Administrator currently

applies this standard differently to threshold and nonthreshold effects. A threshold effect is an effect for which the Administrator is able to identify a level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. A nonthreshold effect is an effect for which the Administrator is not able to identify such a level.

In the case of a threshold effect for a pesticide chemical residue, the Committee expects that a tolerance will provide a "reasonably certainty of no harm" if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined "no observable effect" level when data are extrapolated from animal studies.

In the case of a nonthreshold effect which can be assessed through quantitative risk assessment, such as a cancer effect, the Committee expects, based on its understanding of current EPA practice, that a tolerance will be considered to provide a "reasonable certainty of no harm" if any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than "negligible." It is the Committee's understanding that, under current EPA practice, utilizing quantitative risk assessment to calculate Potency Factors called "Q star", EPA interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation.

The statutory language does not preclude EPA from changing its risk assessment methodology as the science of risk assessment evolves. If the Administrator in the future chooses to adopt a different interpretation of "reasonable certainty of no harm," however, the new interpretation should be adopted by regulation and should be at least equally protective of public health. Any new interpretation must be scientifically based and the Administrator should bear the burden to demonstrate that the revised interpretation is equally protective of the public.

New Section 408(b)(2)(B)—Tolerances for Eligible Pesticide Chemical Residues allows EPA to maintain or modify a tolerance for an eligible pesticide residue which does not fall under subsection (A) if: (1) EPA is not able to identify a level of exposure that will not cause or contribute to known or anticipated harm to human health (that is, there is a nonthreshold effect); (2) the lifetime risk of the nonthreshold effect is assessed by means of quantitative risk assessment; and (3) aggregate exposure to the residue is safe with respect to other effects for which EPA can identify a safe level of exposure (that is, threshold effects). The EPA Administrator may leave a tolerance in effect or modify it if: (1) the use of the pesticide that produces the residue protects consumers from adverse effects to health that pose a greater risk than the dietary risk from the residue, or the pesticide use avoids significant disruption in domestic production of an adequate, wholesome, and economical

food supply; and (2) the annual risk from the nonthreshold effect (from aggregate exposure to the residue) does not exceed 10 times the annual risk allowed under a safe tolerance level, and the lifetime risk of the nonthreshold effect is not greater than twice the safe lifetime risk for such effect. In addition, all such tolerances must be safe for children. New Section 408(b)(2)(B)(v) directs EPA to review the need for the pesticide use and the risks of such use within 5 years of determining to leave in effect or modify such a tolerance, and as necessary thereafter. If it has not been demonstrated that the tolerance continues to meet the requirements of this subparagraph, EPA must issue a regulation to modify or revoke the tolerance within 180 days, in accordance with procedures under subsection (e).

Clause (b)(2)(B)(iii) establishes the conditions regarding use that must be present before a tolerance may be modified or left in effect under subsection (b)(2)(B). Subclause (iii)(I) provides that the authority of subsection (b)(2)(B) may be used when use of the pesticide that produces the residue protects consumers from adverse effects on health that pose a greater risk than the dietary risk from the pesticide chemical residue. In this situation, eating food treated with the pesticide chemical is safer for consumers than eating the same food that is not treated with the pesticide. The Committee intends to address a situation in which, for example, a pesticide is the only effective way to prevent or minimize a dietary risk from a fungus or other crop condition. The fungus aflatoxin, a dangerous fungus which can be present on peanuts and corn, is one such representative example. Although there is currently no pesticide chemical which can protect these crops from aflatoxin, if such a pesticide were to be developed, the Committee believes it would be a candidate for a tolerance under this subparagraph if its dietary risks were lower than the dietary risks of aflatoxin.

Subclause (iii)(II) provides that the authority of subsection (b)(2)(B) may be used when use of the pesticide that produces the residue is necessary to avoid a significant disruption in domestic production of a safe, economical, and wholesome food supply. This standard is a more precise version of the current provision in section 408(b). By adding reference to a "significant disruption," the Committee intends to clarify the general understanding of the type of effect on farmers and consumers that is covered by this language. In determining whether the loss of a pesticide would cause a significant disruption in the production of an adequate, wholesome, and economical food supply, EPA is expected at take into account the availability and effectiveness of alternative pest control methods, the impact of loss of the pesticide on crops, the impact on the national availability and cost of food combined with the dietary impact of such loss, and the impact on the ability of consumers to access a nutritious food supply.

The Committee expects this type of analysis to apply in exceptional situations such as the one illustrated here: In the 1980s, unusual weather conditions caused a substantial increase in aflatoxin on corn used for animal feed across the Southeast. The FDA determined that it was necessary to raise the action level for aflatoxin on corn to avoid widespread shortages of animal feed. Although FDA's action in this illustrative case occurred under other provi-

sions of this Act, the potential significant disruption that triggered the action is of the type the Committee envisions as representative.

New Section 408(b)(2)(C)—Exposure to Infants and Children mandates criteria relating to safety of infants and children to be considered when establishing, modifying, leaving in effect, or revoking tolerances or exemptions for pesticide residues. In making such decisions, the Administrator shall (i) assess the risk of the pesticide residue based on: (I) data on consumption patterns among infants and children, if these patterns are likely to result in a disproportionately high consumption of foods bearing the residue as compared with the consumption by the general population; (II) data on the special susceptibility of infants and children to pesticide residues, including data on the neurological differences between infants, children, and adults and effects of in-utero exposure to chemicals; and (III) data on the cumulative effects on infants and children of such residues that have common mechanisms of toxicity. In the decision, the Administrator shall also (ii): (I) ensure that there is a reasonable certainty of no harm to infants and children from aggregate exposure to the pesticide chemical residue; and (II) publish a determination regarding the safety of the residue for infants and children.

When data relating to infants and children are incomplete, and also to account for potential pre- and post-natal toxicity, the Administrator is to apply, under new Section 408(b)(2)(C), an additional tenfold margin of safety for infants and children. However, EPA may apply a different margin of safety if reliable data indicate that it will be safe for infants and children. The Secretary of Health and Human Services (DHHS) and the Secretary of Agriculture (USDA), in consultation with EPA, will document, through surveys, dietary exposure to pesticides among infants and children.

It is the intention of the Committee that EPA interpret the language of this section in furtherance of the following recommendation of the National Research Council's Study, "Pesticides in the Diets of Infants and Children":

> At present, to provide added protection during early development, a third uncertainty factor of 10 is applied to the NOEL, to develop the RfD. This third 10-fold factor has been applied by the EPA and FDA whenever toxicity studies and metabolic/disposition studies have shown fetal developmental effects.
>
> Because there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete. The committee wishes to emphasize that this is not a new, additional uncertainty factor but, rather, an extended application of a uncertainty factor now routinely used by the agencies for a narrower purpose. (page 9)

New Section 408(b)(2)(D)—Factors lists nine factors that EPA should consider in establishing, modifying, leaving in effect, or re-

voking a pesticide chemical residue tolerance or exemption. These include: (i) the validity, completeness, and reliability of the data from studies of the pesticide and its residue; (ii) the nature of any toxic effect shown to be caused by the pesticide or its residue; (iii) available information concerning the relationships of such studies to human risk; (iv) available information on dietary consumption patterns of consumers and major subgroups; (v) available information concerning cumulative effects of residues and other substances with a common toxicity mechanism; (vi) available information about the aggregate exposure levels of consumers and major subgroups to the residues and related substances, including dietary exposure under the tolerance and all other tolerances in effect for that pesticide, and exposure from other non-occupational sources; (vii) information about the variability of the sensitivities of major identifiable subgroups of consumers; (viii) information as EPA may require on whether the pesticide may have similar health effects as naturally occurring estrogen, or other endocrine effects; and (ix) safety factors which experts believe are generally recognized as appropriate for use of animal experimentation data.

New Section 408(b)(2)(E)—Data and Information Regarding Anticipated and Actual Residue Levels authorizes EPA to consider data on the anticipated residue levels on or in food and the actual residue levels that have been measured in food, including residue data collected by FDA, when the agency establishes, modifies, leaves in effect, or revokes a tolerance. However, within 5 years of a tolerance decision and thereafter as needed, clause (ii) requires EPA to require the submission of residue data demonstrating that residue levels have not increased above levels relied upon for a decision to establish, modify, or retain a tolerance. If data are not submitted or do not demonstrate this, Section 408(b)(2)(E) directs EPA to issue an order or regulation to modify or revoke the tolerance.

New Section 408(b)(2)(F)—Percent of Food Actually Treated authorizes considering information on the percent of food actually treated with the pesticide, including aggregate pesticide use data collected by USDA, when EPA assesses chronic dietary risk and establishes a tolerance. The section limits use of such information to situations in which EPA finds: (i) the data are reliable and valid indicators of the percentage of food likely to contain the residue derived from the crop; (ii) the exposure is not underestimated for any significant subpopulation; and (iii) available data for a particular area do not indicate higher levels of dietary exposure. In addition, clause (iv) requires that EPA provide for the periodic reevaluation of the estimate of anticipated dietary exposure.

New Section 408(b)(3)—Detection Methods concerns methods for detecting and measuring residue levels at the level of the tolerance. As a general rule, the EPA is prohibited from setting a tolerance unless there is a practical method for detecting and measuring residues. Subparagraph (B)-Detection Limit prohibits setting tolerance levels below the limit of detection of the method for measuring residues identified by EPA.

New Section 408(b)(4)—International Standards requires EPA to consider any maximum residue level (MRL) established for a chemical by the international Codex Alimentarius Commission (Codex),

when the Agency determines tolerance levels.[2] If a Codex MRL exists, and the EPA decides not to adopt the same level, the bill requires EPA to publish for public comment a notice explaining the departure. This new subsection is intended to avoid unnecessary restraints on international food trade by requiring EPA explicitly to consider international standards when setting U.S. tolerances and encouraging EPA to support international harmonization efforts.

Sec. 408(c). Authority and standard for exemptions

Section 408(c) of current law requires the Administrator to promulgate regulations exempting any pesticide from the necessity of a tolerance if such an exemption is safe.

New subsection (c)(1)—Authority authorizes the Administrator, in response to a petition or on the Administrator's initiative, to issue a regulation establishing, modifying, or revoking an exemption from the requirement for a pesticide residue tolerance on food. The Committee expects EPA to continue to issue exemptions for GRAS substances under this authority.

New subsection (c)(2)—Standard limits the Administrator's authority to issue exemptions. Subsection (c)(2)(A)—General Rule provides that an exemption only can be established if it is safe, and that EPA must modify or revoke an exemption that is not safe. Clause (ii) defines "safe" as a determination that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including all dietary and other exposures for which reliable data exist. Subsection (c)(2)(B)—Factors requires the Administrator, in deciding on an exemption, to consider relevant factors, including those related to infants and children that are specified in subparagraph (C) and the nine factors specified in subparagraph (D)[3] of the new subsection (b)(2). The Committee understands that EPA currently issues exemptions only for the pesticide chemical residues that do not pose a dietary risk under reasonably foreseeable circumstances. The Committee intends that EPA retain its current practice.

New subsection (c)(3)—Limitation prohibits an exemption, unless there is (A) a practical method for detecting and measuring the levels of the residue, or (B) there is no need for such a method, and the reasons are stated in the regulation establishing or modifying the exemption.

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[2] The Codex is sponsored by the United Nations Food and Agriculture Organization and the World Health Organization. Its purpose is to negotiate international standards for food. The United States is represented on various standing committees of the Codex by officials from FDA, EPA, and USDA.

[3] These 9 factors include: (i) the validity, completeness, and reliability of the data from studies of the pesticide and its residue; (ii) the nature of any toxic effect shown to be caused by the pesticide or its residue; (iii) available information concerning the relationships of such studies to human risk; (iv) available information on dietary consumption patterns of consumers and major subgroups; (v) available information concerning cumulative effects of residues and other substances with a common toxicity mechanism; (vi) available information about the aggregate exposure levels of consumers and major subgroups to the residues and related substances, including dietary exposure under the tolerance and all other tolerances in effect for that pesticide, and exposure from other non-occupational sources; (vii) information about the variability of the sensitivities of major identifiable subgroups of consumers; (viii) information as EPA may require on whether the pesticide may have similar health effects as naturally occurring estrogen or other endocrine effects; and (ix) safety factors which experts believe are generally recognized as appropriate for use of animal experimentation data.

Sec. 408(d). Petition for tolerance or exemption

Existing FFDCA Section 408(d) authorizes any applicant for a pesticide registration under FIFRA to file a petition for the issuance of a tolerance or an exemption. It requires the petition to contain data showing the name, chemical identity, and composition of the pesticide; the amount, frequency, and time of application of the pesticide; full reports of safety studies conducted; results of tests on pesticide residues on crops and identification of analytical methods used; practical methods for removing residue that exceeds a proposed tolerance; proposed tolerances, if they are being proposed; and reasonable grounds in support of the petition. The law also requires petitioners to provide samples of the pesticide upon request. The EPA must publish a notice of the petition filing within 30 days, which must include discussion of the analytical methods to determine the pesticide residue levels. Within 90 days after a certification of usefulness of the pesticide by the Secretary of Agriculture, the Administrator is required either to establish a tolerance or to exempt the pesticide from a tolerance, unless the petitioner requests or the Administrator decides to refer the petition to an advisory committee. In that case, the Administrator must submit the petition and data to an advisory committee which must report to the Administrator with their recommendation within 60 days. The Administrator is required within 30 days of the committee report to issue a regulation establishing a tolerance or exempting the pesticide; the regulation becomes effective on publication.

New subsection (d) is similar, for the most part, to current law, but the amended subsection authorizes any person to file a tolerance petition rather than only an applicant for a pesticide registration. New subsection (d)(1)—Petitions and Petitioners also authorizes petitions for establishing, modifying, or revoking a tolerance or an exemption.

New subsection (d)(2)—Petition Contents identifies the information required in the petition. Subparagraph (d)(2)(A)—Establishment authorizes the Administrator to require through regulations certain data and information to support a petition for a tolerance or an exemption. A petitioner must provide: (i)(I) a summary of the petition, data, information, and arguments; (II) a statement that the petitioner agrees to have the summary contents published with the notice of petition filing and as part of any proposed or final regulation; (ii) the name, chemical identity, and composition of the parent pesticide and its residue; (iii) data showing the recommended amount, frequency, method, and time of application of that pesticide; (iv) full reports on the results and methods used in safety testing; (v) full reports on the results and analytical methods used to decide on the nature and amount of residue likely to remain in or on the food; (vi) a practical method for detecting and measuring levels of residue (or for exemptions a statement of why it is not needed); (vii) a proposed tolerance for the residue if one is proposed; (viii) if the petition relates to a tolerance for a processed food, studies of the processing methods used to produce the food; (ix) any information that the Administrator requires to assess risk to infants and children; (x) any information that the Administrator requires related to whether the pesticide chemical may have a similar effect in humans as a naturally occurring estrogen or

other endocrine effects; (xi) exposure information due to any tolerance or exemption already granted; (xii) practical methods for removing any residue amount that could exceed a proposed tolerance; and (xiii) other information that EPA requires to support the petition. If the information is already available to the Administrator, the petition may reference it in lieu of submitting it. Samples of the pesticide may be required.

New subsection (d)(2)(B)—Modification or Revocation gives the Administrator authority to establish by regulation information and data requirements to support a petition to modify or revoke a tolerance or an exemption from a tolerance.

New subsection (d)(3)—Notice directs the Administrator to publish the notice of petition filing within 30 days after determining that the petition has met the requirements in paragraph (2). The notice will include an announcement of the availability of a description of the analytical methods for detecting and measuring residues or a statement that such methods are not needed, and the summary of the petition.

New subsection (d)(4)—Actions by the Administrator describes how EPA shall respond to a petition. Subparagraph (A)—In General directs EPA to (i) issue a final regulation; (ii) issue a proposed regulation followed by a final regulation; or (iii) issue an order denying the petition. New subparagraph (B) requires EPA to give priority to petitions for establishing or modifying a tolerance or exemption for the residue of a pesticide that is expected to pose less dietary risk to human health than other pesticide residues for which tolerances are in effect for the same or similar purposes. Subparagraph (C) provides for expedited EPA review of complete petitions for a tolerance or exemption for a pesticide residue posing less risk than a tolerance left in effect or modified for "an eligible pesticide chemical residue" under subsection (b)(2)(B). EPA must act on such a petition within 1 year. Clause (ii) directs EPA to review the need for the tolerance for the eligible pesticide chemical residue within 180 days of the date EPA issues a regulation establishing a tolerance or exemption for the safer pesticide residues. If EPA finds the need for such higher risk pesticide use no longer exists, new Section 408 requires EPA to revoke or modify the tolerance within 180 days of such a finding under the procedures of subsection (e).

Sec. 408(e). Action on administrator's own initiative

The current FFDCA, Section 408(e), authorizes the Administrator to propose a tolerance or an exemption at any time. Thirty days after the proposal is published, the Administrator may publish the final regulation, which becomes effective upon publication, unless a registrant or applicant for a registration of the pesticide chemical named in the proposal requests referral of the proposal to an advisory committee. If requested, the Administrator must submit the proposal, and the advisory committee must report back certified recommendations within 60 days. Within 30 days of such certification, the Administrator may publish a regulation establishing a tolerance for a pesticide or exempting it. A regulation is effective upon publication, but any person adversely affected by it may file an objection.

New subsection 408(e)(1)—General Rule authorizes rule making by the EPA Administrator to establish a tolerance or an exemption. In addition, it authorizes the Administrator to modify or to revoke a tolerance or an exemption, as well as to establish general implementation procedures and requirements. New subsection (e)(2)—Notice requires EPA to issue a notice of proposed rule making and to provide a 60 day public comment period before issuing the final regulation, unless there is good cause and it is in the public interest to shorten this requirement. An opportunity for a public hearing is provided by Section 408(g) below.

Sec. 408(f). Special data requirements

New subsection (f)(1)—Requiring Submission of Additional Data requires EPA to collect additional data when reasonably required to support an existing pesticide tolerance or exemption. The Administrator is allowed to collect data under FIFRA, Section 3(c)(2)(B), or the Toxic Substances Control Act (TSCA), Section 4, or by publishing an order in the Federal Register. In the last case, a 60-day notice-and-comment period is required before the order could be issued. The order (i) directs persons who are required to submit data to identify which of them will provide data to EPA, (ii) describes the type of data and information required and why it could not be obtained under FIFRA or TSCA, (iii) describes the reports that would be prepared from this data, (iv) requires submissions of data and reports, and (v) sets the dates that the information is due. The Administrator may revise the order to make corrections. Subsection (f)(2)—Noncompliance authorizes the Administrator to modify or revoke the tolerance or exemption in question if the required data or reports are not submitted by the due date. The only issue that could be decided if the order were reviewed under subsection (g)(2) is whether a required submission had been made by the time specified. This provision does not prevent the Administrator from acting to modify or revoke a tolerance or exemption which does not meet the safety standard in subsection (b)(2) or (c)(2).

Sec. 408(g). Effective date, objections, hearings, and administrative review

The current FFDCA, Section 408(d)(5), provides 30 days after a regulation is issued for any person adversely affected by the regulation to file an objection with the Administrator and to request a public hearing to receive evidence relevant and material to the issues raised by the objection. A member of the National Academy of Sciences is required to designate a member of the advisory committee to testify before the hearing. As soon as practicable after the hearing, the law directs the Administrator to regulate based only on substantial evidence of record at the hearing. The regulation may take effect no sooner than 90 days after the rule is published, unless an emergency condition exists.

New subsection (g)(1)—Effective Date states that any regulation or order will take effect upon publication unless the regulation or order specifies otherwise. The Administrator may adjust this effective date if objections are filed with respect to such a regulation or order.

New subsection (g)(2)—Further Proceedings lists criteria for raising objections. New subparagraph (A) authorizes any person, not just a person adversely affected, to file an objection to a regulation or order issued under subsections (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) and doubles the time allowed for filing from 30 days to 60 days. It also requires the Administrator to give the petitioner a copy of the objections, if the regulation or order was issued in response to a petition filed under subsection (d)(1).

New subparagraph (g)(2)(B) allows an objector to request a public evidentiary hearing. The Administrator would decide whether a hearing were necessary to receive factual evidence relevant to material issues of fact raised by the objections. The Committee expects EPA to use this discretion fairly and to grant hearings to responsible parties on all sides. The bill provides the hearing officer with various authorities, for example, to issue a subpoena to compel testimony, but requires the presiding officer to follow the Federal Rules of Civil Procedure in ordering protection of witnesses or documents and payment of expenses for witnesses. A subpoena may be enforced by a Federal district court.

New subparagraph (g)(2)(C) requires the Administrator to issue an order as soon as practicable after the hearing, stating action to be taken. But, as under current law, any action taken must be based on substantial evidence in the hearing record and, if a hearing is held, explained in detail.

Sec. 408(h). Judicial review

New Section 408(h) retains most of the existing provisions of FFDCA, Section 408(i). New subsection 408(h)(1)—Petition allows any person adversely affected by a regulation under subsection (c)(1)(a) or an order, issued under subsection (e)(1)(C), (f)(1)(C), or (g)(2)(C) or any regulation that is the subject of such an order within 60 days of its publication, to petition to have the regulation or order set aside and to obtain judicial review in the U.S. Court of Appeals for the circuit wherein that person resides or has a business or with the U.S. Court of Appeals for the District of Columbia Circuit. New subsection (h)(2)—Record and Jurisdiction requires the Administrator to file with the court the administrative record. The court has exclusive jurisdiction to affirm or set aside the order or regulation in whole or in part. The findings of the Administrator are required to be sustained only if supported by substantial evidence when considered on the record as a whole. New subsection 408(h)(3)—Additional Evidence allows for additional evidence to be presented to EPA if it appears proper to do so. The EPA can then modify its order or regulation to take into account that evidence. New subsection 408(h)(4)—Final Judgment; Supreme Court Review makes the judgment of the court final, subject to review by the U.S. Supreme Court (as provided in section 1254 of Title 28 U.S.C.). Any petition or this appeal may not operate as a stay of the order or regulation, unless specifically ordered by the court. New subsection 408(h)(5)—Application prohibits review under any other section of law of issues subject to review under this subsection.

Sec. 408(i). Confidentiality and use of data

Existing FFDCA, Section 408(f), requires that all data submitted under Section 408 or Section 409 be considered confidential by EPA or an advisory committee until publication of a regulation. New subsection 408(i)(1)—General Rule requires EPA to treat all submitted data and information confidentially and to provide for exclusive use and data compensation to the same extent as provided under FIFRA, Sections 3 and 10. New subsection 408(i)(2)—Exceptions allows disclosure of the information at the Administrator's discretion, to authorized Federal employees and contractors in carrying out official duties under this Act or other Federal statutes intended to protect the public health. Subparagraph (B) notes that information may not be withheld from either House of Congress or from any Committee, Subcommittee, or Joint Committee or Subcommittee to the extent that the matter lies within its jurisdiction. New subsection 408(i)(3)—Summaries permits publication of an informative summary of the data. The Committee intends that this section apply to data submitted to EPA prior to enactment, under old section 408 or 409, including data submitted under EPA guidelines by manufacturers of inert ingredients of pesticides. This provision is not intended to bring political forces to bear on EPA decision-making. The Committee expects EPA to issue regulations adequate to ensure appropriate protection of trade secret or confidential business information.

Sec. 408(j). Status of previously issued regulations

New subsection 408(j)(1)—Regulations Under Section 406 retains the provisions of FFDCA, Section 408(k), which concern regulations promulgated based on hearings held before 1953, but subjects modifications and revocations of such regulations to new Section 408, subsections (d) and (e), as well as to review under subsection (q). New subsections 408(j)(2)—Regulations under Section 409 and new subsection 408(j)(3)—Regulations under Section 408 are technical amendments which continue in effect all current regulations affecting pesticide residues that have been promulgated under current FFDCA Sections 408 or 409 and subjects modifications and revocations of such rules to new subsections (d) and (e) and to review under subsection (q).

Sec. 408(k). Transitional provision

New section 408(k) exempts from tolerance regulations those pesticide residues that before enactment (1) the Administrator or Secretary of Health and Human Services regarded as generally-recognized-as-safe (GRAS) within the meaning of subsection 408(a) or section 201(s). The new subsection (k)(2) also exempts from regulation any particular pesticide chemical on a particular food that was regarded as described in FFDCA section 201(s)(4). EPA is required to publish regulations listing which substances are covered by this exemption. Any exemption could be modified or revoked as if it had been issued under new subsection (c).

If a new pesticide chemical residue would be generally regarded as safe, the Committee expects the Administrator to use the authority of subsection (c) to exempt the residue from the requirement for a tolerance. Under subsection (c), the Administrator has

the authority to grant the residue a broad exemption covering multiple types of food in a single proceeding. Any petition to establish such an exemption should generally be given priority by the Administrator under subparagraph (d)(4)(B).

Sec. 408(l). Harmonization with action under other laws

New subsection (l)(1)—Limitation directs EPA, to the extent practicable and consistent with deadlines for review in subsection (q), to coordinate any final action to suspend or revoke a tolerance or exemption with related action that might be necessary under FIFRA. The Committee expects EPA to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties.

New subsection (l)(2)—Revocation of Tolerance or Exemption Following Cancellation of Associated Registrations states that if EPA cancels or modifies the FIFRA registration of a pesticide for a food use because of dietary risks to human health posed by the residues, EPA also must revoke any tolerance or exemption that would allow the presence of the pesticide chemical in or on that food, using procedures set forth in subsection (e). A revocation under this paragraph becomes effective not later than 180 days after the date on which the use of the canceled pesticide becomes unlawful.

New subsection 408(l)(3)—Suspension of Tolerance or Exemption Following Suspension of Associated Registrations—(A) Suspension requires the suspension of tolerances for food use pesticides, if the pesticide registration is suspended under FIFRA. A tolerance suspension becomes effective not later than 60 days after the registration is suspended. Subparagraph (B)—Effect of Suspension restores tolerances or exemptions if the Administrator rescinds a suspension of the registration for use of the pesticide.

New subsection 408(l)(4)—Tolerances For Unavoidable Residues authorizes the Administrator to establish tolerances for unavoidably persistent residues of canceled or suspended pesticides on food. The required tolerance level is set taking into account the potential risk from exposure to the pesticide residue. These tolerances will be revisited periodically and modified as necessary to allow only that level of residue that is unavoidable due to its environmental persistence.

New subsection 408(l)(5)—Pesticide Residues Resulting From Lawful Application of Pesticide allows pesticide residues on foods that were the result of lawful application of a pesticide. In a case where a tolerance or exemption for a pesticide residue is revoked, suspended, or modified, a food that was treated legally with the pesticide cannot be deemed unsafe, if: (A) the residue is present because of a lawful use under FIFRA, and (B) the pesticide residue did not exceed the previously authorized tolerance, exemption, food additive regulation, or other sanction level. EPA retains the power to declare legally treated food unlawful, but only after determining that consumption of the legally treated food during the period of its likely availability in commerce poses an unreasonable dietary risk. This provision allows continued use of existing food stocks that were treated with a lawful pesticide, thus protecting against unnecessary destruction of legally treated food, disruption in the marketplace, and economic loss. It also ensures that food producers are

not unfairly penalized for legal use of pesticides that were subject to regulatory action at a subsequent date.

New subsection 408(l)(6)—Tolerance for Use of Pesticides under an Emergency Exemption requires EPA to establish a tolerance or exemption for a pesticide residue if the agency grants a local or State exemption in the case of an emergency under FIFRA Section 18. Such a tolerance or exemption must terminate on a given date. EPA is not required to provide notice or a comment period on such a tolerance or exemption. The bill requires EPA, within 365 days of enactment of H.R. 1627, to promulgate regulations concerning tolerances and exemptions under this paragraph. These regulations must be consistent with the safety standard established in Section 408 (b)(2) and (c)(2) and with FIFRA Section 18.

The Committee intends this requirement for Section 18 tolerances or exemptions to resolve a long-standing dilemma regarding legal pesticide residues that, because there were no tolerances or exemptions, could have been considered technically in violation of law. However, the Committee also intends for the extremely important Section 18 process to continue in place, and for EPA to issue emergency exemption tolerances or exemptions expeditiously.

Sec. 408(m). Fees

New subsection 408(m)(1)—Amount requires EPA to assess fees to cover, for example, the Agency's costs for accepting petitions, writing regulations, accepting objections, and certifying and filing court transcripts. Waivers or refunds of fees may be given by the Administrator, if it is equitable and not contrary to the purposes of this subsection. New subsection 408(m)(2)—Deposit requires all collected fees to be deposited in the FIFRA 4(k) Reregistration and Expedited Processing Fund, and made available without fiscal year constraints for EPA's tolerance-related activities which are specified in Section 408(m)(1).

Sec. 408(n). National uniformity of tolerances.

New section 408(n) preempts State and local regulation of food with pesticide residues under certain conditions. Under current law, States and local governments can set tolerances for pesticide residues in foods that are lower (more stringent) than those established by EPA. They also may require warnings for food products that contain legal pesticide residues (that is, below Federal tolerance levels). New subsection 408(n)(1)—Qualifying Pesticide Chemical Residues defines "qualifying pesticide chemical residue" as (A) a residue from a pesticide use (A) first registered under section 3(c)(5) of FIFRA on or after April 25, 1985 (the pesticides not subject to reregistration requirements of FIFRA Section 4(g)) or (B) residues of "older" pesticides (subject to reregistration requirements) that EPA has evaluated and approved for reregistration for that use.

New subsection 408(n)(2)—Qualifying Federal Determination defines "qualifying Federal determination" as a tolerance or exemption (A) issued after enactment of this Act, and determined by the Administrator to meet the safety standard of new Section 408(b)(2)(A) (tolerances) or (c)(2) (exemptions); or (B) left in effect or deemed to have been issued under Section 408 pursuant to sub-

section (j), or regarded as exempt under subsection (k), and determined by EPA to meet the relevant safety standard. A determination to modify or leave in effect a tolerance under subsection (b)(2)(B) is not a qualifying Federal determination.

New subsection 408(n)(3)—Limitation requires the Administrator to establish the safety of a "qualifying Federal determination" that was deemed to have been issued under Section 408, rather than actually issued after enactment, by issuing a rule in accord with Section 408(d) or (e), after first proposing the rule and allowing at least 30 days for public comment. The rule is reviewable in accordance with subsections (g) and (h).

New subsection 408(n)(4)—State Authority prohibits State and local regulation of any "qualifying pesticide chemical residue" to which any "qualifying Federal determination" applies except as provided in paragraphs (5), (6), and (8). State and local governments are not authorized to regulate qualifying pesticide chemical residues covered by a qualifying Federal determination unless the State or local regulation is identical to the qualifying Federal determination.

New subsection (n)(5)—Petition Procedures establishes petition procedures for States to request exceptions to the prohibition on State regulations. Subsection (n)(5)(A)—In General allows States to petition for a regulatory limit on a qualifying residue different than the Federal limit, if the State's petition establishes adequate justification to EPA. Subsection (n)(5)(B)—Petition Requirement requires that this justification include supporting scientific data about the pesticide, consumption data, and exposure data of people residing in the State, and any other EPA requirements. Subsection (n)(5)(C)—Authorization authorizes State exemptions from uniform Federal limits if (i) they are justified by compelling local conditions and (ii) they would not cause any food to be in violation of Federal law. Subsection (n)(5)(D)—Treatment of Petition allows the Administrator to treat a State petition as if it were a petition to modify or revoke a tolerance or exemption under Section 408(d). Subsection (n)(5)(E)—Review subjects to review under subsections (g) and (h) (pertaining to administrative and judicial review, respectively) any EPA order granting or denying State authority in response to a petition.

New subsection (n)(6)—Urgent Petition Procedure provides for temporary State regulations if EPA does not act within 30 days of receiving an urgent petition for State authorization. If a State petition demonstrates that a significant public health threat exists from acute exposure to a pesticide residue on food during the period that such food is available in that State, the petition will be considered urgent. If EPA does not issue an order to grant or deny State authority that is requested in an urgent petition within 30 days of its receipt, the State is authorized to establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The final EPA order will validate or terminate the temporary regulatory limit.

New subsection (n)(7)—Residues from Lawful Application assures that no State or political subdivision can declare a food unlawful because it contains a residue that resulted from the application of a pesticide at a time when such residue level complied with

all Federal and State laws. An exception is allowed if the State can demonstrate that the residue level will pose an unreasonable dietary risk to the health of persons within that State due to consumption of that food during the period in which it is likely to be available.

New subsection (n)(8)—Savings excludes from the preemption provisions of subsection (n) "warning requirements" and other statements relating to the presence of such residues in food.

Sec. 408(o). Consumer right to know

This section requires EPA within 2 years of enactment and annually thereafter, in consultation with USDA and DHHS, to publish and distribute to large retail grocers for public display (in a manner determined by each grocer) certain information relevant to pesticide residues. The information, which must be conveyed in a format understandable to a lay person, includes: (1) a discussion of the risks and benefits of pesticide chemical residues in or on food; (2) a list of actions taken under subsection (b)(2)(B) relating to eligible pesticide residues that may result in risks greater than allowed for under subparagraph (A), and of the food on which the pesticides producing such residues are used; and (3) recommendations on how consumers might reduce dietary exposures to pesticide residues while maintaining a healthy diet. The Committee expects the EPA recommendations to be consistent with established nutritional guidelines. Retail grocers may provide additional information.

Sec. 408(p). Estrogenic substances screening program

New *Section 408(p)(1)* directs EPA, in consultation with DHHS, to develop a screening program within 2 years to gather information scientifically to evaluate whether certain substances may have effects in humans that are similar to effects produced by naturally occurring estrogen or other endocrine effects. Paragraph (2) requires EPA to solicit public comments on and review of the screening program by the scientific advisory panel for pesticide policy or the EPA science advisory board, which evaluates a broader range of EPA programs. The program must be implemented within 3 years of enactment of H.R. 1627. Paragraph (3) mandates testing of all pesticide chemicals and authorizes EPA to test any other substance that may have an effect cumulative to that of a pesticide chemical residue, if a substantial population may be exposed to it. Paragraph (4) authorizes EPA to issue orders exempting substances from the testing requirements if they are not expected to produce an estrogenic effect in humans. EPA must issue an order to conduct testing of covered substances and to submit reports to pesticide registrants and to persons who manufacture or import covered substances. The bill requires such orders to establish a reasonable time period for generating the information and reporting to EPA. EPA implementing regulations and orders should minimize duplicative testing requirements, provide equitable arrangements for sharing testing costs, and develop procedures to handle confidential business information. The other substances that may be tested under this paragraph are intended by the Committee to be other environmental contaminants. Paragraph (5)(C) requires issu-

ance of a notice of intent to suspend the sale or distribution of a substance if a registrant fails to comply with a test order. Such suspension will become final after 30 days unless a hearing is requested or the EPA decides that the registrant has complied fully with paragraph (5). However, EPA must terminate a suspension if the registrant has fully complied with paragraph (5). Any hearing held will be conducted in accordance with section 554 of title 4 U.S.C. (that is, the formal adjudicatory hearing process). The only matter to be resolved at the hearing is whether the registrant failed to comply with an EPA order. An EPA decision after the hearing is a final agency action and thus may be judicially reviewed under the Administrative Procedure Act (5 U.S.C. 701). If a manufacturer or an importer who is not a registrant fails to comply with a test order, that person is liable for the penalties and sanctions provided under TSCA Section 16, which may include up to $25,000 per day in fines and, if the person knowingly or willfully violates an order, imprisonment for up to one year. A person assessed a fine may request a hearing and, if ordered to pay the fine after the hearing, may file a petition for judicial review of EPA's order. The bill mandates EPA action "as is necessary to ensure the protection of public health" if the screening program finds a substance to have an endocrine effect on humans. Any action is to be taken under EPA's existing statutory authority. EPA must report to Congress within 4 years on its findings from the screening program and any recommendations for further testing and actions.

Sec. 408(q). Schedule for review

New Section 408(q) directs EPA to review tolerances and exemptions for pesticide residues in effect before enactment of H.R. 1627. Review should take place as expeditiously as practicable and assure that (A) 33 percent of the tolerances and exemptions are reviewed within 3 years, (B) 66 percent are reviewed within 6 years, and (C) all tolerances and exemptions are reviewed within 10 years. In reviewing the tolerances and exemptions, EPA is required to determine whether they meet the requirements of subsections (b)(2) or (c)(2). Before the deadline for review, the bill directs EPA to issue regulations under subsection (d)(4) or (e)(1) to modify or revoke tolerances and exemptions that do not meet the requirements of subsections (b)(2) or (c)(2).

Paragraph (2) orders the Administrator to give priority to the review of tolerances or exemptions that appear to pose the greatest risk to public health. New paragraph (3) requires that EPA publish within 12 months a schedule for review of tolerances and exemptions established prior to enactment of H.R. 1627. Priority setting for the review of tolerances and exemptions under this subsection is not to be considered a rulemaking and is not subject to judicial review. However, if EPA fails to take final action pursuant to the schedule, this failure shall be subject to judicial review.

In establishing an orderly review of existing tolerances and providing EPA with discretion in setting priorities, the Committee intends for the Agency to align such priorities responsibly with other important business, such as reviewing and responding to petitions. The Committee does not intend the petition process to be used in

a way that is disruptive of EPA's priorities, except in cases where an action is needed urgently to protect the public health.

Sec. 408(r). Temporary tolerance or exemption

New Section 408(r) provides, as in current FFDCA, section 408(j), that EPA may issue temporary tolerances or exemptions for the use of pesticides under a FIFRA experimental use permit.

Sec. 408(s). Savings clause

New Section 408(s) clarifies that the section does not modify or amend TSCA or FIFRA.

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING

Section 6 authorizes to be appropriated an additional $12 million for increased monitoring by FDA of pesticide residues in imported and domestic food.

SEC. 407. ALTERNATIVE ENFORCEMENT

Section 407 amends FFDCA Section 303(g) (21 U.S.C. 333(f)) to insert a new paragraph (2). It subjects any person who introduces into interstate commerce or delivers for introduction into interstate commerce any food that is adulterated by a pesticide chemical residue to a civil money penalty of not more than $50,000 for an individual or $250,000 for a corporation for such introduction or delivery. An aggregate limit of $500,000 is set for all individuals and corporations subject to adjudication in a single proceeding. This paragraph does not apply to growers. Persons assessed a civil penalty may not be sanctioned under the criminal authorities for the introduction or delivery for introduction into interstate commerce of the adulterated food. Nor may seizure authorities of Section 304 or the injunction authorities of Section 302 be used against a person who is assessed a civil penalty. Subparagraph (C) provides the presiding officer in a hearing to assess a civil penalty with the same authority to compel testimony or production of documents as a presiding officer has under Section 408(g)(2)(B). The third sentence of paragraph (3)(A) (of Section 303(g), as amended by this section, which authorizes the Secretary to issue subpoenas) does not apply to any investigation under Section 303(g)(2).

The Committee intends for FDA to use this new civil penalty authority judiciously and to impose penalties that are commensurate with the level of violation and with other factors such as the history of past violations and ability of the individual or company to pay a fine. The Committee intends that one important factor to be considered in determining whether to levy a civil monetary penalty, and the amount of such penalty, is whether the individual or company has acted promptly and responsibly to remove a violative product from the market and to correct the cause of the violation. Finally, the Committee intends that all civil penalties collected under this authority shall be deposited in the general fund.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by title IV of the

bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * * * *

[(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135–135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.]

(q)(1) The term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding paragraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

* * * * * * *

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as hav-

ing been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

[(1) a pesticide chemical in or on a raw agricultural commodity; or

[(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or]

* * * * * * *

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection*; or the violating of section 408(i)(2) or any regulation issued under that section.* This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

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(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

* * * * * * *

PENALTIES

SEC. 303. (a) * * *

* * * * * * *

(g)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed

$1,000,000 for all such violations adjudicated in a single proceeding.

* * * * * * *

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

[(2)**]** *(3)*(A) A civil penalty under paragraph (1) *or (2)* shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) *or (2)*. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

[(3)**]** *(4)* Any person who requested, in accordance with paragraph **[**(2)(A)**]** *(3)(A)*, a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for

any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

[(4)**]** *(5)* If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph **[**(3)**]** *(4)*, or

(B) after a court in an action brought under paragraph **[**(3)**]** *(4)* has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph **[**(3)**]** *(4)* or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

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CHAPTER IV—FOOD

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ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or **[**(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512; (3) if it consists**]** *(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide*

chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

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[TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

[SEC. 408. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402(a) unless—

[(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the "Administrator") under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

[(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402(a).

[(b) The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary

to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (l) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Administrator may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.

[(c) The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

[(d)(1) Any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Administrator, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

[(A) the name, chemical identity, and composition of the pesticide chemical;

[(B) the amount, frequency, and time of application of the pesticide chemical;

[(C) full reports of investigations made with respect to the safety of the pesticide chemical;

[(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

[(E) practicable methods for removing residue which exceeds any proposed tolerance;

[(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

[(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

[(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) with respect to the pesticide chemical named in the petition, the Administrator shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

[(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

[(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Administrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

[(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l), with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Administrator within such period otherwise deems such referral necessary, the Administrator shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

[(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

[(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

[(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

[(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection [1], or pursuant to subsection (e), may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee shall be made a part of the record of the hearing,

if relevant and material, subject to the provisions of section 556(c) of title 5, United States Code. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided,* That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[(e) The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

[(f) All data submitted to the Administrator or to an advisory committee in support of a petition under this section shall be considered confidential by the Administrator and by such advisory

committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Administrator or by an advisory committee in the carrying out of their official duties under this section.

[(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary, the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with subsection (b)(5)(D) of section 721. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee.

[(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health and Human Services, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

[(i)(1) In a case of actual controversy as to the validity of any order under subsection (d)(5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after entry of such order, a petition praying that the order be set aside in whole or in part.

[(2) In the case of a petition with respect to an order under subsection (d)(5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

[(3) In the case of a petition with respect to an order under subsection (l), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which

he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

[(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

[(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

[(j) The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Administrator shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

[(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701(e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

[(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such [a pesticide], shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him, either—

[(1) certify to the Administrator that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

[(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Administrator [1] on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the certification as proposed. In the event that the action described in clause (A) or (C) taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Administrator shall submit to the Administrator with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

[(m) The Administrator shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

[(n) The provisions of section 303(c) with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

[(o) The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) the acceptance of fil-

ing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such waiver or refund is equitable and not contrary to the purposes of this subsection.]

TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe

within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all an-

ticipated dietary exposures and all other exposures for which there is reliable information.

(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

(i) DEFINITION.—As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that

would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized

as appropriate for the use of animal experimentation data.

(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) DETECTION METHODS.—

(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) PETITION FOR TOLERANCE OR EXEMPTION.—

(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) PETITION CONTENTS.—

(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) NOTICE.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) ACTIONS BY THE ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or ex-

emption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

(1) GENERAL RULE.—The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) SPECIAL DATA REQUIREMENTS.—

(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) FURTHER PROCEEDINGS.—

(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person

other than the petitioner shall be served by the Administrator on the petitioner.

(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of a reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole

or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) ADDITIONAL EVIDENCE.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) CONFIDENTIALITY AND USE OF DATA.—

(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) EXCEPTIONS.—

(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or

any joint committee of Congress or any subcommittee of such joint committee.

(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any

related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the

Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) FEES.—

(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term

to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d);

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g); or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(n) NATIONAL UNIFORMITY OF TOLERANCES.—

(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) PETITION PROCEDURE.—

(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

"(5) COLLECTION OF INFORMATION.—

"(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

"(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

"(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

"(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an

order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

"(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

"(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

"(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) SCHEDULE FOR REVIEW.—

(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protec-

tion Act of 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

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In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITION FOR REVIEW

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and 8th Cir. R. 26.1.A,

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International Inc.** states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

Petitioners Red River Valley Sugarbeet Growers Association, US Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and

Vegetable Association, and Georgia Fruit and Vegetable Growers Association, National Cotton Council of America and Gharda Chemicals International, Inc. are hereinafter referred to as "Petitioners."

Summary of Grounds for Petition

Petitioners continue to seek review of a final rule promulgated by EPA on August 30, 2021 and effective on February 28, 2022. "Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule") (Att. 1). And because Petitioners are likely to succeed on the merits and the Final Rule has caused and will cause them irreparable harm, Petitioners continue to seek a partial stay of the Final Rule.

Petitioners first sought such relief in a petition (No. 22-1294) filed on February 9, 2022, Doc. ID 5126162 (the "First Petition") and a motion for partial stay filed on February 10, 2022, Doc. ID 5126280 (the "First Motion to Stay"). Petitioners carefully crafted their request for a stay to align with EPA's scientific findings and with EPA's legal obligations. For example, Petitioners sought a stay of the Final Rule consistent with EPA's December 2020 Proposed Interim Decision for Chlorpyrifos ("PID"), 22-1294 Doc. ID 5126162 at 31, in which EPA's

expert scientists concluded that eleven crop uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in specifically designated regions are safe ("EPA's Designated Safe Uses"). As set forth in EPA's PID, EPA's Designated Safe Uses are as follows:

Agricultural Uses Proposed for Retention in Chlorpyrifos Labels with an FQPA Safety Fact of 10X		
No.	**Agricultural Commodity**	**States for Retention**
1	Alfalfa	AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WY
2	Apple	AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV
3	Asparagus	MI
4	Cherry (tart)	MI
5	Citrus	AL, FL, GA, NC, SC, TX
6	Cotton	AL, FL, GA, NC, SC, VA
7	Peach	AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV
8	Soybean	AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY
9	Strawberry	OR
10	Sugar beet	IA, ID, IL, MI, MN, ND, OR, WA, WI
11A 11B	Wheat (spring) Wheat (winter)	CO, KS, MO, MT, ND, SD, WY CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY

PID (22-1294 Doc. ID 5126162 at 70-71)

Petitioners' First Motion to Stay remains pending. To date, EPA has resisted review of the Final Rule through a series of procedural maneuvers. First, EPA contended that it had not made any final decisions that could be reviewed, only to reveal those final decisions one business day later by signing a 193-page order denying all of Petitioners' objections and requests. *See* Respondents' Motion to Dismiss, Doc. ID 5129068 at 6; Respondents' Rule 28(j) Notice, Doc. ID 5130160 at 1. Those final decisions were published in the Federal Register on February 28, 2022, the same day the Final Rule took effect. "Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule," 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("EPA's Denial") (Att. 2).

On that same day, February 28, 2022, Petitioners filed a second petition for review incorporating all issues raised in the First Petition as well as a challenge to EPA's Denial. Petition No. 22-1422, Doc. ID 5131400 (the "Second Petition"). Petitioners also updated the First Motion to Stay in light of EPA's Denial, and filed a Renewed Motion for Partial Stay in Case No. 22-1422. Doc. ID 5132688 ("the Renewed

Motion to Stay"). Petitioners' Renewed Motion to Stay sought the same relief as the First Motion to Stay.

In the midst of this briefing, EPA has now advanced a new argument that, to Petitioners' knowledge, had never before been made: EPA contends that under 40 C.F.R. § 23.10, federal courts do not have jurisdiction to review a final rule, published and in effect, until 14 days had expired following the rule's publication in the Federal Register. Respondents' Reply on their Motion to Dismiss, Case No. 22-1294, Doc. ID 5133911 at 6.

That is not the law. 40 C.F.R. § 23.10 creates no jurisdictional bar to review of any of the issues raised by Petitioners in the pending petitions for review of: (1) the Final Rule published on Aug. 30, 2021; (2) the constructive denial of Petitioners' requests for administrative stay; and (3) the decisions announced in EPA's Denial on February 28, 2022. Congress determines the jurisdiction of the federal courts, not agencies. *Cf. Karcher v. May*, 484 U.S. 72, 77 (1987) ("The power of federal courts to hear and decide cases is defined by Article III of the Constitution and by the federal statutes enacted thereunder."). Section 408(h)(1) of the FFDCA provides for judicial review of "any order" on

objections to a final tolerance rule, like EPA's Denial, "within 60 days *after publication* of such order." 21 U.S.C. § 346a(h)(1) (emphasis added). EPA's Denial was published in the Federal Register on February 28, 2022, and as tolerance expiration took effect that same day, there can be no dispute that it is a final, reviewable order under the FFDCA.

EPA's attempt to shield EPA's Denial and the underlying Final Rule from this Court's review by invoking 40 C.F.R. § 23.10 is unavailing. The purpose of Section 23.10, as with similar EPA timing regulations, was to bring greater fairness to so-called "races to the courthouse," in which litigants relied on elaborate schemes to be the first to learn of and file a petition for review of a final rule in their preferred forum. *See* Judicial Review Under EPA-Administered Statutes; Races to the Courthouse, 50 Fed. Reg. 7268, 7268 (Feb. 21, 1985). This issue was largely eliminated with Congress's enactment of Pub. L. 100-236, which created the random selection process for deciding the forum to hear multiple petitions filed in different circuits. *See* 28 U.S.C. § 2112(a)(3); *see also* S. Rep.'t No. 100–263. The regulation has no application here, where (i) all interested parties are

plainly on notice of the Final Rule and EPA's Denial, (ii) Petitioners' petition for review of EPA's Final Rule has been pending for ***over a month*** in Case No. 22-1294 and (iii) Petitioners have and continue to suffer irreparable harm as a result of the Final Rule. There is simply no authority—and EPA cites none—for EPA's claim that EPA's regulation deprives the Court of jurisdiction conferred by Congress to redress a final agency order that is unquestionably already in effect and causing irreparable harm. This is yet another attempt by EPA to frustrate and delay resolution of the Petition.

Nevertheless, EPA has asserted that this Court lacks jurisdiction over the Second Petition because it was filed fewer than 14 days after publication of EPA's Denial in the Federal Register. Respondents' Reply in Support of their Mot. to Dismiss, No. 22-1294, Doc. ID 5133911 at 6. In order to remove any doubt about this Court's ability to proceed, Petitioners hereby file this third petition for review, incorporating the Second Petition and its attachments in their entirety. This third petition for review also incorporates and renews the Renewed Motion for Stay, Doc. ID 5132688.

Given the significant overlap of the three pending petitions, consolidation of the three petitions into one action is appropriate. Petitioners will soon present a request to consolidate the three pending petitions into one action, after determining whether that request can be made jointly with EPA.

The filing of this third petition and consolidation of the three petitions into one action moots all jurisdictional, claims-processing, exhaustion and procedural arguments EPA has raised in its attempt to avoid dealing with the merits of Petitioners' claims. Petitioners' claims, as set forth in each of its petitions and motions to stay, are based upon EPA's own science. Petitioners' claims raise a straight-forward question of statutory interpretation—a fact EPA cannot dispute:

> EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [i.e., EPA's Designated Safe Uses]. …. [A]s a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time of the Final Rule. Ultimately, this issue comes down to whether EPA properly interpreted its obligation under the FFDCA in assessing aggregate exposure to chlorpyrifos, and that is ultimately a question of law and not one of fact.

EPA's Denial, 87 Fed. Reg. at 11241. Thus, the Court does not need to decide which uses of chlorpyrifos are safe. EPA has already identified the uses it considers safe, applying the relevant safety standards of the FFDCA and FQPA. EPA did so in specifying EPA's Designated Safe Uses in the PID published in 2020, in reaffirming the findings of the PID in the Final Rule released in 2021, and in confirming the validity of "its own scientific conclusions and findings" from the PID in EPA's Denial in 2022.

The Court should consolidate this petition with the two pending petitions, deny EPA's motion to dismiss the first petition as moot, and proceed to rule on the pending motion to stay, renewed by Doc. ID 5132688.

Statement of Issues for Review

Petitioners incorporate by reference the issues for review identified in their Second Petition. Namely, Petitioners hereby petition the United States Court of Appeals for the Eighth Circuit for review of (1) EPA's final rule entitled "Chlorpyrifos; Tolerance Revocations," issued on August 30, 2021, published at 86 Fed. Reg. 48,315 (the "Final

Rule") (Att. 1)[1]; (2) EPA's constructive denial of Petitioners' requests for an administrative stay of the Final Rule; and (3) EPA's order denying Petitioners' objections to the Final Rule and confirming denial of Petitioners' requests for an administrative stay of the Final Rule, entitled "Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule" issued on February 22, 2022 and published at 87 Fed. Reg. 11222 ("EPA's Denial") (Att. 2).[2] As a result of EPA's Denial, the Final Rule took effect on February 28, 2022.

Petitioners previously filed petitions for review of EPA's Final Rule in this Court on February 9, 2022, Case No. 22-1294 and on February 28, 2022, Case No. 22-1422. Petitioners described there the irreparable harm they have and will continue to suffer as a result of the Final Rule and sought a partial stay of that rule to allow continued use of chlorpyrifos for certain limited uses that EPA found to be safe ("EPA's Designated Safe Uses"). Petitioners also sought a partial stay

[1] Attachment 1 hereto is the same as Att. 1, Long Decl. Ex. A, Doc. ID 5131400 at 7, in Case No. 22-1422.

[2] Attachment 2 hereto is the same as Att. 1, Long Decl. Ex. FF, Doc. ID 5131400 at 706, in Case No. 22-1422.

of the tolerance expiration date for all other crop uses of chlorpyrifos until EPA issues an appropriate existing stocks order for those uses. Petitioners' motion to stay remains pending.

Now that 14 days have elapsed following publication of EPA's Denial in the Federal Register, Petitioners file this third petition incorporating by reference its Second Petition. Petitioners hereby renew their challenge of (1) the Final Rule, (2) EPA's constructive denial of their requests for an administrative stay of the Final Rule, and (3) EPA's decisions in EPA's Denial overruling their objections to the Final Rule and confirming denial of Petitioners' requests to stay the Final Rule. EPA's constructive denial of Petitioners' requests for administrative stay and rejection of Petitioners' objections and requests to stay the Final Rule are arbitrary and capricious and contrary to law, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.*, for the same reasons previously set forth by Petitioners. *See* Petition 22-1294, Doc. ID 5126162; Partial Motion to Stay in 22-1294, Doc. ID 5126280; Petition 22-1422, Doc. ID 5131400; Renewed Partial Motion to Stay in 22-1422, Doc. ID 5132688.

This Court has jurisdiction to consider this petition under 21 U.S.C. § 346a(h)(1), and has authority to stay implementation of the Final Rule under 5 U.S.C. § 705.[3] A stay of the Final Rule is necessary to prevent irreparable harm, as set forth in the declarations submitted in support of the Second Petition, which are incorporated herein by reference. *See* Petition 22-1422, Att. 2, Exs. A-W (Doc. ID 5131400) and Declaration of Ram Seethapathi on Behalf of Petitioner Gharda Chemicals International, Inc. (Doc. ID 5133345).

Given the significant overlap of the issues raised by both petitions, Petitioners will soon be filing a motion to have this matter consolidated with Case Nos. 22-1294 and 22-1422. Petitioners have a pending motion to consolidate Case Nos. 22-1294 and 22-1422, which EPA does not oppose. *See* Petitioners' Mot. to Consolidate, Doc. ID 5131564; EPA Response to Mot. to Consolidate, Doc. ID 5133354.

[3] EPA concedes that this Court has jurisdiction to review petitions concerning the Final Rule and/or EPA's Denial filed on or after today's date: March 14, 2022. Respondents' Reply on their Motion to Dismiss, Doc. ID 5133911 at 6.

Conclusion

With the filing of this petition, the Court can have no doubt about its jurisdiction to review the Final Rule and to rule on Petitioners' Renewed Motion to Stay. The Court should (1) deny as moot Respondents' Motion to Dismiss, Case No. 22-1294, Doc. ID 5129068, (2) consolidate all three petitions together for briefing and resolution by the Court, and (3) proceed to rule on Petitioners' Renewed Motion to Stay.

March 14, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have, on this day, served by certified mail, return receipt requested, a copy of the foregoing document upon the following parties:

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s/ Nash E. Long
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22-1530

ATTACHMENT 1

Final Rule for Chlorpyrifos Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) – Final Rule

(2) Tolerances are established for residues of thiabendazole, including its metabolites and degradates, in or on the commodities in table 2 to paragraph (a)(2). Compliance with the tolerance levels specified to table 2 to paragraph (a)(2) is to be determined by measuring only the sum of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite 5-hydroxythiabendazole (free and conjugated) calculated as the stoichiometric equivalent of thiabendazole, in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

* * * * *

[FR Doc. 2021–18390 Filed 8–27–21; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; FRL–5993–04–OCSPP]

Chlorpyrifos; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 29, 2021, the United States Court of Appeals for the Ninth Circuit ordered EPA to issue a final rule concerning the chlorpyrifos tolerances by August 20, 2021. Based on the currently available data and taking into consideration the currently registered uses for chlorpyrifos, EPA is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA). Accordingly, EPA is revoking all tolerances for chlorpyrifos.

DATES: This final rule is effective October 29, 2021. The tolerances for all commodities expire on February 28, 2022.

Written objections, requests for hearings, or requests for a stay identified by the docket identification (ID) number EPA–HQ–OPP–2021–0523 must be received on or before October 29, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** unit in this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room are closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 703–347–0206; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT.**

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0523 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 29, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although at this time, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges (OALJ) are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA OALJ, a person should utilize the OALJ e-filing system, at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is

impossible for a person to submit documents electronically or receive service electronically, *e.g.,* the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178 and above, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0523, using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

If you would like to submit CBI with your hearing request, please first contact the Pesticide Re-Evaluation Division by telephone, 703–347–0206, or by email address: *OPPChlorpyrifosInquiries@epa.gov.* Do not submit CBI to EPA through the Federal eRulemaking Portal or email.

D. What can I do if I want the Agency to maintain a tolerance that the Agency has revoked?

Any affected party has 60 days from the date of publication of this order to file objections to any aspect of this order with EPA and to request an evidentiary hearing on those objections (21 U.S.C. 346a(g)(2)). A person may raise objections without requesting a hearing.

The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objection (40 CFR 178.25). While 40 CFR 180.33(i) indicates a fee is due with each objection, EPA currently cannot collect such fees per 21 U.S.C. 346a(m)(3). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27).

Although any person may file an objection, EPA will not consider any legal or factual issue presented in objections, if that issue could reasonably have been raised earlier in the Agency's review of chlorpyrifos relative to this petition. Similarly, if you fail to file an objection to an issue resolved in the final rule within the time period specified, you will have waived the right to challenge the final rule's resolution of that issue (40 CFR 178.30(a)). After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings on this rule. See Nader v EPA, 859 F.2d 747 (9th Cir. 1988), cert denied 490 U.S. 1931 (1989).

EPA will review any objections and hearing requests in accordance with 40 CFR 178.30, and will publish its determination with respect to each in the **Federal Register**. A request for a hearing will be granted only to resolve factual disputes; objections of a purely policy or legal nature will be resolved in the Agency's final order, and will only be subject to judicial review pursuant to 21 U.S.C. 346a(h)(1), (40 CFR 178.20(c) and 178.32(b)(1)). A hearing will only be held if the Administrator determines that the material submitted shows the following: (1) There is a genuine and substantial issue of fact; (2) There is a reasonable probability that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims to the contrary; and (3) Resolution of the issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.30).

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0523 in the subject line on the first page of your submission. All requests must be in writing and must be received by the Hearing Clerk as required by 40 CFR part 178 on or before October 29, 2021.

II. Background

A. What action is the Agency taking?

EPA is revoking all tolerances for residues of chlorpyrifos. In 2007, the Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC) filed a petition with EPA under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), requesting that EPA revoke all chlorpyrifos tolerances. (Ref. 1). In an April 29, 2021 decision concerning the Agency's orders denying that 2007 Petition and the subsequent objections to that denial, the Ninth Circuit ordered EPA to "(1) grant the 2007 Petition; (2) issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA 'has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information,' including for 'infants and children'; and (3) modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. 346a(a)(1)." *League of United Latin Am. Citizens* v. *Regan,* 996 F.3d 673 (9th Cir. 2021) (the *LULAC* decision).

In today's action, EPA is granting the 2007 Petition, which requested revocation of the tolerances. While EPA previously responded to and denied the individual claims in the original petition, the Court found EPA's denial, at least with regard to the issues raised in the litigation, to be unsupported by the record before the Court and ordered EPA to grant the 2007 Petition and issue a final rule revoking or modifying tolerances. EPA is granting the petition by granting the relief sought by the petition, *i.e.,* the revocation of the chlorpyrifos tolerances, for the reasons stated in this rulemaking. Moreover, the Court expressly ordered EPA to respond to the petition by issuing a final rule under FFDCA section 408(d)(4)(A)(i). 996 F.3d at 702. That provision of the statute involves the issuance of a final rule "without further notice and without further period for public comment." 21 U.S.C. 346a(d)(4)(A)(i). While the FFDCA provides an option for EPA to respond to a petition with the issuance of a proposed rule under FFDCA section 408(d)(4)(A)(ii) and thereafter to finalize the proposal, the Court did not direct EPA to exercise its authority to finalize its 2015 proposal to revoke tolerances pursuant to subparagraph (d)(4)(A)(ii). Nothing in the Ninth Circuit's opinion reflects an expectation that, in complying with the Court's order, EPA would or should finalize the 2015 proposed rule. As such, EPA is viewing this action as independent from the 2015 proposal, and this final rule is based on the Agency's current assessment of the available scientific information, rather

than a continuation of and finalization of the Agency's proposal in 2015 to revoke chlorpyrifos tolerances.

In this final rule, EPA is revoking all tolerances for residues of chlorpyrifos contained in 40 CFR 180.342. This includes tolerances for residues of chlorpyrifos on specific food and feed commodities (180.342(a)(1)); on all food commodities treated in food handling and food service establishments in accordance with prescribed conditions (180.342(a)(2) and (a)(3)); and on specific commodities when used under regional registrations (180.342(c)).

EPA finds that, taking into consideration the currently available information and the currently registered uses of chlorpyrifos, EPA cannot make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA section 408(b)(2). 21 U.S.C. 346a(b)(2). As described in greater detail below, the Agency's analysis indicates that aggregate exposures (*i.e.*, exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels, when relying on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment and including the statutory tenfold (10X) margin of safety to account for uncertainties related to the potential for neurodevelopmental effects to infants, children, and pregnant women. Accordingly, the Agency is therefore revoking all tolerances because given the currently registered uses of chlorpyrifos, EPA cannot determine that there is a reasonable certainty that no harm will result from aggregate exposure to residues, including all anticipated dietary (food and drinking water) exposures and all other exposures for which there is reliable information.

B. What is the Agency's authority for taking this action?

EPA is taking this action pursuant to the authority in FFDCA sections 408(b)(1)(A), 408(b)(2)(A), and 408(d)(4)(A)(i). 21 U.S.C. 346a(b)(1)(A), (b)(2)(A), (d)(4)(A)(i).

C. Overview of Final Rule

When assessing pesticides, EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA, see *https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act,* and for a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program* and *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/epas-risk-assessment-process-tolerance-reassessment.*

In general, to assess the risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps: (1) Identification of the toxicological hazards posed by a pesticide; (2) Determination of the exposure "level of concern" for humans, which includes choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide, as well as uncertainty factors; (3) Estimation of human exposure to the pesticide through all applicable routes; and (4) Characterization of human risk based on comparison of the estimated human exposure to the level of concern. For tolerances, if aggregate exposure to humans is greater than the Agency's determined level of concern, the Agency's determination is the tolerances are not safe.

The following provides a brief roadmap of the Units in this rule.

- Unit III. contains an overview of the statutory background, including the safety standard in FFDCA, and the registration standard under FIFRA. FFDCA provides the statutory basis for evaluating tolerances and directs the Agency to revoke tolerances that are not safe.
- Unit IV. provides an overview of the FFDCA petition that requested that EPA revoke chlorpyrifos tolerances on the grounds that those tolerances were not safe under the FFDCA. While that petition raised numerous issues, the primary scientific challenge to the chlorpyrifos tolerances that was before the Ninth Circuit related to whether EPA had selected the correct PoD for assessing risk. While EPA's PoD was based on inhibition of the enzyme acetylcholinesterase (AChE), petitioners asserted that the most sensitive health endpoint was neurodevelopmental outcomes from exposure to chlorpyrifos. A summary of that petition, EPA's response to that petition, and the subsequent litigation and Ninth Circuit's order directing EPA to revoke or modify the chlorpyrifos tolerances is included in this section.
- Unit V. provides an overview of the regulatory background for chlorpyrifos, including the numerous human health risk assessments EPA has conducted and FIFRA Scientific Advisory Panels (SAPs) that were convened to discuss the complex scientific issues associated with chlorpyrifos.
- Units VI. through VIII. summarizes EPA's risk assessment, which reflect the four-step process described above.
- Unit VI, which focuses on the hazard assessment of chlorpyrifos, combines the first two steps to provide a full picture of how EPA conducts its hazard assessment. After describing the process generally, this unit discusses EPA's analysis of the hazards posed by chlorpyrifos, including a discussion of the available data on AChE inhibition and the potential for neurodevelopmental outcomes in the young. Unit VI. also discusses the Agency's process for determining the endpoint on which to regulate chlorpyrifos exposure and the rationale for basing the PoD analysis on 10% AChE inhibition. Finally, this Unit includes a discussion of the FQPA safety factor and the Agency's reasons for retaining the default 10X value.
- Unit VII. describes EPA's exposure assessment for chlorpyrifos. The unit includes a description of the general approach for estimating exposures to pesticide residues in or on food and in drinking water, as well as exposures that come from non-occupational and non-dietary sources, also referred to as residential exposures. The unit walks through how EPA conducted those exposure assessments for chlorpyrifos, including a detailed discussion of the recent refinements to the drinking water analysis conducted by EPA for chlorpyrifos.
- Unit VIII. describes the Agency's process for assessing aggregate risk based on the hazard discussed in Unit VI. and the exposure discussed in Unit VII. and provides the Agency's rationale and conclusions concerning the overall risks posed by chlorpyrifos based on the currently registered uses. Unit VIII. concludes that the aggregate risks exceed the level of concern and therefore the chlorpyrifos tolerances must be revoked.

Units IX. and X. address procedural matters, international obligations, statutory and executive order review requirements, and the specific revisions that will be made to the Code of Federal Regulations with this final rule.

III. Statutory Background

A. Federal Food, Drug, and Cosmetic Act (FFDCA) Tolerances

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed

foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications of tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, pesticide residues in or on food is considered unsafe, 21 U.S.C. 346a(a)(1), and such food, which is then rendered "adulterated" under FFDCA section 402(a), 21 U.S.C. 342(a), may not be distributed in interstate commerce, 21 U.S.C. 331(a).

Section 408(b)(2) of the FFDCA directs that EPA may establish or leave in effect a tolerance for a pesticide only if it finds that the tolerance is safe, and EPA must revoke or modify tolerances determined to be unsafe. FFDCA 408(b)(2)(A)(i) (21 U.S.C. 346a(b)(2)(A)(i)). Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through food, drinking water and all non-occupational exposures (*e.g.*, in residential settings), but does not include occupational exposures to workers (*i.e.*, occupational). Risks to infants and children are given special consideration. Specifically, pursuant to section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

This provision further directs that "in the case of threshold effects, . . . an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (21 U.S.C. 346a(b)(2)(C)). Due to Congress's focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to prenatal exposure as well as to exposure during childhood years. This section providing for the special consideration of infants and children in section 408(b)(2)(C) was added to the FFDCA through the Food Quality Protection Act (FQPA) (Pub. L. 104–170, 110 Stat. 1489 (1996)); therefore, this additional margin of safety is often referred to as the "FQPA safety factor (SF)".

Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), authorizes EPA to revoke tolerances in response to an administrative petition submitted by any person. As explained in more detail in Unit IV, PANNA and NRDC submitted a petition in 2007 requesting revocation of all chlorpyrifos tolerances. The Ninth Circuit has directed EPA to grant that petition and issue a rule revoking or modifying those tolerances. EPA is issuing this rule in response to that petition and revoking all chlorpyrifos tolerances because EPA is unable to determine, based on data available at this time, that aggregate exposures to chlorpyrifos are safe.

B. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Registration Review

Under FIFRA, a pesticide may not be sold or distributed in the United States unless it is registered. (7.U.S.C. 136a(a)). EPA must determine that a pesticide "will not generally cause unreasonable adverse effects on the environment in order to register a pesticide." 7 U.S.C. 136a(c)(5). The term "unreasonable adverse effects on the environment" is defined to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21." 7 U.S.C. 136(bb). Thus, the FIFRA registration standard incorporates the FFDCA safety standard and requires consideration of safety at the time of registration and during the registration review process.

Under section 3(g) of FIFRA (7 U.S.C. 136(a)(g)), EPA is required to re-evaluate existing registered pesticides every 15 years in a process called "registration review." The purpose of registration review is "to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration," 40 CFR 155.40(a)(1), taking into account changes that have occurred since the last registration decision, including any new relevant scientific information and any changes to risk-assessment procedures, methods, and data requirements. 40 CFR 55.53(a). To ensure that a pesticide continues to meet the standard for registration, EPA must determine, based on the available data, including any additional information that has become available since the pesticide was originally registered or re-evaluated, that the pesticide does not cause "unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(1), (5); *see also* 40 CFR 152.50.

Chlorpyrifos is currently undergoing registration review, which must be completed by October 1, 2022. 7 U.S.C. 136a(g)(1)(A)(iv). For information about the ongoing registration review process for chlorpyrifos, see *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0850.*

IV. FFDCA Petition and Related Litigation

A. 2007 FFDCA Petition

In 2006, EPA issued the Registration Eligibility Decision (RED) for chlorpyrifos, which concluded that chlorpyrifos was eligible for reregistration as it continued to meet the FIFRA standard for registration. In September 2007, PANNA and NRDC submitted to EPA a petition (the Petition) seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA. (Ref. 1). That petition raised several claims regarding EPA's 2006 FIFRA reregistration decision for chlorpyrifos and the active registrations in support of the request for tolerance revocations and product cancellations. Those claims are described in detail in EPA's earlier order denying the petition (82 FR 16581, April 5, 2017) (FRL–9960–77).

B. Agency Responses and 2017 Order Denying Petition

On March 29, 2017, EPA denied the Petition in full (82 FR 16581, April 5, 2017) (FRL–9960–77). Prior to issuing that order, EPA provided the Petitioners with two interim responses on July 16, 2012 and July 15, 2014, which denied six of the Petition's claims. EPA made clear in both the 2012 and 2014 responses that, absent a request from Petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request, and EPA therefore finalized its response to those claims in the March 29, 2017 Denial Order.

As background, three of the Petition's claims all related to the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children

at exposure levels below EPA's existing regulatory standard (10% RBC AChE inhibition). Because the claims relating to the potential for neurodevelopmental effects in children raised novel, highly complex scientific issues, EPA originally decided it would be appropriate to address these issues in connection with the registration review of chlorpyrifos under FIFRA section 3(g) and decided to expedite that review, intending to finalize it in 2015, well in advance of the October 1, 2022 registration review deadline (Ref. 2). EPA decided as a policy matter that it would address the Petition claims raising these matters on a similar timeframe. Id. at 16583.

The complexity of these scientific issues precluded EPA from finishing its review according to EPA's original timeline, and the Petitioners brought legal action in the Ninth Circuit Court of Appeals to compel EPA to either issue an order denying the Petition or to grant the Petition by initiating the tolerance revocation process. The result of that litigation was that on August 10, 2015, the Court ordered EPA to "issue either a proposed or final revocation rule or a full and final response to the administrative [P]etition by October 31, 2015." *In re Pesticide Action Network N. Am.,* 798 F.3d 809, 815 (9th Cir. 2015).

In response to that 2015 order, EPA issued a proposed rule to revoke all tolerances for chlorpyrifos on October 28, 2015 (published in the **Federal Register** on November 6, 2015 (80 FR 69080)), based on its unfinished registration review risk assessment. EPA acknowledged that it had had insufficient time to complete its drinking water assessment and its review of data addressing the potential for neurodevelopmental effects. Although EPA noted that further evaluation might enable more tailored risk mitigation, EPA was unable to conclude, based on the information before EPA at the time, that the tolerances were safe, since the aggregate exposure to chlorpyrifos exceeded safe levels.

On December 10, 2015, the Ninth Circuit issued a further order requiring EPA to take final action on its proposed revocation rule and issue its final response to the Petition by December 30, 2016. *In re Pesticide Action Network N. Am.,* 808 F.3d 402 (9th Cir. 2015). In response to EPA's request for an extension of the deadline in order to be able to fully consider the July 2016 FIFRA Scientific Advisory Panel (SAP) report regarding chlorpyrifos toxicology, the Ninth Circuit ordered EPA to complete its final action by March 31, 2017. *In re Pesticide Action Network of North America* v. *EPA,* 840 F.3d 1014 (9th Cir. 2016). Following that order, EPA published a Notice of Data Availability (NODA), seeking comment on EPA's revised risk assessment and water assessment and reopening the comment period on the proposal to revoke tolerances. (81 FR 81049, November 17, 2016) (FRL–9954–65).

On March 29, 2017, and as published in the **Federal Register** on April 5, 2017, the EPA issued an order denying the Petition (the Denial Order) (82 FR 16581). The specific responses are described in full in that Denial Order and summarized again in the Agency's denial of objections (84 FR 35555, July 24, 2019) (FRL–9997–06). EPA's Denial Order did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA concluded that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. EPA therefore denied the remaining Petition claims, concluding that it was not required to complete—and would not complete—the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without resolution of those issues during the ongoing FIFRA registration review of chlorpyrifos.

C. Objections and EPA's Denial of Objections

In June 2017, several public interest groups and states filed objections to the Denial Order pursuant to the procedures in FFDCA section 408(g)(2). Specifically, Earthjustice submitted objections on behalf of the following 12 public interest groups: Petitioners PANNA and NRDC, United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens, Learning Disabilities Association of America, National Hispanic Medical Association and Pineros y Campesinos Unidos del Noroeste. Another public interest group, the North Coast River Alliance, submitted separate objections. With respect to the states, New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submitted a joint set of objections (Ref. 1). The objections focused on three main topics: (1) The Objectors asserted that the FFDCA requires that EPA apply the FFDCA safety standard in reviewing any petition to revoke tolerances and that EPA's decision to deny the Petition without making a safety finding failed to apply that standard; (2) The Objectors contended that the risk assessments EPA conducted in support of the 2015 proposed rule and the 2016 Revised Human Health Risk Assessment (HHRA) demonstrated that chlorpyrifos results in unsafe drinking water exposures and adverse neurodevelopmental effects and that EPA therefore was required to issue a final rule revoking all chlorpyrifos tolerances; and (3) The Objectors claimed that EPA committed procedural error in failing to respond to comments, and they specifically pointed to comments related to neurodevelopmental effects, inhalation risk, and Dow AgroSciences' (now doing business as Corteva AgriScience) physiologically based pharmacokinetic model (PBPK model) used in EPA's 2014 and 2015 human health risk assessments, which are discussed further in Unit V.

On July 18, 2019, EPA issued a final order denying all objections to the Denial Order and thereby completing EPA's administrative denial of the Petition (the Final Order) (84 FR 35555). Again, the Final Order did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA denied the objections in part on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the petitioners' burden.

D. Judicial Challenge to Objections Denial and 2021 Ninth Circuit Order

On August 7, 2019, the Objectors (LULAC Petitioners) and States petitioned the Ninth Circuit for review of the Denial Order and the Final Order. The LULAC Petitioners and States argued that EPA was compelled to grant the 2007 Petition and revoke chlorpyrifos tolerances because (1) EPA lacked authority to maintain chlorpyrifos tolerances without an affirmative finding that chlorpyrifos is safe, (2) EPA's findings that chlorpyrifos is unsafe in the Agency's risk assessments from 2014 and 2016, compel it to revoke chlorpyrifos tolerances, and (3) The 2007 Petition provided a sufficient basis for EPA to reconsider the question of chlorpyrifos's safety and was not required to prove that a pesticide is unsafe.

On April 29, 2021, the Ninth Circuit issued its decision, finding that when EPA denied the 2007 Petition to revoke chlorpyrifos tolerances, it was essentially leaving those chlorpyrifos tolerances in effect, which, the Court noted, the FFDCA only permits if EPA has made a determination that such tolerances were safe. *League of United*

Latin Am. Citizens v. *Regan,* 996 F.3d. 673 (9th Cir. 2021). Although EPA argued that it was not compelled to reconsider its safety determination because the 2007 Petition had failed to meet the threshold requirement of providing reliable evidence that the tolerances were unsafe, the Court found that the Petition provided the necessary "reasonable grounds," which triggered EPA's duty to ensure the tolerances were safe. *Id.* at 695. Since EPA's Denial Order and Final Order failed to make any safety determinations for chlorpyrifos, the Court concluded that EPA violated the FFDCA by leaving those tolerances in place without the requisite safety findings. *Id.* at 695–96. Moreover, in light of the record before the Court, including the 2016 HHRA indicating that the current chlorpyrifos tolerances are not safe, the Court found EPA's denial of the 2007 Petition to be arbitrary and capricious. *Id.* at 697. Based on the available record, the Court concluded that EPA must grant the Petition and issue a final rule modifying or revoking the tolerances under FFDCA section 408(d)(4)(A)(i). *Id.* at 701.

The Court recognized that EPA had been continuing to evaluate chlorpyrifos in registration review and had issued additional regulatory documents concerning chlorpyrifos after the record closed in the litigation, *e.g.,* the 2020 Proposed Interim Registration Review Decision and 2020 SAP, both of which are discussed in more detail in Unit V. below, and noted that such information could be relevant to a safety determination. *Id.* at 703. The Court allowed that if the new information could support a safety determination, EPA might issue a final rule modifying chlorpyrifos tolerances rather than revoking them, although the Court directed EPA to act "immediately" and not engage in "further factfinding." *Id.* at 703. As a result, the Court ordered EPA to: (1) Grant the 2007 Petition; (2) Issue a final rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances, provided that such modification is supported by a safety finding, and (3) Modify or cancel related FIFRA registrations for food use in a timely fashion. *Id.* at 703–04. Since the mandate was issued on June 21, 2021, the deadline for issuing this final rule is August 20, 2021.

V. Chlorpyrifos Background and Regulatory History

Chlorpyrifos (0,0-diethyl-0–3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide. Given the complex scientific nature of the issues reflected in this rule, EPA is alerting the reader that many of the technical terms used in this unit will be described more fully in a subsequent unit.

Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting acetylcholinesterase (AChE), an enzyme necessary for the proper functioning of the nervous system. This can ultimately lead to signs of neurotoxicity. As discussed in more detail below, while there are data that indicate an association between chlorpyrifos and neurodevelopmental outcomes, there remains uncertainty in the dose-response relationship and the levels at which these outcomes occur. In an effort to resolve this scientific uncertainty, evaluation of toxicology and epidemiology studies of chlorpyrifos, specific to determining the appropriate regulatory endpoint, has been the focus of EPA's work on chlorpyrifos for over a decade.

Chlorpyrifos has been registered for use in the United States since 1965. Currently registered use sites include a large variety of food crops (including fruit and nut trees, many types of fruits and vegetables, and grain crops), and non-food use settings (*e.g.,* golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products). Public health uses include aerial and ground-based fogger mosquito adulticide treatments, roach bait products, and individual fire ant mound treatments. In 2000, the chlorpyrifos registrants reached an agreement with EPA to voluntarily cancel all residential use products except those registered for ant and roach baits in child-resistant packaging and fire ant mound treatments. *See, e.g.,* 65 FR 76233, December 6, 2000) (FRL–6758–2); 66 FR 47481, September 12, 2001) (FRL–6799–7).

In 2006, EPA completed FIFRA section 4 reregistration and FFDCA tolerance reassessment for chlorpyrifos and the OP class of pesticides, concluding that the existing tolerances were safe and that chlorpyrifos continued to meet the FIFRA standard for registration. In that effort, EPA relied on RBC AChE inhibition as the endpoint for examining risk.

Subsequently, given ongoing scientific developments in the study of the OPs generally, EPA chose to prioritize the FIFRA section 3(g) registration review (the subsequent round of re-evaluation following reregistration) of chlorpyrifos and the OP class. The registration review of chlorpyrifos and the OPs has presented EPA with numerous novel scientific issues which the Agency has taken to multiple independent FIFRA SAP reviews. (*Note:* The SAP is a federal advisory committee created by FIFRA section 25(d), 7 U.S.C. 136w(d), and serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides.)

These SAPs, which have included the review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, and the evaluation of a chlorpyrifos-specific physiologically-based pharmacokinetic-pharmacodynamic (PBPK–PD, see Unit VII. for definitions) model. These FIFRA SAP reviews have resulted in significant developments in EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. In particular, and partly in response to the issues raised in the 2007 Petition, EPA has conducted extensive reviews of available data to evaluate the possible connection between chlorpyrifos and adverse neurodevelopmental effects, and to assess whether the neurodevelopmental effects could be used to determine points of departure (PoDs) for assessing chlorpyrifos. On this particular topic, EPA has convened three FIFRA SAP reviews. EPA has taken FIFRA SAP recommendations into consideration as it has developed risk assessments and regulatory documents for chlorpyrifos. The remainder of this Unit provides a brief regulatory overview for chlorpyrifos by presenting a summary of the chronology of the FIFRA SAPs and Agency assessments of chlorpyrifos.

The 2008 FIFRA SAP evaluated the Agency's preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action. (Ref. 3) The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the points of departure (PoDs, see Unit VII. for definitions), but noted that despite some uncertainties, the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies "is epidemiologically sound" and "provided extremely valuable information" for evaluating the potential neurodevelopmental effects of chlorpyrifos (Ref. 3). See Unit VI.A.2. for neurodevelopmental toxicity.

The 2010 FIFRA SAP favorably reviewed EPA's 2010 draft epidemiology framework. (Ref. 4, 5) This draft framework, titled "Framework for Incorporating Human

Epidemiologic & Incident Data in Risk Assessments in Pesticides," described the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. As suggested by the 2010 FIFRA SAP, EPA did not immediately finalize the draft framework but instead used it in several pesticide evaluations prior to making revisions and finalizing it. EPA's Office of Pesticide Program's (OPP) finalized this epidemiology framework in December 2016 (Ref. 5).

In 2011, EPA released its preliminary human health risk assessment (2011 HHRA) for the registration review of chlorpyrifos. The 2011 HHRA used 10% RBC AChE inhibition from laboratory rats as the critical effect (or PoD) for extrapolating risk. It also used the default 10X uncertainty factors for inter- and intra-species extrapolation. The 10X FQPA SF was removed with a note to the public that a weight of evidence (WOE) evaluation would be forthcoming, as described in the 2010 draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment."

In 2011, EPA convened a meeting of the FIFRA SAP to review the PBPK–PD model for chlorpyrifos. The panel made numerous recommendations for the improvement of the model for use in regulatory risk assessment, including the inclusion of dermal and inhalation routes. From 2011–2014, Dow AgroSciences, in consultation with EPA, refined the PBPK–PD model, and those refinements were sufficient to allow for use of the PBPK–PD model in the next HHRA.

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to RBC AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the United States, including those from the CCCEH, Mount Sinai, and University of California, Berkeley. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies.

The 2012 FIFRA SAP described the Agency's epidemiology review as "very clearly written, accurate" and "very thorough review". (Ref. 6 at 50–52, 53) It went further to note that it "believes that the [Agency's] epidemiology review appropriately concludes that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7–9 years, and attention and behavior problems at 3 and 5 years of age. . . . ." The 2012 FIFRA SAP concluded that the RBC AChE inhibition remained the most robust dose-response data, though expressed significant concerns about the degree to which 10% RBC AChE inhibition is protective for neurodevelopmental effects, pointing to evidence from epidemiology, *in vivo* animal studies, and *in vitro* mechanistic studies, and urged the EPA to find ways to use the CCCEH data.

In 2014, EPA released a revised human health risk assessment (2014 HHRA. (Ref. 7). The revised assessment used the chlorpyrifos PBPK–PD model for deriving human PoDs for RBC AChE inhibition, thus obviating the need for the inter-species extrapolation factor (as explained later in this Unit) and providing highly refined PoDs which accounted for gender, age, duration and route specific exposure considerations. The PBPK–PD model was also used to develop data derived intra-species factors for some lifestages. The 10X FQPA SF was retained based on the outcome of the 2012 FIFRA SAP and development of a WOE analysis on potential for neurodevelopmental outcomes according to EPA's "Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides." The 2014 HHRA, taken together with the Agency's drinking water assessment, identified estimated aggregate risks exceeding the level of concern for chlorpyrifos.

On November 6, 2015, EPA issued a proposed rule to revoke all tolerances of chlorpyrifos, based on the aggregate risks exceeding the level of concern (80 FR 69079) (FRL–9935–92). In this proposed rulemaking, EPA specified that it was unable to conclude that aggregate exposures from use of chlorpyrifos met the FFDCA's "reasonable certainty of no harm" standard due to risks identified from the drinking watering using a national-scale assessment (*i.e.*, using default values and conservative assumptions). At that time, the EPA had not completed a refined drinking water assessment (*i.e.*, a higher-tier and more resource-intensive assessment relying on more targeted inputs) or an additional analysis of the hazard of chlorpyrifos that was suggested by several commenters to the 2014 HHRA. Those commenters raised the concern that the use of 10% RBC AChE inhibition for deriving PoDs for chlorpyrifos may not provide a sufficiently health protective human health risk assessment given the potential for neurodevelopmental outcomes.

In 2015, EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood reported by the CCCEH study investigators. The Agency convened another meeting of the FIFRA SAP in April 2016 to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for the PoDs. The 2016 SAP did not support the "direct use" of the cord blood and working memory data for deriving the regulatory endpoint, due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations, and lack of raw data from the epidemiology study. (Ref. 8)

Despite its critiques of uncertainties in the CCCEH studies, the 2016 FIFRA SAP expressed concern that 10% RBC AChE inhibition is not sufficiently protective of human health. Specifically, the FIFRA SAP stated that it "agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition (*i.e.*, toxicity at lower doses)." (Id. at 18). (Ref. 8)

Taking into consideration the conclusions of the 2016 SAP, EPA issued another HHRA using a dose reconstruction approach to derive the PoD based on the neurodevelopmental effects observed in the CCCEH study. In 2016, EPA also issued a revised drinking water assessment (2016 DWA). EPA issued a Notice of Data Availability seeking public comment on the 2016 HHRA and 2016 DWA. (81 FR 81049, November 17, 2016) (FRL–9954–65).

In 2017, in response to a Ninth Circuit order, EPA denied the 2007 Petition on the grounds that "further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos." (82 FR at 16583). As part of this commitment to further evaluate the science, EPA evaluated the new laboratory animal studies with results

suggesting effects on the developing brain occur at doses lower than doses that cause AChE inhibition, and concluded that they are not sufficient for setting a PoD. While EPA sought to verify the conclusions of the epidemiology studies conducted by Columbia University it has been unable to confirm the findings of the CCCEH papers or conduct alternative statistical analyses to evaluate the findings. In summary, while EPA sought to address the potential neurodevelopmental effects associated with chlorpyrifos exposure over the past decade, these efforts ultimately concluded with the lack of a suitable regulatory endpoint based on these potential effects. However, these efforts do not alleviate the Agency's concerns regarding potential neurodevelopmental effects.

In October 2020, EPA released its latest human health risk assessment (2020 HHRA) and drinking water assessment (2020 DWA). (Ref. 9 and 10) Due to the shortcomings of the data upon which the 2016 HHRA was based and the uncertainty surrounding the levels around which neurodevelopmental effects may occur, the 2020 HHRA uses the same endpoint and PoDs as those used in the 2014 HHRA (*i.e.*, the PBPK–PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon). The 2020 HHRA retained the default 10X FQPA SF, but also presented risk estimates at a reduced 1X FQPA SF, though it did not adopt or attempt to justify use of this approach.

Then, in December 2020, as part of its FIFRA registration review, EPA issued its Proposed Interim Registration Review Decision (2020 PID) for chlorpyrifos (85 FR 78849, December 7, 2020) (FRL–10017–13). The 2020 PID was based on comparing estimates in the 2020 HHRA with the values from the 2020 DWA, and retaining the 10X FQPA safety factor, the PID proposed to limit applications of chlorpyrifos in this country would be reduced to certain uses in certain regions of the United States. The PID proposed to conclude that the Agency could make a safety finding for the approach in this path forward, as risk would be based on limited uses in limited geographic areas, as specified. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos, which the Agency had determined would exceed risk levels of concern without the proposed use restrictions.

In December 2020, EPA requested public comment on the 2020 PID, 2020 HHRA, and 2020 DWA. EPA extended the 60-day comment period by 30 days and it closed on March 7, 2021.

VI. EPA's Hazard Assessment for Chlorpyrifos

A. General Approach to Hazard Identification, Dose-Response Assessment, and Extrapolation

Any risk assessment begins with an evaluation of a chemical's inherent properties, and whether those properties have the potential to cause adverse effects (*i.e.*, a hazard identification). In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. The animal toxicity database for a conventional, food use pesticide usually consists of studies investigating a broad range of endpoints including potential for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and neurotoxicity. These studies include gross and microscopic effects on organs and tissues, functional effects on bodily organs and systems, effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential), effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransferase and cholinesterases), and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). Further, EPA evaluates potential adverse effects in different age groups (adults as well as fetuses and juveniles). (Ref. 11 at 8–10).

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). In evaluating a chemical's dietary risks, EPA uses a reference dose (RfD) approach, which typically involves a number of considerations including:

- *A "point of departure" (PoD):* Typically, the PoD is the value from a dose-response curve that is at the low end of the observable data in laboratory animals and that is the toxic dose that serves as the 'starting point' in extrapolating a risk to the human population, although a PoD can also be derived from human data as well. PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario, and are chosen from toxicity studies that show clearly defined No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Adverse Effect Levels (LOAELs), dose-response relationships, and relationships between the chemical exposure and effect. EPA will select separate PoDs, as needed, for each expected exposure duration (*e.g.*, acute, chronic, short-term, intermediate-term) and route of exposure (*e.g.*, oral, dermal, inhalation). For chlorpyrifos, as discussed later in this Unit, EPA derived PoDs based on 10% RBC AChE inhibition.
- *Interspecies extrapolation:* Because most PoDs are derived from toxicology studies in laboratory animals, there is a need to extrapolate from animals to humans. In typical risk assessments, a default tenfold (10X) uncertainty factor is used to address the potential for a difference in toxic response between humans and animals used in toxicity tests. For chlorpyrifos, as described further below, EPA used a sophisticated model called a physiologically based pharmacokinetic-pharmacodynamic (PBPK–PD) model that accounts for differences in laboratory animals and humans, thereby obviating the need for the default interspecies factor.
- *Intraspecies extrapolation:* To address the potential for differences in sensitivity in the toxic response across the human population, EPA conducts intraspecies extrapolation. In typical risk assessments, a 10X default uncertainty factor is used. For chlorpyrifos, the PBPK–PD model used to derive PoDs also accounts for differences in metabolism and toxicity response across the human population for some age groups and some subpopulations, which allows the default factor of 10X to be refined in accordance with EPA's 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.*

• *Food Quality Protection Act safety factor (FQPA SF)):* The FFDCA section 408(b)(2)(C) instructs EPA, in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of data with respect to exposure and toxicity to infants and children." Section 408(b)(2)(C) further states that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." For chlorpyrifos, as discussed later in this Unit, EPA is retaining the default 10X FQPA SF.

In the human health risk assessment process, as indicated above, EPA uses the selected PoD to calculate a RfD for extrapolating risk. The RfD is calculated by dividing the selected PoD by any applicable interspecies and intraspecies factors and other relevant uncertainty factors such as LOAEL to NOAEL factor or database uncertainty factor.

After calculating the RfD, as indicated above, EPA retains an additional safety factor of 10X to protect infants and children (the FQPA safety factor), unless reliable data support selection of a different factor, as required under the FFDCA. As described in EPA's policy for determining the appropriate FQPA safety factor, this additional safety factor often overlaps with other traditional uncertainty factors (*e.g.,* LOAEL to NOAEL factor or database uncertainty factor), but it might also account for residual concerns related to pre- and postnatal toxicity or exposure. (Ref. 35 at 13–16) In implementing FFDCA section 408, EPA calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD), by dividing the RfD by the FQPA SF. Risk estimates less than 100% of the PAD are safe.

B. Toxicological Effects of Chlorpyrifos

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information for chlorpyrifos in support of this action. For over a decade, EPA has evaluated the scientific evidence surrounding the different health effects associated with chlorpyrifos. The Agency has conducted extensive reviews of the scientific literature on health outcomes associated with chlorpyrifos and presented approaches for evaluating and using that information to the FIFRA SAP on several occasions, as discussed above in Unit V. Chlorpyrifos has been tested in toxicological studies for the potential to cause numerous different adverse outcomes (*e.g.,* reproductive toxicity, developmental toxicity, cancer, genotoxicity, dermal toxicity, endocrine toxicity, inhalation toxicity, and immunotoxicity). The inhibition of AChE leading to cholinergic neurotoxicity and the potential for effects on the developing brain (*i.e.,* neurodevelopmental effects) are the most sensitive effects seen in the available data. (2020 HHRA p. 6). The SAP reports have rendered numerous recommendations for additional study and sometimes conflicting advice for how EPA should consider (or not consider) the data in conducting EPA's registration review human health risk assessment for chlorpyrifos.

Unit VI. discusses the Agency's assessment of the science relating to AChE inhibition and the potential for neurodevelopmental effects. Other adverse outcomes besides AChE inhibition and neurodevelopment are less sensitive and are thus not discussed in detail here. Further information concerning those effects can be found in the 2000 human health risk assessment which supported the RED and the 2011 preliminary human health risk assessment. (Ref. 12 and 13).

1. Acetylcholinesterase (AChE) Inhibition

Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting AChE, an enzyme necessary for the proper functioning of the nervous system and ultimately leading to signs of neurotoxicity. This mode of action, in which AChE inhibition leads to neurotoxicity, is well-established, and thus has been used as basis for the PoD for OP human health risk assessments, including chlorpyrifos. This science policy is based on decades of work, which shows that AChE inhibition is the initial event in the pathway to acute cholinergic neurotoxicity.

The Agency has conducted a comprehensive review of the available data and public literature regarding this adverse effect from chlorpyrifos. (Ref. 8 at 24–25, Ref. 13 at 25–27) There are many chlorpyrifos studies evaluating RBC AChE inhibition or the brain in multiple lifestages (gestational, fetal, post-natal, and non-pregnant adult), multiple species (rat, mouse, rabbit, dog, human), methods of oral administration (oral gavage with corn oil, dietary, gavage via milk) and routes of exposure (oral, dermal, inhalation via vapor and via aerosol). In addition, chlorpyrifos is unique in the availability of AChE data from peripheral tissues in some studies (*e.g.,* heart, lung, liver). There are also literature studies comparing the *in vitro* AChE response to a variety of tissues which show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral AChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues. Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

Female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.,* developmental neurotoxicity (DNT), reproductive, and subchronic data).

In addition, studies are available in juvenile pups which show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon. As discussed above, this sensitivity is not derived from differences in the AChE enzyme itself but instead are derived largely from the immature metabolic clearance capacity in the juveniles.

2. Neurodevelopmental Toxicity

In addition to information on the effects of chlorpyrifos on AChE, there is an extensive body of information (in the form of laboratory animal studies, epidemiological studies, and mechanistic studies) studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos.

There are numerous laboratory animal studies on chlorpyrifos in the literature that have evaluated the impact of chlorpyrifos exposure in pre- and post-natal dosing on the developing brain. These studies vary substantially in their study design, but all involve gestational and/or early postnatal dosing with behavioral evaluation from adolescence to adulthood. The data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain with adverse outcomes in several neurological domains including cognitive, anxiety and emotion, social interactions, and neuromotor function. It is, however, important to note that there is little consistency in patterns of effects across studies. In addition, most of these studies use doses that far exceed EPA's 10% benchmark response level for RBC AChE inhibition. There are only a few studies with doses at or near the 10% brain or RBC AChE inhibition levels;

among these only studies from Carr laboratory at Mississippi State University are considered by EPA to be high quality. EPA has concluded that the laboratory animal studies on neurodevelopmental outcomes are not sufficient for quantitatively establishing a PoD. Moreover, EPA has further concluded that the laboratory animal studies do not support a conclusion that adverse neurodevelopmental outcomes are more sensitive than 10% RBC AChE inhibition. (Ref. 8 at 25–31, Ref. 9 at 88–89).

EPA evaluated numerous epidemiological studies on chlorpyrifos and other OP pesticides in accordance with the "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment." (Ref. 8, 14, and 15) The most robust epidemiologic research comes from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University; (2) the Mount Sinai Inner-City Toxicants, Child Growth and Development Study or the "Mt. Sinai Child Growth and Development Study;" and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley. (Ref. 8 at 32–43).

In the case of the CCCEH study, which specifically evaluated the possible connections between chlorpyrifos levels in cord blood and neurodevelopmental outcomes on a specific cohort, there are a number of notable associations. (Ref. 8 at 36–38). Regarding infant and toddler neurodevelopment, the CCCEH authors reported statistically significant deficits of 6.5 points on the Psychomotor Development Index at three years of age when comparing high to low exposure groups. Notably, these decrements persist even after adjustment for group and individual level socioeconomic variables. These investigators also observed increased odds of mental delay and psychomotor delay at age three when comparing high to low exposure groups. The CCCEH authors also report strong, consistent evidence of a positive association for attention disorders, attention deficit hyperactivity disorder (ADHD), and pervasive development disorder (PDD) when comparing high to low chlorpyrifos exposure groups. Moreover, it was reported that for children in the CCCEH cohort at age seven for each standard deviation increase in chlorpyrifos cord blood exposure, there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In addition, the CCCEH authors evaluated the relationship between prenatal chlorpyrifos exposure and motor development/movement and reported elevated risks of arm tremor in children around 11 years of age in the CCCEH cohort.

Notwithstanding the observed associations, EPA and the 2012 and 2016 FIFRA SAPs identified multiple uncertainties in the CCCEH epidemiology studies (Ref. 6 and 8). Some of these include the relatively modest sample sizes, which limited the statistical power; exposure at one point in prenatal time with no additional information regarding postnatal exposures; representativeness of a single point exposure where time-varying exposures or the ability to define cumulative exposures would be preferable; lack of specificity of a critical window of effect and the potential for misclassification of individual exposure measures; and lack of availability of the raw data from the studies that would allow verification of study conclusions.

One of the notable uncertainties in the CCCEH epidemiology studies identified by EPA and the 2016 FIFRA SAP is the lack of specific exposure information on the timing, frequency, and magnitude of chlorpyrifos application(s) in the apartments of the women in the study. Despite extensive effort by EPA to obtain or infer this exposure information from various sources, the lack of specific exposure data remains a critical uncertainty. EPA made efforts in 2014 and 2016 to develop dose reconstruction of the exposures to these women. These dose reconstruction activities represent the best available information and tools but are highly uncertain. In addition, the pregnant women and children in the CCCEH studies were exposed to multiple chemicals, including multiple potent AChE inhibiting OPs and *N*-methyl carbamates. Moreover, using EPA's dose reconstruction methods from 2014 suggest that the pregnant women likely did not exhibit RBC AChE inhibition above 10%. The 2012 and 2016 FIFRA SAP reports expressed concern that it is likely that the CCCEH findings occurred at exposure levels below those that result in 10% RBC AChE inhibition (Ref. 6 and 8). However, given the available CCCEH exposure information and the exposures to multiple potent AChE inhibiting pesticides, EPA cannot definitively conclude the level of AChE inhibition. EPA remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by CCCEH investigators. (Ref. 8) Moreover, given the uncertainties, particularly in the exposure information available from CCCEH (single timepoints, lack of time varying exposure, lack of knowledge about application timing), uncertainties remain about the dose-response relationships from the epidemiology studies.

Finally, there are several lines of evidence for actions of chlorpyrifos distinct from the classical mode of action of AChE inhibition. This information has been generated from model systems representing different levels of biological organization and provide support for molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling), and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Among the many *in vitro* studies on endpoints relevant to the developing brain available for chlorpyrifos, only three have identified outcomes in picomole concentrations, including concentrations lower than those that elicit AChE inhibition *in vitro*. However, as is the case for many other developmental neurotoxicants, most of these studies have not been designed with the specific goal of construction or testing an adverse outcome pathway. Thus, there are not sufficient data available to test rigorously the causal relationship between effects of chlorpyrifos at the different levels of biological organization in the nervous system. (Ref. 8 at 27–31)

Due to the complexity of nervous system development involving the interplay of many different cell types and developmental timelines, it is generally accepted that no single *in vitro* screening assay can recapitulate all the critical processes of neurodevelopment. As a result, there has been an international effort to develop a battery of new approach methodologies (NAMs) to inform the DNT potential for individual chemicals. This DNT NAM battery is comprised of *in vitro* assays that assess critical processes of neurodevelopment, including neural network formation and function, cell proliferation, apoptosis, neurite outgrowth, synaptogenesis, migration, and differentiation. In combination the assays in this battery provide a mechanistic understanding of the underlying biological processes that may be vulnerable to chemically-induced disruption. It is noteworthy, however, that to date the quantitative relationship between alterations in these

neurodevelopmental processes and adverse health outcomes has not been fully elucidated. Moreover, additional assays evaluating other critical neurodevelopmental processes such as myelination are still being developed (Ref. 15).

In September 2020, EPA convened a FIFRA SAP on developing and implementing NAMs using methods such as *in vitro* techniques and computational approaches. Included in that consideration was use of the DNT NAM battery to evaluate OP compounds as a case study. These methods presented to the 2020 FIFRA SAP provide a more systematic approach to evaluating pharmacodynamic effects on the developing brain compared to the existing literature studies. Initial data from the NAM battery were presented to the SAP for 27 OP compounds, including chlorpyrifos and its metabolite, chlorpyrifos oxon, and, when possible, compared to *in vivo* results (by using *in vitro* to *in vivo* extrapolation). On December 21, 2020, the SAP released its final report and recommendations on EPA's proposed use of the NAMs data. (Ref. 16). The advice of the SAP is currently being taken into consideration as EPA develops a path forward on NAMs, but analysis and implementation of NAMs for risk assessment of chlorpyrifos is in progress and was unable to be completed in time for use in this rulemaking. The Agency is continuing to explore the use of NAMs for the OPs, including chlorpyrifos, and intends to make its findings available as soon as it completes this work.

C. Hazard Identification: Using AChE as the Toxicological Endpoint for Deriving PADs

The RED for chlorpyrifos was completed in 2006 and relied on RBC AChE inhibition results from laboratory animals to derive PoDs and retained the FQPA 10X safety factor due to concerns over age-related sensitivity and uncertainty associated with potential neurodevelopmental effects observed in laboratory animals. Based on a review of all the studies (guideline data required, peer reviewed literature, mechanistic), AChE inhibition remains the most robust quantitative dose-response data and thus continues to be the critical effect for the quantitative risk assessment. This approach is consistent with the advice of the SAP from 2008 and 2012. The Agency typically uses a 10% response level for AChE inhibition in human health risk assessments. This response level is consistent with the 2006 OP cumulative risk assessment and other single chemical OP risk assessments. (Ref. 17 and 18).

In response to the 2015 proposed rule to revoke chlorpyrifos tolerances, as noted above, the Agency received some comments raising a concern that the use of the 10% AChE inhibition may not be sufficiently health protective. Taking those comments into consideration, EPA conducted an additional hazard analysis and convened the 2016 FIFRA SAP to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for PoDs. The 2016 FIFRA SAP did not support the "direct use" of the cord blood and working memory data for deriving the regulatory endpoint, due to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, and lack of a second laboratory to reproduce the analytical blood concentrations. (Ref. 8) Despite their critiques regarding uncertainties in the CCCEH studies, the 2016 SAP expressed concern that 10% RBC AChE inhibition is not sufficiently protective of human health.

The 2016 FIFRA SAP, however, did present an alternative approach for EPA to consider. First, it is important to note that this SAP was supportive of the EPA's use of the PBPK–PD model as a tool for assessing internal dosimetry from typical OPP exposure scenarios. Use of the PBPK–PD model coupled with typical exposure scenarios provides the strongest scientific foundation for chlorpyrifos human health risk assessment. Given that the window(s) of susceptibility are currently not known for the observed neurodevelopmental effects, and the uncertainties associated with quantitatively interpreting the CCCEH cord blood data, this SAP recommended that the Agency use a time weighted average (TWA) blood concentration of chlorpyrifos for the CCCEH study cohort as the PoD for risk assessment. Thus, in 2016 EPA attempted, using the PBPK–PD model, to determine the TWA blood level expected from post-application exposures from the chlorpyrifos indoor crack-and-crevice use scenario. Despite that effort, EPA's position is that the shortcomings of the data with regard to the dose-response relationship and lack of exposure information discussed above, continue to raise issues that make quantitative use of the CCCEH data in risk assessment not scientifically sound.

Thus, taking into consideration the robustness of the available data at this time, EPA has determined that the most appropriate toxicological endpoint for deriving points of departure for assessing risks of chlorpyrifos is 10% RBC AChE inhibition. The Agency is not ignoring or dismissing the extensive data concerning the potential for adverse neurodevelopmental outcomes, however. As discussed later in this Unit, the Agency is addressing the uncertainties surrounding the potential for adverse neurodevelopmental outcomes by retaining the default 10X FQPA safety factor.

1. Durations of Exposure

As noted in Unit VI.A., EPA establishes PoDs for each expected exposure duration likely to result from pesticide exposure. For chlorpyrifos, exposure can occur from a single event or on a single day (*e.g.*, eating a meal) or from repeated days of exposure (*e.g.*, residential). With respect to AChE inhibition, effects can occur from a single exposure or from repeated exposures. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute exposures. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with most OPs show a consistent pattern of inhibition reaching a "steady state" of inhibition at or around 2–3 weeks of exposure in adult laboratory animals (Ref. 19). This pattern observed with repeated dosing is a result of the amount of inhibition coming to equilibrium with production of new enzyme. As such, AChE studies of 2–3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.*, up to 2 years of exposure). Thus, for most of the human health risk assessments for the OPs, the Agency is focusing on the critical durations ranging from a single day up to 21 days (*i.e.*, the approximate time to reach steady state for most OPs). As such, EPA has calculated PoDs for the acute and steady-state durations. As described below, these PoDs have been derived for various lifestages, routes, and exposure scenarios.

2. Deriving PODs, Inter- and Intra-Species Extrapolation: Use of the PBPK Model

The process for developing RfDs and PADs typically involves first deriving PoDs directly from laboratory animal studies, followed by dividing the PoD by the default uncertainty factors of 10X for interspecies extrapolation and intraspecies extrapolation, and the FQPA safety factor. For chlorpyrifos, as discussed previously in Unit V, there is a sophisticated PBPK–PD model available for chlorpyrifos. Numerous

Federal Advisory Committees and external review panels have encouraged the use of such a modeling approach to reduce inherent uncertainty in the risk assessment and facilitate more scientifically sound extrapolations across studies, species, routes, and dose levels. The PBPK–PD model for chlorpyrifos has undergone extensive peer review by various individual or groups, including the FIFRA SAPs. Significant improvements have been made to the model over the years in response to recommendations from the 2008, 2011, and 2012 FIFRA SAPs and comments from both internal and external peer reviewers. (Ref. 9 at 20). As a result, EPA has concluded that the current PBPK–PD model is sufficiently robust and is using it for deriving PoDs for chlorpyrifos.

a. Derivation of PoDs

As noted above, the PoDs for chlorpyrifos are based on the levels at which 10% RBC AChE inhibition is observed. The PBPK–PD model accounts for pharmacokinetic and pharmacodynamic characteristics to derive age-, duration-, and route-specific PoDs. Separate PoDs have been calculated for dietary (food, drinking water) and residential exposures by varying inputs on types of exposures and populations exposed. Specifically, the following characteristics have been evaluated: Duration [24-hour (acute), 21-day (steady state)]; route (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency [events per day (eating, drinking)]. For each exposure scenario, the appropriate body weight for each age group or sex was modeled as identified from the Exposure Factors Handbook (Ref. 21) for residential exposures and from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey (NHANES)/What We Eat in America (WWEIA) Survey for dietary exposures.

Within the PBPK–PD model, the Agency evaluated the following exposure scenarios: Oxon (chlorpyrifos metabolite) exposures via drinking water (acute and steady-state exposures for infants, children, youths, and female adults); chlorpyrifos exposures via food (acute and steady-state exposures for infants, children, youths, and female adults); steady-state residential exposures to chlorpyrifos via skin for children, youths, and female adults; steady-state residential exposures to chlorpyrifos via hand-to-mouth ingestion for children 1–2 years old; steady-state residential exposures to chlorpyrifos via inhalation for children 1–2 years old and female adults. (Ref. 9 at 22–25).

Steady-state dietary exposure was estimated daily for 21 days. For drinking water exposure, infants and young childrens (infants <1 year old, children between 1–2 years old, and children between 6–12 years old) were assumed to consume water 6 times per day, with a total consumption volume of 0.69 L/day. For youths and female adults, they were assumed to consume water 4 times per day, with a total consumption volume of 1.71 L/day.

For all residential dermal exposures to chlorpyrifos the dermal PoDs were estimated assuming 50% of the skin's surface was exposed. Exposure times for dermal exposure assessment were consistent with those recommended in the 2012 Residential Standard Operating Procedures (SOPs) (Ref. 18). For residential inhalation exposures following public health mosquitocide application, the exposure duration was set to 1 hour per day for 21 days. The incidental oral PoDs for children 1 to <2 years old for other turf activities were estimated assuming that there were six events, 15 minutes apart, per day.

The PBPK-modeled PoDs derived for the various lifestages, routes, and exposure scenarios discussed above, can be found in Table 4.2.2.1.2 of the 2020 HHRA (Ref 8).

b. Inter-Species Extrapolation

As indicated above, the PBPK–PD model directly predicts human PoDs based on human physiology and biochemistry, and thus there is no need for an inter-species uncertainty factor to extrapolate from animal PoDs.

c. Intra-Species Extrapolation

The PBPK–PD model can account for variability of critical physiological, pharmacokinetic, and pharmacodynamic parameters in a population to estimate, using the Monte Carlo analysis, the distribution of doses that result in 10% RBC AChE inhibition. Therefore, Data-Derived Extrapolation Factors (DDEF) for intra-species extrapolation have been estimated to replace the default intra-species uncertainty factor for some groups (Ref. 22).

According to EPA's DDEF guidance (Ref. 22), when calculating a DDEF intra-species extrapolation factor, administered doses leading to the response level of interest (in the case of chlorpyrifos, the 10% change in RBC AChE inhibition) are compared between a measure of average response and response at the tail of the distribution representing sensitive individuals. The tail of the distribution may be selected at the 95th, 97.5th, and 99th percentile.

As to chlorpyrifos, the 99th percentile was used in risk assessment to provide the most conservative measure (Ref. 7). In addition to estimating DDEF using the above approach for specific age groups, intra-species DDEF was also calculated by comparing between average responses between adults and 6-month old infants. For the 2020 HHRA, the largest calculated DDEFs, 4X for chlorpyrifos and 5X for the oxon metabolite, were used for intraspecies extrapolation for all groups except women of childbearing age. There was a slightly higher variability between adults and infants when considering the distributions for the oxon metabolite, thus, the slightly higher intra-species factor. For women of childbearing age, the Agency is applying the standard 10X intra-species extrapolation factor due to limitations in the PBPK–PD model to account for physiological, anatomical, and biochemical changes associated with pregnancy. (Ref. 9 at 21–22).

d. Summarizing the PoDs, Inter- and Intra-Species Extrapolation Factors

In summary, for assessing the risks from exposure to chlorpyrifos, the human PBPK–PD model has been used to derive PoDs based on 10% RBC AChE inhibition for various populations, durations, and routes. The model, which calculates a human PoD directly, obviates the need for an interspecies extrapolation factor since animal data are not used. To account for variations in sensitivities, the Agency has determined that an intra-species factor of 4X for chlorpyrifos and 5X for the oxon is appropriate for all groups except women of childbearing age. For women of childbearing age, the typical 10X intra-species factor is being applied, due the lack of appropriate information and algorithms to characterize physiological changes during pregnancy.

3. FQPA Safety Factor

As noted above, the FFDCA requires EPA, in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children." 21 U.S.C. 346A(b)(2)(C). Section 408(b)(2)(C) further states that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of

reliable data, such margin will be safe for infants and children."

In applying the FQPA safety factor provision, EPA has interpreted it as imposing a presumption in favor of retaining it as an additional 10X safety factor. (Ref. 5 at 4, 11). Thus, EPA generally refers to the 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the 10X is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (Id.). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in FFDCA section 408(b)(2)(C)—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Id. at 24–25, 35).

EPA's 2020 HHRA assessed the potential risks from exposures to chlorpyrifos in two ways—with one scenario being the retention of the default 10X FQPA SF, and the other scenario being the reduction of the FQPA SF to 1X. The purpose of using both values was to provide an indication of what the potential risk estimates would be under either scenario. The 2020 document, however, retained the 10X and did not adopt or offer support for reducing to 1X. To reduce the FQPA safety factor to 1X, the FFDCA requires that EPA determine that reliable data demonstrate that the 1X would be safe for infants and children. The 2020 document did not make that determination. For chlorpyrifos, of the three factors mentioned in the previous paragraph, the primary factor that undercuts a determination that a different safety factor would be safe for children is the uncertainty around the potential for pre- and post-natal toxicity for infants and children in the area of neurodevelopmental outcomes.

Based on the weight of the evidence concerning the potential for neurodevelopmental outcomes as discussed in Unit VI.B.2. above, there is ample qualitative evidence of a potential effect on the developing brain; however, there remains uncertainty around the levels at which these potential neurodevelopmental outcomes occur. Although the laboratory animal studies do not support a conclusion that neurodevelopmental outcomes are more sensitive than AChE inhibition, the mechanistic data are, at this time, incomplete in their characterization of dose-response. This conclusion may be further evaluated upon EPA's completion of the review of the 2020 FIFRA SAP report concerning NAMs; however, due to the time constraints of this rule, EPA has not been able to include that information in the current assessment of chlorpyrifos. Finally, while the epidemiology data indicates an association between chlorpyrifos and adverse neurodevelopmental outcomes, there remains some uncertainty in the dose-response relationship. As such, because the data available at this time indicate remaining uncertainties concerning pre- and post-natal toxicity due to insufficient clarity on the levels at which these outcomes occur, the Agency is unable to conclude, at this time, that a different safety factor would be safe for infants and children; thus, the Agency is retaining the default 10X FQPA safety factor.

4. Total Uncertainty Factors and PADs

In conclusion, the Agency used a total uncertainty factor of 100X for determining the food and drinking water PADs for females of childbearing age (1X interspecies factor, 10X intra-species factor, and 10X FQPA safety factor); 40X for determining the food PADs for remaining populations (1X interspecies factor, 4X intra-species factor, and 10X FQPA safety factor); and 50X for determining the PADs for drinking water for remaining populations (1X interspecies factor, 5X intra-species factor, and 10X FQPA safety factor).

Taking into consideration the PoDs, intra-species extrapolation factors, and FQPA safety factor, the Agency calculated acute PADs (aPADs) and steady state PADs (ssPADs) for infants (less than 1 year old), children (1 to 2 years old), children (6 to 12 years old), youths (13 to 19 years old), and females (13–49 years old); these subpopulations will be protective of other subpopulations. (Ref. 9 at 30–32.) Values may be found in table 5.0.1 in the 2020 HHRA.

VII. EPA's Exposure Assessment for Chlorpyrifos

Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological endpoints for those hazards is estimating human exposure. Under FFDCA section 408, EPA must evaluate the aggregate exposure to a pesticide chemical residue. This means that EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)).

Pursuant to FFDCA section 408(b), EPA has evaluated chlorpyrifos's risks based on "aggregate exposure" to chlorpyrifos. By "aggregate exposure," EPA is referring to exposure to chlorpyrifos by multiple pathways of exposure, *i.e.,* food, drinking water, and residential. EPA uses available data and standard analytical methods, together with assumptions designed to be protective of public health, to produce separate estimates of exposure for a highly exposed subgroup of the general population, for each potential pathway and route of exposure.

The following reflect a summary of the Agency's exposure assessment from the 2020 HHRA unless otherwise specified. (Ref. 10).

A. Exposure From Food

1. General Approach for Estimating Food Exposures

There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed; and (2) The residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the U.S. Department of Agriculture (USDA), (Ref. 11 at 12). Information on residue values can come from a range of sources including crop field trials; data on pesticide reduction (or concentration) due to processing, cooking, and other practices; information on the extent of usage of the pesticide; and monitoring of the food supply. (Id. at 17).

Data on the residues of chlorpyrifos in foods are available from both field trial data and monitoring data, primarily the USDA's Pesticide Data Program (PDP) monitoring data. Monitoring data generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide immediately after harvest.

EPA uses a computer program known as the Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database

(DEEM–FCID version 3.16/Calendex) to estimate exposure by combining data on human consumption amounts with residue values in food commodities. The model incorporates 2003–2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*e.g.*, apple pie) are linked to EPA-defined food commodities (*e.g.*, apples, peeled fruit—cooked; fresh or N/S (Not Specified); baked; or wheat flour—cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA Agricultural Research Service (ARS) and EPA. For chronic exposure assessment (or in the case of chlorpyrifos, for steady-state exposure assessment), consumption data are averaged for the entire U.S. population and within population subgroups; however, for acute exposure assessment, consumption data are retained as individual consumption events. Using this consumption information and residue data, the exposure estimates are calculated for the general U.S. population and specific subgroups based on age, sex, ethnicity, and region.

For chlorpyrifos, EPA determined that acute and steady-state exposure durations were relevant for assessing risk from food consumption. EPA calculates potential risk by using probabilistic techniques to combine distributions of potential exposures in sentinel populations. The resulting probabilistic assessments present a range of dietary exposure/risk estimates.

Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the aPAD, the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. (The same assumptions apply to estimates for steady state dietary exposure and the ssPAD.) To the extent that one or a few values seem to "drive" the exposure estimates at the high-end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making (Ref. 20).

2. Estimating Chlorpyrifos Exposures in Food

The residue of concern, for tolerance expression and risk assessment, in plants (food and feed) and livestock commodities is the parent compound chlorpyrifos. EPA has determined that the metabolite chlorpyrifos oxon is not a residue of concern in food or feed, based on available field trial data and metabolism studies that indicate that the oxon is not present in the edible portions of the crops. In addition, the chlorpyrifos oxon is not found on samples in the USDA PDP monitoring data. Furthermore, the oxon metabolite was not found in milk or livestock tissues (Ref. 9 at 33).

Acute and steady-state dietary (food only) exposure analyses for chlorpyrifos were conducted using the DEEM–FCID version 3.16/Calendex software (Ref. 23). These analyses were performed for the purpose of obtaining food exposure values for comparison to the chlorpyrifos doses predicted by the PBPK–PD model to cause RBC AChE Inhibition. The acute and steady-state dietary (food only) exposure analyses do not include drinking water exposures, which were assessed separately, see Unit VII.B.2.

Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed. EPA also used food processing factors from submitted studies as appropriate. In addition, EPA's acute and steady state dietary exposure assessments used percent crop treated (PCT) information. (Ref. 23)

The chlorpyrifos acute dietary exposure analysis was conducted using the DEEM–FCID, version 3.16, which incorporates 2003–2008 survey consumption data from USDA's NHANES/WWEIA. The acute risk estimates were presented for the sentinel populations for infants (less than 1 yr old); children (1–2 years old); youths (6–12 years old); and adults (females 13–49 years old). The assessment of these index lifestages is protective of other population subgroups.

The chlorpyrifos steady-state dietary exposure analysis was conducted using the Calendex component of DEEM–FCID (with 2003–2008 survey consumption data from USDA's NHANES/WWEIA). Calendex provides a focus detailed profile of potential exposures to individuals across a calendar year. A calendar-based approach provides the ability to estimate daily exposures from multiple sources over time to an individual and is in keeping with two key tenets of aggregate risk assessment: (1) That exposures when aggregated are internally consistent and realistic; and (2) that appropriate temporal and geographic linkages or correlations/associations between exposure scenarios are maintained.

The chlorpyrifos steady state assessment considers the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year. For this assessment, the same food residue values used in the acute assessment were used for the 21-day duration. In the Calendex software, one diary for each individual in the WWEIA is selected to be paired with a randomly selected set of residue values for each food consumed. The steady-state analysis calculated exposures for the sentinel populations for infants (less than 1 year old); children (1–2 years old); youths (6–12 years old); and adults (females 13–49 years old). The assessment of these index lifestages is protective of other population subgroups.

B. Exposure From Drinking Water

1. General Approach for Assessing Exposure From Drinking Water

a. Modeling and Monitoring Data

Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (*i.e.*, the locations of sampling, the times of the year samples were taken, and the frequency by which samples were collected). Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use water exposure models as the primary means to estimate pesticide exposure levels in drinking water. Modeling is a useful tool for characterizing vulnerable sites and can be used to estimate upper-end pesticide water concentrations from infrequent, large rain events. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label (Ref. 24 at 27–28). EPA's models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground water and surface water. Depending on the modeling algorithm (*e.g.*, surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and groundwater. The most common model used to conduct drinking water assessments is the Pesticide in Water Calculator (PWC). PWC couples the Pesticide Root Zone Model (PRZM) and Variable Volume Water Model (VVWM) models together to simulate pesticide fate and transport from the field of application to an adjacent reservoir. (Ref. 24 at 27–28). The PWC estimates pesticide concentrations for an index reservoir that is modeled for site-specific scenarios (*i.e.*, weather and soil data) in different areas of the country. A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Aquatic Models website: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model "typical" concentrations occurring across the nation. Consequently, EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

When monitoring data meet certain data quantity criteria, EPA has tools available to quantify the uncertainty in available monitoring data such that it can be used quantitively to estimate pesticide concentrations in drinking water. (Ref. 25) Furthermore, monitoring data can be used in a weight of evidence approach with model estimated concentrations to increase confidence in the conclusions of a drinking water assessment.

b. Drinking Water Level of Comparison (DWLOC)

The drinking water level of comparison (DWLOC) is a benchmark that can be used to guide refinements of the drinking water assessment (DWA). This value relates to the concept of the "risk cup," which EPA developed to facilitate risk refinement when considering aggregate human health risk to a pesticide. (Ref. 26). The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration and population being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (*e.g.*, acute, short-term, chronic). The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for AChE reversible inhibition from exposure to carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to OP insecticides is usually 21-days based on steady-state kinetics. (Ref. 19)

In practice, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect. Knowing this allowable remaining exposure and the water consumption for each population subgroup (*e.g.*, infants), the Agency can calculate the DWLOC, which is the estimate of safe concentrations of pesticides in drinking water. Using this process of DWLOC calculation allows EPA to determine a target maximum safe drinking water concentration, thereby identifying instances where drinking water estimates require refinement. (Ref. 24 at 19–20).

c. Scale of Drinking Water Assessment

Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly because of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location, and characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure, which influences the application timing, rate used, and number of treatments in a crop production cycle.

EPA may conduct a drinking water assessment (DWA) for a national scale depending on the pesticide use under evaluation. A national scale DWA may use a single upper-end pesticide concentration as a starting point for assessing whether additional refinements are needed or estimated pesticide concentrations for certain site-specific scenarios that are associated with locations in the United States vulnerable to pesticide contamination based on pesticide use patterns. (Ref. 24 at 22.)

EPA may also conduct a regional scale DWA to focus on areas where pesticide concentrations may be higher than the DWLOC. Under this assessment, EPA estimates pesticide concentrations across different regions in the United States that are subdivided into different areas called hydrologic units (HUCs). There are 21 HUC 2 regions with 18 in the contiguous United States. These areas contain either the drainage area of a major river or a combined drainage of a series of rivers. This information can eb found at: *https://water.usgs.gov/GIS/huc.html.* Estimated pesticide concentrations under this approach would be associated with a vulnerable pesticide use area somewhere within the evaluated region. (Ref. 24 at 23).

d. Drinking Water Refinements

EPA has defined four assessment tiers for drinking water assessments. Lower tiered assessments are more conservative based on the defaults or upper bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the certainty in the estimated pesticide concentration. Tier 1 requires the least amount of effort and the least amount of data, whereas Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit, resulting in high confidence in the reported pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. The order in which refinements are considered (*i.e.,* the order in which the assessment is refined) is pesticide-specific and depends on the nature and quality of the available data used to support the refinement. Additional information on the conduct of drinking water assessments can be found in the "Framework for Conducting Pesticide Drinking Water Assessment for Surface Water" (USEPA, 2020).

As discussed in the Framework document, EPA can incorporate several refinements in higher tiered modeling. Two such refinements are the percent cropped area (PCA) and the percent crop treated (PCT). These are described in the recently completed document titled "*Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment*" (Ref. 27) The PCA refers to the amount of area in a particular community water system that is planted with the crop of interest (*e.g.,* the default assumption is that the entire watershed is planted with a crop of interest). The PCT refers to the amount of the cropped area that is treated with the pesticide of interest (*e.g.,* the default is that the entire cropped area is treated with the pesticide of interest). With additional use and usage data, EPA can refine assumptions about the application rate and PCT for use in modeling to generate estimated drinking water concentrations (EDWCs) that are appropriate for human health risk assessment and more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations.

2. Drinking Water Assessment for Chlorpyrifos.

For the chlorpyrifos drinking water assessment, the metabolite chlorpyrifos oxon, which forms because of drinking water treatment and is more toxic than chlorpyrifos, was chosen as the residue of concern. (Ref. 28 and 29) The range of conversion from parent to oxon depends upon the type of water treatment and other conditions. Based on available information regarding the potential effects of certain water treatments (*e.g.,* chlorination appears to hasten transformation of chlorpyrifos to chlorpyrifos oxon), EPA assumed that all chlorpyrifos in source water is converted to chlorpyrifos oxon upon treatment.

The Agency used a DWLOC approach for assessing aggregate risk from chlorpyrifos. As such, EPA calculated DWLOCs for different age groups for both the acute aggregate assessment and the steady-state aggregate assessment, taking into consideration the food and residential contributions to the risk cup. These numbers were provided as a benchmark for evaluating drinking water contributions from uses of chlorpyrifos across the United States, and whether such concentrations would result in aggregate exposures to chlorpyrifos that exceeded the Agency's levels of concern. The lowest acute DWLOC calculated was for exposure to chlorpyrifos oxon to infants (<1 year old) at 23 ppb; the lowest steady state DWLOC calculated was also for exposure to chlorpyrifos oxon to infants (<1 year old) at 4.0 ppb. (Ref. 9 at 45–45). In other words, EDWCs of chlorpyrifos oxon greater than 4.0 ppb for a 21-day average would exceed EPA's DWLOC and present a risk that exceeds the Agency's level of concern.

In its 2014 drinking water assessment, EPA concluded that there were multiple uses of chlorpyrifos that could lead to exposures to chlorpyrifos oxon in drinking water that exceed the DWLOC identified at that time. (Ref. 29). This assessment provided the basis for the Agency's proposal to revoke tolerances in 2015. (Ref. 30). In 2016, EPA conducted a refined drinking water assessment that estimated drinking water concentrations based on modeling of all registered uses, as well as all available surface water monitoring data. That assessment considered several refinement strategies in a two-step process to derive exposure estimates for chlorpyrifos and chlorpyrifos oxon across the country. The first step was an assessment of potential exposure based on the current maximum label rates at a national level. This indicated that the EDWCs could be above the DWLOC.

Because estimated concentrations at the national level exceeded the DWLOC, the Agency conducted a more refined assessment of uses on a regional level. (Ref. 28 at 73–86). This more refined analysis derived EDWCs using the PWC modeling for maximum labeled rates and 1 pound per acre by region for each use. The analysis indicated that approved uses of chlorpyrifos in certain vulnerable watersheds in every region of the country would result in EDWCs that exceed the DWLOC. For example, Table 25 of EPA's 2016 DWA, which provides the range of estimated concentrations of chlorpyrifos in drinking water from uses on golf courses and agricultural or production crops, shows EDWCs that exceed the DWLOC in vulnerable watersheds in every region in the country. While the lower end of some of the ranges provided in that table are below the DWLOC, those lower numbers reflect a single use (*i.e.,* single crop) and do not reflect potential exposure from other uses where applications occur at higher rates, more frequently, or in more locations made more vulnerable due to soil type, weather, or agronomic practices. The relevant estimated concentration for risk assessment purposes is the highest concentration across all uses because it reflects concentrations that may occur in vulnerable sources of drinking water (Ref. 28 at 73–74).

In addition, a robust quantitative analysis of the monitoring data was conducted resulting in concentrations consistent with model-estimated concentrations above the DWLOC. (Ref. 28 at 90–121). Considering both monitoring data and modeling estimates together supports the conclusion that drinking water concentrations in regions across the country will exceed the DWLOC. (Ref. 28 at 121–123).

After the EPA's 2016 DWA showed that the DWLOC exceedances are possible from several uses, EPA developed refinement strategies to examine those estimated regional/watershed drinking water concentrations to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At that time, EPA was anticipating that a more refined drinking water assessment might allow EPA to better identify where at-risk watersheds are located throughout the country to support more targeted risk mitigation through the registration review process. The refinements better account for variability in the use area treated within a watershed that may

contribute to a drinking water intake (referred to as PCA or percent use area when considering non-agricultural uses) and incorporate data on the amount of a pesticide that is actually applied within a watershed for agricultural and non-agricultural uses (referred to as PCT). These refinement approaches underwent external peer review and were issued for public comment in January 2020: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.* In addition, EPA used average application rates, average numbers of annual applications for specific crops, and estimated typical application timing at the state-level based on pesticide usage data derived from a statistically reliable private market survey database, publicly available survey data collected by the USDA, and state-specific scientific literature from crop extension experts.

The recently developed refinements were integrated in the *Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review,* which was issued in September 2020. (2020 DWA) (Ref. 10) The updated assessment applied the new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state level PCT data, incorporated refined usage and application data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information. In addition, given the 2016 DWA calculation of estimated drinking water concentrations exceeding the DWLOC of 4.0 ppb, the Agency decided to focus its refinements for the 2020 updated drinking water assessment on a subset of uses in specific regions of the United States. The purpose of the focus on this subset of uses was to determine, if these were the only uses permitted on the label, whether or not the resulting estimated drinking water concentrations would be below the DWLOC. The subset of uses assessed were selected because they were identified as critical uses by the registrant and/or high-benefit uses to growers. That subset of currently registered uses included alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. The results of this analysis indicated that the EDWCs from this subset of uses limited to certain regions are below the DWLOC. (Ref. 10 at 16–17). However, the 2020 DWA refined estimates did not include chlorpyrifos exposures from uses beyond that subset. In the 2020 DWA, EPA stated that if additional uses were added or additional geographic areas included, a new separate assessment would need to be prepared in order to evaluate whether concentrations would remain below the DWLOC. In addition to the modeling of the EDWCs for the specific subset of uses, the 2020 DWA conducted a quantitative surface water monitoring data analysis. That analysis indicated that monitored chlorpyrifos concentrations, which reflect existing uses, are above the DWLOC. (Ref. 10 at 62, 75). These data would need to be considered in the context of any additional uses beyond the subset evaluated.

C. Residential Exposure to Pesticides

1. General Approach to Assessing Non-Occupational Exposures

Residential assessments examine exposure to pesticides in non-occupational or residential settings (*e.g.,* homes, parks, schools, athletic fields or any other areas frequented by the general public), based on registered uses of the pesticide. Exposures to pesticides may occur to persons who apply pesticides (which is referred to as residential handler exposure) or to persons who enter areas previously treated with pesticides (which is referred to as post-application exposure). Such exposures may occur through oral, inhalation, or dermal routes and may occur over different exposure durations (*e.g.,* short-term, intermediate-term, long-term), depending on the type of pesticide and particular use pattern.

Residential assessments are conducted through examination of significant exposure scenarios (*e.g.,* children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To regularize this process, EPA has prepared SOPs for conducting residential assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment (*e.g.,* homes, schools, parks, athletic fields, or other publicly accessible locations). (Ref. 18) The SOPs identify relevant generic data and construct algorithms for calculating exposure amounts using these generic data in combination with pesticide-specific information. The generic data generally involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities) and transfer coefficient data. Transfer coefficient data measure the amount of pesticide that transfers from the environment to humans from a defined activity (*e.g.,* hand contact with a treated surface or plant). Specific information on pesticides can include information on residue levels as well as information on environmental fate such as degradation data.

Once EPA assesses all the potential exposures from all applicable exposure scenarios, EPA selects the highest exposure scenario for each exposed population to calculate representative risk estimates for use in the aggregate exposure assessment. Those specific exposure values are then combined with the life stage appropriate exposure values provided for food and drinking water to determine whether a safety finding can be made.

2. Residential Exposure Assessment for Chlorpyrifos

Most chlorpyrifos products registered for residential treatment were voluntarily cancelled or phased out by the registrants between 1997 and 2001; however, some uses of chlorpyrifos remain that may result in non-occupational, non-dietary (*i.e.,* residential) exposures. Based on the remaining registered uses, the Agency has determined that residential handler exposures are unlikely. Chlorpyrifos products currently registered for residential use are limited to roach bait products or ant mound treatments. Exposures from the application of roach bait products are expected to be negligible. The roach bait product is designed such that the active ingredient is contained within a bait station, which eliminates the potential for contact with the chlorpyrifos containing bait material. Since the ant mound treatments can only be applied professionally, residential handler exposure is also not anticipated. (Ref. 9 at 36–44).

There is a potential for residential post-application exposures. Chlorpyrifos is registered for use on golf courses and as an aerial and ground-based ultra-low volume (ULV) mosquito adulticide applications made directly in residential areas. Based on the anticipated use patterns reviewed under the SOP, EPA assessed these exposures as steady-state residential post-application exposures, which would be protective of shorter durations of exposure. There is a potential for dermal post-application exposures from the golf course uses for adults (females 13–49 years old); youths (11 to less than 16 years old); and children (6 to less than 11 years old). There is also a potential for dermal, incidental oral, and inhalation post-application exposures

for children (1 to less than 2 years old) and dermal and inhalation post-application exposures for adults from exposure to mosquitocide uses. The Agency combined post-application exposures for children (1 to less than 2 years old) for dermal, inhalation, and incidental oral exposure routes because these routes all share a common toxicological endpoint. EPA used the post-application exposures and risk estimates resulting from the golfing scenarios in its aggregate exposure and risk assessment.

VIII. Aggregate Risk Assessment and Conclusions Regarding Safety for Chlorpyrifos

The final step in the risk assessment is the aggregate exposure assessment and risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern (LOC)/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. The aggregated exposure assessment process considers exposure through multiple pathways or routes of exposure (*e.g.,* food, water, and residential) for different sub-populations (*e.g.,* infants, children ages 1–6) and exposure duration or types of effects (*e.g.,* acute noncancer effects (single dose), chronic noncancer effects, and cancer). The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and are dependent on the level of refinement or assessment tier.

As noted above, EPA evaluates aggregate exposure by comparing combined exposure from all relevant sources to the safe level. Where exposures exceed the safe level, those levels exceed the risk cup and are of potential concern. There are risk cups for each pertinent duration of exposure for a pesticide because the amount of exposure that can be incurred without adverse health effects will vary by duration (*e.g.,* acute, short-term, chronic). The risk cup is equal to the PAD (either acute, chronic, or steady-state), or the maximum safe exposure for short- and intermediate-term durations.

Whether risks will exceed the risk cup (*i.e.,* whether exposures are expected to exceed safe levels) is expressed differently, depending on the type of level of concern the Agency has identified. For dietary assessments, the risk is expressed as a percentage of the acceptable dose (*i.e.,* the dose which EPA has concluded will be "safe"). Dietary exposures greater than 100% of the percentage of the acceptable dose are generally cause for concern and would be considered "unsafe" within the meaning of FFDCA section 408(b)(2)(B). For non-dietary (and combined dietary and non-dietary) risk assessments of threshold effects, the toxicological level of concern is typically not expressed as an RfD/PAD, but rather in terms of an acceptable (or target) Margin of Exposure (MOE) between human exposure and the PoD. The "margin" that is being referred to in the term MOE is the ratio between the PoD and human exposure which is calculated by dividing human exposure into the PoD. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, when the Agency retains the default uncertainty factors for dietary or aggregate risk (a 10X interspecies uncertainty factor, a 10X intraspecies uncertainty factor, and a 10X FQPA safety factor), the total uncertainty factors (or level of concern) is 1000, and any MOE above 1000 represents exposures that are not of concern. Like RfD/PADs, specific target MOEs are selected for exposures of different durations and routes. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral. Target MOEs for a given pesticide can vary depending on the characteristics of the studies relied upon in choosing the PoD for the various duration and route scenarios.

In addition, in a DWLOC aggregate risk assessment, the calculated DWLOC is compared to the EDWC. Where EPA has calculated a DWLOC, EPA can determine whether drinking water exposures will result in aggregate risks of concern by comparing estimated pesticide concentrations in drinking water to the DWLOC. As noted above, an aggregate DWLOC represents the amount of allowable safe residues of pesticide in drinking water because it represents the room remaining in the risk cup after accounting for the food and residential exposures. The DWLOC provides an estimate of the allowable safe concentrations of pesticides in drinking water for comparison to EDWCs. When the EDWC is less than the DWLOC, there are no risk concerns for aggregate exposures because the Agency can conclude that the contribution from drinking water when aggregated with food and non-occupational exposures will not exceed save levels of exposure. Conversely, an EDWC at or exceeding the DWLOC would indicate a risk of concern, as those exposures to chlorpyrifos in drinking water, when aggregated with exposures from food and residential exposures, would exceed safe levels of exposure. (Ref. 31).

A. Dietary Risks From Food Exposures

As noted above, EPA's acute and steady state dietary exposures assessments for chlorpyrifos were highly refined and incorporated monitoring data for almost all foods. The Agency assessed food exposures based on approved registered uses of chlorpyrifos. This includes field uses of chlorpyrifos but not potential exposure from food handling establishment uses since the Agency did not identify any registered food handling establishment uses. (Ref. 9 at 33–36).

Considering food exposures alone, the Agency did not identify risks of concern for either acute or steady state exposures. Acute dietary (food only) risk estimates, which are based on risk from a single exposure event in the 2020 HHRA were all below 100 percent of the acute population adjusted dose for food ($aPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. The population with the highest risk estimate was females (13–49 years old) at 3.2% $aPAD_{food}$. Steady-state dietary (food only) risk estimates, which are based on the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year, were also all below 100% of the steady state PAD for food ($ssPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. The population with the highest risk estimate was children (1–2 years old) at 9.7% $ssPAD_{food}$.

Although EPA's most recent risk assessment calculated two sets of risk estimates as a result of the dual approach to assess the range of risks that would occur if the Agency determined reliable data existed to support a 1X FQPA safety factor, EPA has determined that it is appropriate to retain the 10X FQPA safety factor, see Unit VI.C.3. Therefore, the risk estimates associated with the 1X FQPA are not relevant to today's action.

B. Non-Occupational, Non-Dietary (Residential) Risks

Because there are some uses of chlorpyrifos that may result in residential exposures, EPA assessed risk from those uses. All residential post-application risk estimates for the registered uses of chlorpyrifos were

below the Agency's level of concern. (Ref. 9 at 38). The residential post-application LOC for children is 40, and the lowest risk estimate for children (11 to less than 16 years old) was 1,200; the residential post-application LOC for adults is 100, and the MOE is 1,000. Because the calculated MOEs are above the Agency's level of concern, there are no risks of concern from residential exposures.

C. Risks From Drinking Water

As noted above, the Agency aggregated exposures to chlorpyrifos from food and residential exposures and calculated the DWLOC, *i.e.,* the amount of drinking water exposures that would be considered safe. The Agency calculated acute and steady state DWLOCs for infants (less than 1 year old); children (1 to 2 years old); youths (6–12 years old), and adults (females 13–49 years old), which would be protective of other subpopulations. The most sensitive acute DWLOC was 23 ppb chlorpyrifos oxon, and the most sensitive steady state DWLOC was 4 ppb.

As indicated above in Unit VII.B.2., the Agency estimated drinking water contributions from registered uses of chlorpyrifos in its 2016 DWA. That document indicated that EDWCs exceed the DWLOC of 4.0 ppb on a national level and in every region of the United States. (Ref. 28).

While the 2020 DWA produced estimated drinking water concentrations that were below the DWLOC of 4.0 ppb, those EDWCs were contingent upon a limited subset of chlorpyrifos use. When assessing different combinations of only those 11 uses in specific geographic regions, the modeling assumed that chlorpyrifos would not be labeled for use on any other crops and would not otherwise be used in those geographic regions. At this time, however, the currently registered chlorpyrifos uses go well beyond the 11 uses in the specific regions assessed in the 2020 DWA. Because the Agency is required to assess aggregate exposure from *all* anticipated dietary, including food and drinking water, as well as residential exposures, the Agency cannot rely on the 2020 DWA to support currently labeled uses. When one assesses the potential of all currently registered uses nationwide and in specific geographical areas, as was done in the 2016 DWA, the estimates of drinking water concentrations exceed the DWLOC of 4.0 ppb, in certain vulnerable watersheds across the United States.

D. A ate Exposure and Determination Concerning Safety

As noted above, in accordance with FFDCA section 408(b)(2), EPA must, when establishing or leaving in effect tolerances for residues of a pesticide chemical, determine that the tolerances are safe. That is, EPA must determine that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (21 U.S.C. 346a(b)(2)).

As discussed earlier in this Unit, exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern. The Agency determined that risks from exposures to chlorpyrifos residues in food comprised 3.2% of the aPAD for females (13–49 years old) and 9.7% of the ssPAD for children (1–2 years old), the highest exposed subpopulations. Combining those exposures with relevant residential exposures, the Agency calculated the allowable levels of drinking water concentrations. Based on the Agency's assessment of drinking water concentrations based on the currently registered uses, however, drinking water exposures significantly add to those risks. When considering the drinking water contribution from currently registered uses, the Agency's levels of concern are exceeded when combined with food and residential exposures.

As indicated above, the Agency calculated acute and steady-state DWLOCs, and the lowest DWLOC is for steady-state exposures to infants at 4.0 ppb; therefore, any EDWCs of chlorpyrifos oxon exceeding 4.0 ppb indicate that aggregate exposures of chlorpyrifos would be unsafe. The Agency's 2016 DWA demonstrates that DWLOC will be exceeded for some people whose drinking water is derived from certain vulnerable watersheds throughout the United States, which means that drinking water contributions will result in aggregate exposures that exceed the Agency's determined safe level of exposure. When taking into consideration aggregate exposures based on current labeled uses, the EDWCs exceed the DWLOC of 4.0 ppb. For example, as noted above in Unit VII.B.2., the 2016 DWA presented EDWCs for uses of chlorpyrifos, including concentrations based on use on golf courses and agricultural crops. For those uses alone, the Agency estimated concentrations exceeding 4.0 ppb in every region in the country; See Table 25 of the 2016 DWA. (Ref. 28 at 73–74.) Comparing the calculated EDWCs from the 2016 DWA with the DWLOC calculated in the 2020 HHRA shows that drinking water concentrations from chlorpyrifos uses will exceed the safe allowable level for contributions from drinking water. This means that aggregate exposure (food, drinking water, and residential exposures) exceeds the Agency's safe level for chlorpyrifos exposure. Because the FFDCA requires EPA to aggregate all dietary and non-occupational exposure, EPA cannot conclude that there is a reasonable certainty that no harm will result from aggregate exposure to chlorpyrifos residues when taking into consideration all labeled uses.

It is worth noting that the Agency's Proposed Interim Registration Review Decision (PID) recognized that there might be limited combinations of uses in certain geographic areas that could be considered safe, if the assessment only includes those specific uses in those areas. The PID noted that "[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern. If considering only the uses that result in DWLOCs below the EDWCs, aggregate exposures are not of concern." (Ref. 32 at 19). The PID proposed limiting chlorpyrifos applications to specific crops in certain regions where the EDWCs for those uses were calculated to be lower than the DWLOC. (*Id.* at 40). The Agency's ability to make the safety finding for any remaining uses would be contingent upon significant changes to the existing registrations, including use cancellations, geographical limitations, and ot abel c es.

Con ently, e the 2020 PID suggested that there may be limited combinations of uses that could be safe, FFDCA section 408(b)(2) requires EPA to aggregate all dietary and non-occupational exposures to chlorpyrifos in making a safety finding. Without effective mitigation upon which to base a reduced aggregate exposure calculation, the products as currently registered present risks above the Agency's levels of concern. Based on the data available at this time and the aggregate exposures expected from currently registered uses, the Agency cannot, at this time, determine that aggregate exposures to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe. Accordingly, as directed by the statute and in compliance with the Court's order, EPA is revoking all chlorpyrifos tolerances.

IX. Procedural Matters

A. When do these actions become effective?

The revocations of the tolerances for all commodities will become effective on February 28, 2022. The Agency has set the expiration date for these tolerances to satisfy its international trade obligations described in Unit X.

Any commodities listed in this rule treated with the pesticide subject to this rule, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(l)(5). Under this section, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

B. Response to Comments

Today's action responds to the Ninth Circuit's order to issue a final rule in response to the 2007 Petition. As such this rule is not finalizing the proposal published in the **Federal Register** issue of November 6, 2015, nor is it implementing or resolving any registration review activity. Thus, this document is not responding to comments received on the 2015 proposal or the most recent registration review documents. Those activities are separate and apart from the procedural posture of this final rule action. Moreover, as the registration review process is ongoing, including a separate review of the comments submitted, the Agency intends to respond to the most recent comments in as part of that process, rather than in this rule.

C. Are the Agency's actions consistent with international obligations?

The tolerance revocations in this final rule are not discriminatory and are designed to ensure that both domestically produced and imported foods meet the food safety standard established by the FFDCA. The same food safety standards apply to domestically produced and imported foods.

EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. Codex MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. The FFDCA requires EPA to take Codex MRLs into consideration when establishing new tolerances, and it is EPA's policy to harmonize U.S. tolerances with Codex MRLs to the extent possible, provided that the MRLs achieve the level of protection required under FFDCA. In the current instance, EPA has determined that the current U.S. tolerances for chlorpyrifos are not safe and must be revoked. EPA has developed guidance concerning submissions for import tolerance support (65 FR 35069, June 1, 2000) (FRL–6559–3).

Under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), to which the United States is a party, Members are required to, except in urgent circumstances, "allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member." (Ref. 33). The WTO has interpreted the phrase "reasonable interval" to mean normally a period of not less than six months. (Ref. 34). In accordance with its obligations, EPA intends to notify the WTO of this regulation and is providing a "reasonable interval" by establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule. After the six-month period expires, the tolerances for residues chlorpyrifos in or on food will no longer be in effect.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

The Office of Management and Budget (OMB) has exempted tolerance regulations from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This final rule does not contain any information collection activities subject to OMB review and approval under the PRA, 44 U.S.C. 3501 *et seq.* An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute. Since this rule, which is issued under FFDCA section 408(d)(4)(A)(i) (21 U.S.C. 346a(d)(4)(A)(i)) directly in response to a petition under FFDCA section 408(d), does not require the issuance of a proposed rule, the RFA requirements do not apply.

D. Unfunded Mandates Reform Act (UMRA)

EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established

by Congress in the preemption provisions of section 408(n)(4) of the FFDCA.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

For the same reasons, this action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994). Nevertheless, the revocation of the tolerances will reduce exposure to the pesticide and lead to a reduction in chlorpyrifos use on food crops. While EPA has not conducted a formal EJ analysis for this rule, the revocation of tolerances will likely reduce disproportionate impacts on EJ communities that are impacted by chlorpyrifos applications on crops.

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

XI. References

The following is a list of the documents that are specifically referenced in this document. The docket, identified by docket ID number docket number EPA–HQ–OPP–2021–0523, includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. All records in docket are part of the record for this rulemaking. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. The Petition from NRDC and PANNA, EPA's various responses to it, and the objections submitted on the Petition denial are available in docket number EPA–HQ–OPP–2007–1005 available at *https://www.regulations.gov.*
2. U.S. EPA. Chlorpyrifos Final Work Plan. 2009. Available at: *https://www.regulations.gov/document/EPA–HQ-OPP-2008-0850-0020.*
3. FIFRA Scientific Advisory Panel (2008). "The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos." Report from the FIFRA Scientific Advisory Panel Meeting of September 16–19, 2008. Available at: *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0274/document.*
4. U.S. EPA (2010). Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2009-0851-0004.*
5. U.S. EPA (2016). Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides. (2016) Available at: *https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.*
6. FIFRA Scientific Advisory Panel (2012). "Scientific Issues Associated with Chlorpyrifos". Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2012-0040-0029.*
7. U.S. EPA (2014). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0195.*
8. U.S. EPA (2016). Scientific Advisory Panel for Chlorpyrifos: Analysis of Biomonitoring Data. Available at: *https://www.epa.gov/sites/default/files/2016-07/documents/chlorpyrifos_sap_april_2016_final_minutes.pdf.*
9. U.S. EPA (2020). Chlorpyrifos Human Health Risk Assessment. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944.*
10. U.S. EPA (2020). Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.*
11. A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food (June 21, 2000). Available at: *https://www.doh.wa.gov/Portals/1/Documents/4000/PASW_exposurefood.pdf.*
12. U.S. EPA (2000). Chlorpyrifos Human Health Risk Assessment. Available at: *https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf.*
13. U.S. EPA (2011). Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0025.*
14. U.S. EPA (2016). Summary Reviews for Additional Epidemiological Literature Studies from Prospective Birth Cohort Studies. Available in docket number EPA–HQ–OPP–2015–0653 at *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0438.*
15. U.S. EPA (2020). The Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment. Available in docket number EPA–HQ–OPP–2020–0263 at *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0033.*
16. U.S. EPA (2020). Transmittal of Meeting Minutes and Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act, Scientific Advisory Panel (FIFRA SAP) Virtual Meeting held on September 15–18, 2020. Available in docket number EPA–HQ–2020–0263 at *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0054.*
17. U.S. EPA (2006). Revised Organophosphorous Pesticide Cumulative Risk Assessment. Available at *http://www.epa.gov/pesticides/cumulative/2006-op/index.htm.*
18. U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment *https://www.epa.gov/sites/default/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.*
19. FIFRA Scientific Advisory Panel (2002). "Organophosphate Pesticides: Preliminary OP Cumulative Risk Assessment." Information on how to obtain the meeting report is available at *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
20. U.S. EPA (2000). Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern. Available at:

https://www.epa.gov/sites/production/files/2015-07/documents/trac2b054_0.pdf.
21. EPA's Exposure Factors Handbook. Available at: *https://www.epa.gov/expobox/about-exposure-factors-handbook.*
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23. U.S. EPA (2014). Chlorpyrifos Acute and Steady Dietary (Food Only) Exposure Analysis to Support Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0197.*
24. U.S. EPA (2020). Framework for Conducting Pesticide Drinking Water Assessments for Surface Water. Environmental Fate and Effects Division. Office of Pesticide Programs. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at: *https://www.epa.gov/sites/default/files/2020-09/documents/framework-conducting-pesticide-dw-sw.pdf.*
25. FIFRA Scientific Advisory Panel (2019) "Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments." Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2019-0417-0019.*
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27. U.S. EPA (2020). Appendix B. Case Study for Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0279-0002.*
28. U.S. EPA (2016). Chlorpyrifos Refined Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437.*
29. U.S. EPA (2014). Chlorpyrifos Updated Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0198.*
30. U.S. EPA (2015). Proposed Rule: Tolerance Revocations: Chlorpyrifos. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0001.*
31. U.S. EPA (2011). Finalization of Guidance on Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Drinking Water Exposure Assessments. Available at: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/finalization-guidance-incorporation-water-treatment.*
32. U.S. EPA (2020). Chlorpyrifos Proposed Interim Registration Review Decision. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971.*
33. For more information on World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), please see: *https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.*
34. For more information on World Trade Organization (2001) Implementation-Related Issues and Concerns, please see: *https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/Min01/17.pdf&Open=True.*

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 18, 2021.

Edward Messina,

Director, Office of Pesticide ms.

Therefore, for the reasons set forth in the preamble, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.342, add introductory text to read as follows:

§ 180.342 Chlorpyrifos; tolerances for residues.

This section and all tolerances contained herein expire and are revoked on February 28, 2022.

* * * * *

[FR Doc. 2021–18091 Filed 8–27–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225 and 252

[Docket DARS–2020–0039]

RIN 0750–AL15

Defense Federal Acquisition Regulation Supplement: Improved Energy Security for Main Operating Bases in Europe (DFARS Case 2020–D030)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020. This section prohibits contracts for the acquisition of furnished energy for a covered military installation in Europe that is sourced from inside the Russian Federation.

DATES: Effective August 30, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 86 FR 3935 on January 15, 2021, to amend the DFARS to implement section 2821 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 2821 prohibits use of energy sourced from inside the Russian Federation in an effort to promote energy security in Europe. The prohibition applies to all forms of energy "furnished to a covered military installation" as that term is defined in the statute. No public comments were received in response to the proposed rule.

II. Discussion and Analysis

A. Summary of Significant Changes

No changes are made to the final rule as a result of public comments.

B. Other Changes

One change is made to the rule as proposed to clarify the same language that appears in section 225.7019–2, paragraph (b); the provision 252.225–7053, paragraph (b)(2); and clause 252.225–7054, paragraph (b)(2). In all three locations, the statement "Does not apply to a third party that uses it to create some other form of energy (*e.g.,* heating, cooling, or electricity)" is changed to read "Does not apply to energy converted by a third party into another form of energy and not directly delivered to a covered military installation." No other changes are made to the rule.

III. Applicability to Contracts At or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This DFARS rule implements section 2821 of the NDAA for FY 2020 (Pub. L. 116–92). Section 2821 prohibits use of energy sourced from inside the Russian Federation unless a waiver is approved by the head of the contracting activity. To implement section 2821, this rule creates a new solicitation provision and

ATTACHMENT 2

87 Fed. Reg. 1122
(February 28, 2022) – EPA's Denial

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; 5993–05–OCSPP]

Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In response to EPA's August 2021 final rule revoking all tolerances for the insecticide chlorpyrifos under the Federal Food, Drug, and Cosmetic Act (FFDCA), several objections, hearing requests, and requests for stay were filed by numerous parties representing a wide variety of growers and pesticide users. In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the final rule.

DATES: The Order is effective February 28, 2022.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

In this document, EPA denies all objections to, requests for hearing on those objections, and requests for stay of EPA's August 2021 final rule (Ref. 1) revoking all tolerances for the insecticide chlorpyrifos under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346(d). This action may be of interest to all parties filing objections, requests for hearing on those objections, and requests for stay. This action may also be of interest to agricultural producers, food manufacturers or pesticide manufacturers, and others interested in food safety issues generally. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT.**

B. What action is the Agency taking?

In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the August 2021 final rule (Ref. 1). This Order is issued under FFDCA section 408(g)(2)(C), 21 U.S.C. 346a(g)(2)(C)).

Based on information available as of August 20, 2021—the date by which the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) ordered EPA to issue a final rule concerning chlorpyrifos tolerances—EPA was unable to conclude that the tolerances for chlorpyrifos residues were safe in accordance with the FFDCA safety standard. In other words, EPA could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency's analysis indicated that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), resulting from currently registered uses, exceeded safe levels. This decision relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment and included the default Food Quality Protection Act (FQPA) tenfold (10X) margin of safety to account for uncertainties related to the potential for neurodevelopmental effects to infants, children, and fetuses. Accordingly, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. (*See* 86 FR 48315, Aug. 30, 2021) The prepublication of the final rule was issued on August 18, 2021, the final rule was published in the **Federal Register** on August 30, 2021, and the final rule became effective on October 29, 2021.

Pursuant to the procedures set forth in FFDCA section 408(g)(2), objections to, requests for evidentiary hearings on those objections, and/or requests for stays of, the final rule were filed by the persons listed in Unit V. (each, an Objector, and collectively, the Objectors) on or before the close of the objections period on October 29, 2021. (Ref. 1) The Objectors raised challenges to the final rule, including, for example, objections relating to the scope of the revocations in the final rule, retention of the additional FQPA Safety Factor, and use of the 2016 drinking water assessment, as well as raising procedural or other irrelevant concerns that do not change the basis for the final rule itself.

Four Objectors requested a hearing on their objections. The American Soybean Association, American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, "Sugarbeet Associations"), and Cherry Marketing Institute each submitted requests for evidentiary hearings to dispute EPA's revocation of tolerances for the 11 "high-benefit" uses identified in the "Proposed Interim Decision for the Registration Review of Chlorpyrifos" (2020 PID) (Ref. 31)—including soybean uses, sugarbeet uses, and the Michigan tart cherry industry's use. Gharda also submitted a request for an evidentiary hearing on an issue related to the assessment of chlorpyrifos oxon in EPA's aggregate assessment.

Finally, EPA received several written requests for EPA to stay the effective date of the final rule due to impacts on the agricultural industry and in order to provide more time for EPA to fully consider the objections filed.

This Order denies all of the objections, requests for evidentiary hearings on those objections, and requests for stays of the final rule. EPA has undertaken a comprehensive analysis of the merits of each of the Objectors' objections, hearing requests, and requests for stay. That analysis shows, as set out in Units VI., VII., and VIII. of this document, respectively, that none of the Objectors' objections support the claims raised, none of the Objectors' requests for hearing meet the

regulatory standard for granting a hearing, and none of the Objectors' requests for stay warrant staying the effective date of the final rule. There are numerous reasons for EPA's conclusions, for which additional detail is provided in Units VI., VII., and VIII. of this document.

C. What is the Agency's authority for taking this action?

The procedure for filing objections and requests for hearings thereon to EPA's final rule and EPA's authority for acting on such objections is contained in FFDCA section 408(g)(2) (21 U.S.C. 346a(g)(2)) and EPA's regulations at 40 CFR part 178.

II. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing pesticides and tolerances, objections, requests for hearing, and requests for a stay, as well as on pertinent Agency policies and practices.

Unit II.A. summarizes the requirements and procedures in FFDCA section 408 and applicable regulations pertaining to pesticide tolerances, including the procedures for objecting to EPA tolerance actions and the substantive standards for evaluating the safety of pesticide tolerances. This unit also discusses the closely-related statute under which EPA regulates the sale, distribution, and use of pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

Unit II.B. provides an overview of EPA's Office of Pesticide Programs (OPP) risk assessment process. It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern (level of concern), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on the Agency's policy on the FQPA safety factor and acetylcholinesterase (AChE) inhibition.

A. FFDCA/FIFRA and Applicable Regulations

1. General

EPA establishes, modifies, or revokes tolerances for pesticide residues in food under FFDCA section 408. (21 U.S.C. 346a) A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, pesticide residues in or on food are considered unsafe (21 U.S.C. 346a(a)(1)), and such food, which is then rendered "adulterated" under FFDCA section 402(a) (21 U.S.C. 342(a)), may not be distributed in interstate commerce. (21 U.S.C. 331(a)) Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FFDCA section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions establishing a detailed safety standard for pesticides and additional protections for infants and children, among other things. (Pub. L. 104–170, 110 Stat. 1489 (1996))

EPA also regulates pesticides under FIFRA. (7 U.S.C. 136 *et seq.*) While FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution (*Id.* at section 136a(a)), and establishes a registration regime for regulating the use of pesticides. In order for a pesticide to be registered, EPA must determine that a pesticide "will not generally cause unreasonable adverse effects on the environment", among other things. (*Id.* at section 136a(c)(5)) The term "unreasonable adverse effects on the environment" is defined to include "a human dietary risk from residues that results from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21." (*Id.* at section 136(bb)) The FFDCA safety standard was integrated into the FIFRA registration standard in the FQPA, which also directed that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1))

Also under FIFRA, EPA is required to re-evaluate existing registered pesticides every 15 years in a process called "registration review." (7 U.S.C. 136(a)(g)) The purpose of registration review is "to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration," (40 CFR 155.40(a)(1)) taking into account changes that have occurred since the last registration decision, including any new relevant scientific information and any changes to risk-assessment procedures, methods, and data requirements. (40 CFR 155.53(a)) To ensure that a pesticide continues to meet the standard for registration, EPA must determine, based on the available data, including any additional information that has become available since the pesticide was originally registered or re-evaluated, that the pesticide does not cause "unreasonable adverse effects on the environment." (7 U.S.C. 136a(c)(1), (5); *see also* 40 CFR 152.50)

2. Safety Standard for Pesticide Tolerances

FFDCA section 408(b)(2) directs that EPA may establish or leave in effect a tolerance for a pesticide only if it finds that the tolerance is safe and that EPA must revoke or modify tolerances determined to be unsafe. (21 U.S.C. 346a(b)(2)(A)(i)) FFDCA section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (*Id.* At section 346a(b)(2)(A)(ii)) FFDCA section 408(b)(2)(D) directs EPA, in making a safety determination, to consider, among other relevant factors "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources." (*Id.* at section 346a(b)(2)(D)(vi)) As the language indicates, this includes exposure through food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but does not include occupational exposures to workers (*i.e.,* occupational).

Risks to infants and children are given special consideration. Specifically, pursuant to FFDCA section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on "available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals"; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III))

This provision also creates a presumption that EPA will use an additional safety factor for the protection of infants and children. Specifically, it directs that "in the case of threshold effects, ... an additional

tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)) EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (*Id.*) Due to Congress's focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to prenatal exposure as well as to exposure during childhood years. This section providing for the special consideration of infants and children in section 408(b)(2)(C) was added to the FFDCA by the FQPA in 1996; therefore, this additional margin of safety is referred to throughout this Order as the "FQPA safety factor (SF)".

3. Procedures for Establishing, Amending, or Revoking Tolerances

Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (*See* 21 U.S.C. 346a(d)(1)) EPA publishes in the **Federal Register** a notice announcing the filing of a petition filing and requesting public comment. (*Id.* at section 346a(d)(3)) After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance; issue a proposed rule subject to public comments and then finalize a rule to do the same; or deny the petition. (*Id.* at section 346a(d)(4))

Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)) Objections and hearing requests must be filed within 60 days after EPA takes that action. (*Id.*) The statute provides that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." (*Id.* at section 346a(g)(2)(B)) EPA regulations make clear that hearings will only be granted where it is shown that there is "a genuine and substantial issue of fact," the requestor has identified evidence "which, if established, resolve one or more of such issues in favor of the requestor," and the issue is "determinative" with regard to the relief requested. (40 CFR 178.32(b)) EPA's final Order on the objections and requests for hearing is subject to judicial review. (21 U.S.C. 346a(h)(1)) The statute directs that tolerance regulations shall take effect upon publication unless EPA specifies otherwise. (*Id.* at section 346a(g)(1)) EPA is authorized to stay the effectiveness of the tolerance if objections are filed. (*Id.*) Because EPA does not have its own regulations governing stay requests, EPA typically evaluates requests for stay under the criteria set out in FDA's regulations at 21 CFR 10.35(e) due to the fact that the FFDCA provisions governing EPA's objections and hearings process were adapted from the similar parallel statutory process governing FDA objections and hearings.

B. EPA Risk Assessment—Policy and Practice

1. The Safety Determination—Risk Assessment

To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps, which are discussed in further detail in this section: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the "level of concern" with respect to human exposure to the pesticide, which includes choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide and uncertainty factors; (3) estimation of human exposure to the pesticide through all applicable routes; and (4) characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern. For tolerances, characterization of risk involves determining whether the tolerances are safe; if aggregate exposure to humans is greater than the Agency's determined level of concern, the Agency's determination is that the tolerances are not safe.

a. Hazard Identification

Any risk assessment begins with an evaluation of a chemical's potential to cause adverse effects, and whether those properties have the potential to cause adverse effects (*i.e.*, a hazard identification). In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. For most pesticides, the animal toxicity database usually consists of studies investigating a broad range of endpoints including potential for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and neurotoxicity. These studies include gross and microscopic effects on organs and tissues; functional effects on bodily organs and systems; effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential); effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransferase, and cholinesterases); and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). For chlorpyrifos, the Agency examined acute and steady-state durations because of the potential to cause adverse effects based on acute (single day, 24 hours) and steady-state (21-day) exposures. The latter duration is based on the observation in the available studies for organophosphates (OPs) indicating a consistent pattern of AChE inhibition that reaches a steady-state (or comes to an equilibrium) around 2–3 weeks and does not change in studies of longer duration. (Ref. 2 at pg. 7) Further, EPA evaluates potential adverse effects in different age groups (adults as well as fetuses and juveniles). (Ref. 3 at pgs. 8 through 10)

EPA also considers whether the adverse effect has a threshold—a level below which exposure has no appreciable chance of causing the adverse effect. For effects that have no threshold, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur.

b. Level of Concern/Dose-Response Analysis

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA

essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). EPA follows differing approaches to identifying a level of concern for threshold and non-threshold hazards.

i. Threshold effects. In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL), which by definition is the next lower tested dose level below the LOAEL. Generally, EPA will use a NOAEL from the available studies as a starting point (called "the Point of Departure" or "PoD") in estimating the level of concern for humans. At times, however, EPA will use a LOAEL from a study as the Point of Departure when no NOAEL is identified in that study and the LOAEL is close to, or lower than, other relevant NOAELs. PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario and are chosen from toxicity studies that show clearly defined NOAELs or LOAELs and dose-response relationships. The Point of Departure is, in turn, used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and corresponding levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation).

EPA has also used other approaches for choosing the Point of Departure. One approach, called a benchmark dose, or BMD, estimates a point along a dose-response curve that corresponds to a specific response level. (Ref. 4) For example, a BMD_{10} represents a 10% change from the background or typical value for the response of concern. In contrast to the NOAEL/LOAEL approach, a BMD is calculated using a range of dose-response data and thus better accounts for the variability and uncertainty in the experimental results due to characteristics of the study design, such as dose selection, dose spacing, and sample size. In addition to a BMD, EPA generally also calculates a "confidence limit" in the BMD. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency often uses as the PoD. Use of the BMDL for deriving the PoD rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. It also provides a health protective conservative estimate of the safe dose. Numerous scientific peer review panels have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving PoDs in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. (Refs. 5 and 6)

Another approach for deriving Points of Departure uses a sophisticated model called a physiologically based pharmacokinetic-pharmacodynamic (PBPK–PD) model. PBPK models are mathematical descriptions of how a chemical enters the body (*e.g.,* breathing, drinking, eating); the amount of chemical that gets into the blood; how the chemical moves between body tissues (*e.g.,* fat, brain) and the blood; and how the body alters (*i.e.,* metabolizes) and eliminates the chemical (*e.g.,* via urine, feces). PBPK models incorporate information about the body's anatomical and physiological structure as well as biochemical processes into the model structure. EPA uses PBPK models to better translate animal toxicity data to potential human risks (*i.e.,* extrapolation). A PBPK model that describes a chemical in a laboratory animal species can be used for humans by changing the physiological parameters. In the case of chlorpyrifos assessment, the PBPK–PD model is used to derive age-, duration-, and route-specific PoDs that would have resulted in a maximum RBC AChE inhibition level at 10% in humans. Rather than converting an animal BMDL to derive a human POD, the PBPK–PD modeling approach accounts for human physiology, biochemistry, life-stage, and exposure scenarios to derive human PODs based on predicted AChE inhibition in humans. (Ref. 7) Numerous Federal Advisory Committees and external review panels have encouraged the use of such a modeling approach to reduce inherent uncertainty in the risk assessment and facilitate more scientifically sound extrapolations across studies, species, routes, and dose levels. The PBPK–PD model for chlorpyrifos has undergone extensive peer review by various individual and groups, including the FIFRA Scientific Advisory Panel (SAP) (discussed in Unit III.A.3.) Significant improvements have been made to the model over the years in response to recommendations from the 2008, 2011, and 2012 FIFRA SAPs and comments from both internal and external peer reviewers. (Ref. 2 at pg. 20)

In estimating and describing the level of concern, the Point of Departure is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the PoD to calculate an acceptable level of exposure or reference dose (RfD). The RfD is calculated by dividing the PoD by all applicable safety or uncertainty factors. Typically, EPA uses a baseline safety/uncertainty factor of 100X in assessing pesticide risk. That value includes a factor of 10 (10X) where EPA is using data from laboratory animals to account for the possibility that humans potentially have greater sensitivity to the pesticide than animals (also known as the "inter-species factor" or "inter-species extrapolation factor") and another factor of 10X to account for potential variations in sensitivity among members of the human population (also known as the "intra-species factor" or "intra-species extrapolation factor"). These factors may vary if data is available to indicate that another extrapolation factor would be appropriate and protective. For example, where a PBPK–PD model using human parameters is used for deriving Points of Departure, there is no need for an interspecies factor since the model directly predicts human Points of Departure based on human physiology and biochemistry, rather than animal studies. Moreover, because the PBPK–PD model used for assessing chlorpyrifos accounts for differences in metabolism and toxicity response across the human population for some age groups and some subpopulations, the intraspecies extrapolation factor can be refined in accordance with EPA's 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.* (Ref. 8)

Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA additional safety factor largely replaces EPA's pre-FQPA practice regarding additional safety factors (*e.g.,* LOAEL to NOAEL factor or database uncertainty factor), but it might also account for residual concerns related to pre- and postnatal toxicity or exposure. (Ref. 9 at pgs. 4 through 11)

In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). A PAD is the RfD divided by the FQPA safety factor. (*Id.* at pgs. 13 through 16) RfDs and PADs are generally calculated for both acute and chronic dietary risks. Throughout this document, general references to OPP's calculated safe dose are denoted as an RfD/PAD.

For non-dietary, and combined dietary and non-dietary, risk assessments of threshold effects, the toxicological level of concern is not expressed as an RfD/PAD but rather in terms of an acceptable (or target) margin of exposure (MOE) between human exposure and the Point of Departure. The "margin" of interest is the ratio between human exposure and the Point of Departure, which is calculated by dividing human exposure into the Point of Departure. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, if a pesticide needs a 10X factor to account for potential inter-species differences, 10X factor for potential intra-species differences, and 10X factor for the FQPA children's safety provision, the safe or target MOE would be an MOE of at least 1,000. What that means is that for the pesticide in the example to meet the safety standard, human exposure to the pesticide would generally have to be at least 1,000 times smaller than the Point of Departure. Like RfD/PADs, specific target MOEs are selected for exposures of different durations. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral.

ii. Non-threshold effects. For risk assessments for non-threshold effects, EPA does not use the RfD/PAD or MOE approach to choose a level of concern if quantification of the risk is deemed appropriate. Rather, EPA calculates the slope of the dose-response curve for the non-threshold effects from relevant studies frequently using a linear, low-dose extrapolation model that assumes that any amount of exposure will lead to some degree of risk. This dose-response analysis will be used in the risk characterization stage to estimate the risk to humans of the non-threshold effect.

c. Estimating Human Exposure

Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA must evaluate the aggregate exposure to a pesticide chemical residue. This means that EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)) This statutory requirement specifically clarifies that the assessment of dietary exposures includes exposure under the tolerances at issue, as well as "all other tolerances in effect for the pesticide chemical residue". (Id.) Additionally, EPA must take into account exposure from "other related substances." (Id.)

i. Exposure from food. There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed and (2) the residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the USDA. (Ref. 3 at pg. 12) Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction (or concentration) due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (Ref. 3 at pg. 17)

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance, assesses exposure using the worst-case assumptions that 100% of the crop or commodity in question is treated with, or exposed to, the pesticide and 100% of the food from that crop or commodity contains pesticide residues at the tolerance level. (Ref. 3 at pg. 11) When such an assessment shows no risks of concern, a more refined risk assessment is unnecessary. By using worst-case assumptions as a starting point for risk assessment, EPA's resources are conserved, and regulated parties are spared the cost of any additional studies that may be needed. The risk assessments produced using the worst-case assumptions yield conservative and health-protective outcomes; however, if a first-tier assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop or commodity actually treated with, or exposed to, the pesticide and data on the level of residues that may be present on the treated crop or commodity. These latter data are used to estimate what has been traditionally referred to by EPA as "anticipated residues".

Use of percent crop/commodity treated data and anticipated residue information is appropriate because EPA's worst-case assumptions of 100% treatment and residues at tolerance value significantly overstate residue values. There are several reasons why this is true. First, all growers of a particular crop would rarely choose to apply the same pesticide to that crop (some may apply no pesticide; some may apply an alternative pesticide); generally, the proportion of the crop treated with a particular pesticide is significantly below 100%. (70 FR 46706, 46731, August 10, 2005) (FRL–7727–4) Second, the tolerance value represents a high-end or worst-case value. Tolerance values are chosen only after EPA has evaluated data from experimental trials in which the pesticide has been used in a manner, consistent with the draft FIFRA label, that is likely to produce the highest residue in the crop or food in question (*e.g.*, maximum application rate, maximum number of applications, minimum pre-harvest interval between last pesticide application and harvest). (Refs. 3 and 10) These experimental trials are generally conducted in several locations and involve multiple samples. (Ref. 10 at pgs. 5 and 7 and Tables 1 and 5) The results from such experimental trials invariably show that the residue levels for a given pesticide use will vary from as low as non-detectable to measurable values in the parts per million (ppm) range with the majority of the values falling at the lower part of the range. (70 FR 46706 at 46731) EPA uses a statistical procedure to analyze the experimental trial results and identify the upper bound of expected residue values. This upper bound value is typically used as the tolerance value. There may be some commodities for which pesticide residues come close to the tolerance value where the maximum label rates are followed, but most generally fall significantly below the tolerance value. If less than the maximum legal rate is applied, residues will be even lower. Third, residue values measured at the time of treatment do not take into account the lowering of residue values that frequently occurs as a result of degradation over time and through food processing and cooking.

EPA uses several techniques to refine residue value estimates. (Ref. 3 at pgs. 17 through 28) First, where appropriate, EPA will take into account all the

residue values reported in the experimental trials, either through an average of all the field trials or consideration of individual field trials. Second, EPA will consider data showing what portion of the crop or commodity is not treated with, or exposed to, the pesticide. Third, data can be produced showing pesticide degradation and decline over time, and the effect of commercial and consumer food handling and processing practices. Finally, EPA can consult monitoring data gathered by the FDA, the USDA, or pesticide registrants, on pesticide levels in food at points in the food distribution chain distant from the farm, including retail food establishments. Monitoring data, including data gathered by USDA's Pesticide Data Program (PDP), generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real-world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide immediately after harvest.

Another critical component of the exposure assessment is how data on consumption patterns are combined with data on pesticide residue levels in food. Traditionally, EPA has calculated exposure by simply multiplying average consumption by average residue values for estimating chronic risks and high-end consumption by maximum residue values for estimating acute risks. Using average residues is a realistic approach for chronic risk assessment due to the fact that variations in residue levels and consumption amounts average out over time, especially given the nationwide market for food in the United States. Using average values is inappropriate for acute risk assessments, however, because in assessing acute exposure situations it matters how much of each treated food a given consumer eats in the short-term and what the residue levels are in the particular foods consumed. Yet, using maximum residue values for acute risk assessment tends to greatly overstate exposure because it is unlikely that a person would consume at a single meal multiple food components bearing high-end residues. To take into account the variations in short-term consumption patterns and food residue values for acute risk assessments, EPA uses probabilistic modeling techniques for estimating exposure when more simplistic models appear to show risks of concerns.

In practice, EPA uses a computer program known as the Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate dietary exposure from pesticide residues in food by combining data on human consumption amounts with residue values in food commodities. The model used for assessment of chlorpyrifos in the 2020 human health risk assessment (HHRA) incorporated 2003–2008 consumption data from USDA's National Health and Nutrition Examination Survey/What We Eat in America database (NHANES/WWEIA). The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*e.g.,* apple pie) are linked to EPA-defined food commodities (*e.g.,* apples, peeled fruit—cooked; fresh or N/S (Not Specified); baked; or wheat flour—cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA Agricultural Research Service (ARS) and EPA. For chronic exposure assessment (or in the case of chlorpyrifos, for steady-state exposure assessment), consumption data are averaged for the entire U.S. population and within population subgroups; however, for acute exposure assessment, consumption data are retained as individual consumption events. Using this consumption information and residue data, the exposure estimates are calculated for the general U.S. population and specific subgroups based on age, sex, ethnicity, and region.

All of these refinements to the exposure assessment process, from use of food monitoring data through probabilistic modeling, can have dramatic effects on the level of exposure predicted, typically reducing worst-case estimates by at least 1 or 2 orders of magnitude. (Ref. 11 at pgs. 16 through 17; 70 FR 46706 at 46732)

For chlorpyrifos, EPA has calculated potential risk by using probabilistic techniques to combine distributions of potential exposures in sentinel populations. The resulting probabilistic assessments present a range of dietary exposure/risk estimates. Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the acute PAD (aPAD), the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. (The same assumptions apply to estimates for steady-state dietary exposure and the steady-state PAD (ssPAD).) To the extent that one or a few values seem to "drive" the exposure estimates at the high-end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making. (Ref. 11)

ii. Exposure from water. (a) Modeling and monitoring data. EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used. When monitoring data meet certain data quantity criteria, EPA has tools available to quantify the uncertainty in available monitoring data such that it can be used quantitively to estimate pesticide concentrations in drinking water. (Ref. 12) Furthermore, monitoring data can be used in a weight of evidence (WOE) approach with model estimated concentrations to increase confidence in the conclusions of a drinking water assessment.

Due often to the limitations in many monitoring studies, EPA uses mathematical water exposure models to estimate pesticide exposure levels in drinking water. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label. (Ref. 13 at pgs. 27 and 28) (*See also* 69 FR 30042, 30058

through 30065, May 26, 2004) (FRL–7355–7) These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. The modeling provides an estimate of pesticide concentrations in ground water and surface water. Depending on the modeling algorithm (*e.g.,* surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites and can be used to estimate peak concentrations from infrequent, large rain events.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and groundwater. The most common model used to conduct drinking water assessments is the Pesticide in Water Calculator (PWC). PWC couples the Pesticide Root Zone Model (PRZM) and Variable Volume Water Model (VVWM) together to simulate pesticide fate and transport from the field of application to an adjacent reservoir. (Ref. 13 at pgs. 27 and 28) The PWC estimates pesticide concentrations for an index reservoir that is modeled for site-specific scenarios (*i.e.,* weather and soil data) in different areas of the country. A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Aquatic Models website: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model "typical" concentrations occurring across the nation. EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

(b) Drinking Water Level of Comparison (DWLOC). The drinking water level of comparison (DWLOC) is an estimate of the maximum concentration of the pesticide (and other residues of concern) that may be in drinking water without triggering a risk concern for human health. (Ref. 13 at pg. 10) The DWLOC is a benchmark that can be used to guide refinements of the drinking water assessment (DWA). This value relates to the concept of the "risk cup," which EPA developed to facilitate risk refinement when considering aggregate human health risk to a pesticide. (Ref. 14) The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration and population being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (*e.g.,* acute, short-term, chronic). The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for AChE reversible inhibition from exposure to *N*-methyl carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to OP insecticides is usually 21-days based on steady-state kinetics. (Ref. 5)

When using the DWLOC approach, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect, and this allowable remaining exposure becomes the remaining space in the "risk cup" for pesticide exposures in drinking water. Knowing this allowable remaining exposure and the water consumption for each population subgroup (*e.g.,* infants), the Agency can calculate the DWLOC, which is the estimate of safe concentrations of pesticides in drinking water. Using this process of DWLOC calculation allows EPA to determine a target maximum safe drinking water concentration, which makes it easier to identify instances where drinking water estimates require refinement. (Ref. 13 at pgs. 19 and 20)

(c) Scale of drinking water assessment. Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly because of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location, characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure, which influences the application timing, rate used, and number of treatments in a crop production cycle.

EPA may conduct a drinking water assessment (DWA) for a national scale depending on the pesticide use under evaluation. A national-scale DWA may use a single upper-end pesticide concentration as a starting point for assessing whether additional refinements are needed or estimated pesticide concentrations for certain site-specific scenarios that are associated with locations in the United States vulnerable to pesticide contamination based on pesticide use patterns. (Ref. 13 at pg. 22)

EPA may also conduct a regional-scale DWA to focus on areas where pesticide concentrations may be higher than the DWLOC. Under this type of assessment, EPA estimates pesticide concentrations across different regions in the United States that correspond with specific hydrologic units identified by a unique hydrologic unit code (HUC). For purposes of assessing chlorpyrifos, EPA evaluated concentrations in the 21 major geographic areas (or regions) used that comprise the United States. These areas contain either the drainage area of a major river or a combined drainage of a series of rivers. This information can be found at: *https://water.usgs.gov/GIS/huc.html.* Estimated pesticide concentrations under this approach would be associated with a vulnerable pesticide use area somewhere within the evaluated region. (Ref. 13 at pg. 23)

(d) Refinements to drinking water assessments. Much like the tiered approach used for assessing exposures of pesticides in food, EPA has defined four tiers for drinking water assessments. Lower-tiered assessments are more conservative based on the defaults or upper bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the

certainty in the estimated pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. Tier 1 requires the least amount of effort and the least amount of data, whereas Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit. The order in which refinements are considered (*i.e.,* the order in which the assessment is refined) is pesticide-specific and depends on the nature and quality of the available data used to support the refinement. Additional information on the conduct of drinking water assessments can be found in EPA's "Framework for Conducting Pesticide Drinking Water Assessment for Surface Water" (Drinking Water Framework) (Ref. 13).

As discussed in the Drinking Water Framework, EPA can incorporate several refinements in higher tiered modeling. Two such refinements are the percent cropped area (PCA) and the percent crop treated (PCT). The PCA refers to the amount of area in a particular community water system that is planted with the crop of interest (*e.g.,* the default assumption is that the entire watershed is planted with a crop of interest). The PCT refers to the amount of the cropped area that is treated with the pesticide of interest (*e.g.,* the default is that the entire cropped area is treated with the pesticide of interest). With additional use and usage data, EPA can refine assumptions about the application rate and PCT for use in modeling to generate estimated drinking water concentrations (EDWCs) that are appropriate for human health risk assessment and more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations. The goal of the PCA and PCT refinements are to generate EDWCs that are appropriate for human health risk assessment that reduce the magnitude of overestimation due to variability in crops and actual pesticide usage. (Ref. 15)

iii. Non-occupational (Residential) exposures. Residential assessments examine exposure to pesticides in non-occupational or residential settings (*e.g.,* homes, parks, schools, athletic fields, or any other areas frequented by the general public), based on registered uses of the pesticide. Exposures to pesticides may occur to persons who apply pesticides (which is referred to as residential handler exposure) or to persons who enter areas previously treated with pesticides (which is referred to as post-application exposure). Such exposures may occur through oral, inhalation, or dermal routes and may occur over different exposure durations (*e.g.,* short-term, intermediate-term, long-term), depending on the type of pesticide and particular use pattern.

Residential assessments are conducted through examination of significant exposure scenarios (*e.g.,* children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To standardize this process, EPA has prepared Standard Operating Procedures (SOPs) for conducting residential assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment. (Ref. 16) SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack-and-crevice treatments.

The SOPs identify relevant generic data and construct algorithms for calculating application and post-application exposures in a residential or non-occupational setting using these generic data in combination with pesticide-specific information. The generic data typically involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities) and transfer coefficient data (*i.e.,* data measuring the amount of pesticide that transfers from the environment to humans during some activity). Specific information on pesticides can include information on residue levels as well as information on environmental fate such as degradation data.

Once EPA assesses all the potential exposures from all applicable residential exposure scenarios, EPA selects the highest exposure scenario for each exposed population to calculate representative risk estimates for use in the aggregate exposure assessment. Those specific exposure values are then combined with the life-stage appropriate exposure values provided for food and drinking water to determine whether a safety finding can be made.

iv. Aggregate exposures. The aggregate exposure assessment process considers exposure through multiple pathways or routes of exposure (*e.g.,* food, water, and residential) for different sub-populations (*e.g.,* infants, children ages 1 through 6) and exposure duration or types of effects (*e.g.,* acute noncancer effects (single dose), chronic noncancer effects, and cancer). The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and are dependent on the level of refinement or assessment tier.

EPA evaluates aggregate exposure by comparing combined exposure from all relevant sources to the safe level. Where exposures exceed the safe level, those levels exceed the risk cup and are of potential concern. There are risk cups for each pertinent duration of exposure for a pesticide because the amount of exposure that can be incurred without adverse health effects will vary by duration (*e.g.,* acute, short-term, chronic, steady-state). The size of the risk cup is dependent on the maximum safe exposure for the different relevant durations (*e.g.,* acute, short-term, intermediate-term, long-term, steady-state).

d. Risk Characterization

The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

Whether exposures will exceed the available space in the risk cup (*i.e.,* whether exposures are expected to exceed safe levels) is expressed differently, depending on the type of level of concern (*i.e.,* RfD/PAD or MOE) the Agency has identified. For dietary assessments for which EPA calculates an RfD/PAD, the risk is expressed as a percentage of the acceptable dose (*i.e.,* the dose which EPA has concluded will be "safe"). Dietary exposures greater than 100% of the percentage of the acceptable dose are generally cause for concern and would be considered "unsafe" within the meaning of FFDCA section 408(b)(2)(B). For non-dietary (and combined dietary and non-dietary) risk assessments of threshold effects, the toxicological level of concern is typically not expressed as an RfD/PAD, but rather in terms of an acceptable (or target) Margin of Exposure (MOE) between human exposure and the PoD. Non-dietary (and combined) exposures that result in an MOE equal to or exceeding the product of all applicable

safety factors would not generally be of concern.

As a conceptual matter, the RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if exposure to a pesticide were found to be acceptable under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa. However, for any specific pesticide, risk assessments for different exposure durations or routes may yield different results. This is a function not of the choice of the RfD/PAD or MOE approach but of the fact that the levels of concern and the levels of exposure may differ depending on the duration and route of exposure.

Where EPA has calculated a DWLOC, the Agency can assess risk by comparing estimated pesticide concentrations in drinking water to the DWLOC. As noted previously, an aggregate DWLOC represents the amount of maximum safe residues of pesticide in drinking water because it represents the room remaining in the risk cup for drinking water exposures, after accounting for the food and residential exposures. When the EDWC is less than the DWLOC, there are no risk concerns for aggregate exposures because the Agency can conclude that the contribution from drinking water, when aggregated with food and non-occupational exposures, will not exceed safe levels of exposure. Conversely, an EDWC at or exceeding the DWLOC would indicate a risk of concern, as pesticide exposures in drinking water, when aggregated with exposures from food and residential exposures, would exceed safe levels of exposure. (Ref. 14)

For non-threshold risks (generally, cancer risks), EPA uses the slope of the dose-response curve for a pesticide in conjunction with an estimation of human exposure to that pesticide to estimate the probability of occurrence of additional adverse effects. Under FFDCA section 408, for non-threshold cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million. EPA describes this quantitative standard as a "range" because it does not want to impart a false precision to numerical cancer risk estimates. EPA seeks to identify risks differing significantly from a 1 in 1 million risk, and that involves both a quantitative as well as qualitative assessment of what a risk estimate represents.

2. EPA Policy on the FQPA Children's Safety Factor

As the summary of EPA's risk assessment practice indicates, the use of safety factors plays a critical role in the process. This is true for traditional safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species factor) and potential differences among humans (intra-species factor), as well as the FQPA's additional 10X children's safety factor.

In implementing the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying a 10X safety factor, in addition to the traditional safety factors for inter- and intra-species extrapolation. (Ref. 9 at pgs. 4 and 11) Thus, EPA generally refers to the FQPA 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the FQPA 10X safety factor is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (*Id.*) In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) of the FFDCA—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and postnatal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a WOE evaluation, does not understate the risk to children. (*Id.* at pgs. 24 through 25 and 35)

3. Acetylcholinesterase Inhibition

Acetylcholinesterase (AChE) inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (*i.e.,* another nerve cell, a muscle fiber, or a gland) is facilitated by the chemical, acetylcholine. When a nerve cell is stimulated, it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to receptors in the target cell, stimulating the target cell in turn. As EPA has explained, "the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (*e.g.,* in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (*e.g.,* sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system." (Ref. 17 at pg. 10)

AChE is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When AChE is inhibited, acetylcholine builds up prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition, these effects can be serious or even fatal.

EPA's cholinesterase inhibition policy statement explains EPA's approach to evaluating the risks posed by AChE-inhibiting pesticides such as chlorpyrifos. (*Id.*) The policy focuses on three types of effects associated with AChE-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) Physiological and behavioral/functional effects; (2) AChE inhibition in the central and peripheral nervous system; and (3) AChE inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving an acceptable dose (*e.g.,* RfD/PAD) for an AChE-inhibiting pesticide.

After clinical signs or symptoms, AChE inhibition in the nervous system provides the next most important endpoint for evaluating AChE-inhibiting pesticides. Although AChE inhibition in the nervous system is not itself regarded as a direct adverse effect, it is "generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects." (*Id.* at pg. 25) As such, the policy states that it should be treated as "direct evidence of potential adverse effects" and "data showing this response provide valuable information in assessing potential hazards posed by anticholinesterase pesticides." (*Id.*) Unfortunately, useful data measuring AChE inhibition in the peripheral nervous system tissues has only been relatively rarely captured by standard toxicology testing. For central nervous system effects, however, more recent neurotoxicity studies "have sought to characterize the time course of inhibition in * * * [the] brain, including brain regions, after acute and 90-day exposures." (*Id.* at pg. 27)

AChE inhibition in the blood is one step further removed from the direct harmful consequences of AChE-inhibiting pesticides. According to the policy, inhibition of blood AChEs "is not an adverse effect, but may indicate a potential for adverse effects on the nervous system." (*Id.* at pg. 28) The policy states that "[a]s a matter of science policy, blood cholinesterase data are considered appropriate surrogate measures of potential effects on peripheral nervous system

acetylcholinesterase activity in animals, for CNS [central nervous system] acetylcholinesterase activity in animals when CNS data are lacking and for both peripheral and central nervous system acetylcholinesterase in humans." (*Id.* at pg. 29) The policy notes that "there is often a direct relationship between a greater magnitude of exposure [to an AChE-inhibiting pesticide] and an increase in incidence and severity of clinical signs and symptoms as well as blood cholinesterase inhibition." (*Id.* at pg. 30) Thus, the policy regards blood AChE data as "appropriate endpoints for derivation of reference doses or concentrations when considered in a weight-of-the-evidence analysis of the entire database * * *." (*Id.* at pg. 29) Between AChE inhibition measured in red blood cell ("RBC") or blood plasma, the policy states a preference for reliance on RBC AChE measurements because plasma cholinesterase is composed of a mixture of acetylcholinesterase and butyrylcholinesterase, and inhibition of the latter is less clearly tied to inhibition of acetylcholinesterase in the nervous system. (*Id.* at pgs. 29 and 32)

In the Agency's analysis for chlorpyrifos, EPA used a response level of 10% RBC AChE inhibition; this value represents the estimated dose where AChE is inhibited by 10%, compared to untreated animals. For the last several years EPA has used the 10% value to regulate AChE-inhibiting pesticides, including other organophosphorous pesticides. For a variety of toxicological and statistical reasons, EPA chose 10% RBC AChE inhibition as the response level for use in its PBPK–PD modeling. (Ref. 2 at pg. 7) EPA analyses have demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies; is generally at or near the limit of sensitivity for discerning a statistically significant decrease in AChE activity across the brain compartment; and is a response level close to the background.

III. Chlorpyrifos Background

A. Regulatory Background

1. General

a. Chlorpyrifos Uses

Chlorpyrifos (0,0-diethyl-0–3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. (The OPs are a group of closely related pesticides that affect functioning of the nervous system.) Pesticide products containing chlorpyrifos are registered for use on many agricultural crops, including, but not limited to, corn, soybeans, alfalfa, oranges, wheat, and walnuts. Additionally, chlorpyrifos products are registered for use on nonfood sites such as ornamental plants in nurseries, golf course turf, and as wood treatment. There are also public health uses including aerial and ground-based mosquito adulticide fogger treatments, use as fire ant control in nursery stock grown in USDA-designated quarantine areas, and for some tick species that may transmit diseases such as Lyme disease. The majority of uses in residential settings were voluntarily canceled over two decades ago (*e.g.*, 65 FR 76233, December 6, 2000 (FRL–6758–2); 66 FR 47481, September 12, 2001 (FRL–6799–7)).

b. Chlorpyrifos Risks

i. Acetylcholinesterase (AChE) inhibition. Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting AChE, an enzyme necessary for the proper functioning of the nervous system, and ultimately leading to signs of neurotoxicity. This mode of action, in which AChE inhibition leads to neurotoxicity, is well-established, and thus has been used as basis for the PoD for OP human health risk assessments, including chlorpyrifos. This science policy is based on decades of work, which shows that AChE inhibition is the initial event in the pathway to acute cholinergic neurotoxicity. (Ref. 17 at pg. 14)

The Agency has conducted a comprehensive review of the available data and public literature regarding this adverse effect from chlorpyrifos. (Ref. 18 at pgs. 25 through 27) There are many chlorpyrifos studies evaluating RBC AChE inhibition or the brain in multiple lifestages (gestational, fetal, postnatal, and non-pregnant adult); multiple species (rat, mouse, rabbit, dog, human); methods of oral administration (oral gavage with corn oil, dietary, gavage via milk); and routes of exposure (oral, dermal, inhalation via vapor and via aerosol). In addition, chlorpyrifos is unique in the availability of AChE data from peripheral tissues in some studies (*e.g.*, heart, lung, liver). There are also literature studies comparing the *in vitro* AChE response to a variety of tissues that show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral AChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues. Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

Female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.*, developmental neurotoxicity (DNT), reproductive, and subchronic data).

In addition, studies are available in juvenile pups that show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon metabolite. This sensitivity is not derived from differences in the AChE enzyme itself but instead are derived largely from the immature metabolic clearance capacity in the juveniles.

ii. Neurodevelopmental toxicity. In addition to information on the effects of chlorpyrifos on AChE, there is an extensive body of information (in the form of laboratory animal studies, epidemiological studies, and mechanistic studies) studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos.

There are numerous laboratory animal studies on chlorpyrifos in the literature that have evaluated the impact of chlorpyrifos exposure in pre- and postnatal dosing on the developing brain. These studies vary substantially in their study design, but all involve gestational and/or early postnatal dosing with behavioral evaluation from adolescence to adulthood. The data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain with adverse outcomes in several neurological domains including cognitive, anxiety and emotion, social interactions, and neuromotor function. It is, however, important to note that there is little consistency in patterns of effects across studies. In addition, most of these studies use doses that far exceed EPA's 10% benchmark response level for RBC AChE inhibition. There are only a few studies with doses at or near the 10% brain or RBC AChE inhibition levels; among these only studies from Carr laboratory at Mississippi State University are considered by EPA to be high quality. EPA has concluded that the laboratory animal studies on neurodevelopmental outcomes are not sufficient for quantitatively establishing a PoD. (Ref. 2 at pgs. 88 and 89)

EPA evaluated numerous epidemiological studies on chlorpyrifos and other OP pesticides in accordance with the Agency's "Framework for

Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" ("Epidemiologic Framework"). (Ref. 19) The most robust epidemiologic research comes from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University ("CCCEH study"); (2) the Mount Sinai Inner-City Toxicants, Child Growth and Development Study ("Mt. Sinai study"); and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley ("CHAMACOS study"). (Ref. 20 at pgs. 32 through 43)

In the case of the CCCEH study, which specifically evaluated the possible connections between chlorpyrifos levels in cord blood and neurodevelopmental outcomes on a specific cohort, there are a number of notable associations. (*Id.* at pgs. 35 through 38) Regarding infant and toddler neurodevelopment, the CCCEH study authors reported statistically significant deficits of 6.5 points on the Psychomotor Development Index at three years of age when comparing high to low exposure groups. Notably, these decrements persist even after adjustment for group and individual level socioeconomic variables. These investigators also observed increased odds of mental delay and psychomotor delay at age three when comparing high to low exposure groups. The CCCEH study authors also report strong, consistent evidence of a positive association for attention disorders, attention deficit hyperactivity disorder (ADHD), and pervasive development disorder (PDD) when comparing high to low chlorpyrifos exposure groups. Moreover, it was reported that for children in the CCCEH study cohort at age seven for each standard deviation increase in chlorpyrifos cord blood exposure, there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In addition, the CCCEH study authors evaluated the relationship between prenatal chlorpyrifos exposure and motor development/movement and reported elevated risks of arm tremor in children around 11 years of age in the CCCEH cohort.

Notwithstanding the observed associations, EPA and the 2012 and 2016 FIFRA SAPs identified multiple uncertainties in the CCCEH epidemiology studies. (Refs. 21 and 22) Some of these include the relatively modest sample sizes, which limited the statistical power; exposure at one point in prenatal time with no additional information regarding postnatal exposures; representativeness of a single-point exposure where time-varying exposures or the ability to define cumulative exposures would be preferable; lack of specificity of a critical window of effect and the potential for misclassification of individual exposure measures; and lack of availability of the raw data from the studies that would allow verification of study conclusions.

One of the notable uncertainties in the CCCEH epidemiology studies identified by EPA and the 2016 FIFRA SAP is the lack of specific exposure information on the timing, frequency, and magnitude of chlorpyrifos application(s) in the apartments of the women in the study. Despite extensive effort by EPA to obtain or infer this exposure information from various sources, the lack of specific exposure data remains a critical uncertainty. EPA made efforts in 2014 and 2016 to develop dose reconstruction of the exposures to these women. These dose reconstruction activities represent the best available information and tools but are highly uncertain. In addition, the pregnant women and children in the CCCEH studies were exposed to multiple chemicals, including multiple potent AChE inhibiting OPs and *N*-methyl carbamates. Moreover, using EPA's dose reconstruction methods from 2014 suggest that the pregnant women likely did not exhibit RBC AChE inhibition above 10%. The 2012 and 2016 FIFRA SAP reports expressed concern that it is likely that the CCCEH findings occurred at exposure levels below those that result in 10% RBC AChE inhibition. (Refs. 21 and 22) However, given the available CCCEH exposure information and the exposures to multiple potent AChE inhibiting pesticides, EPA cannot definitively attribute all AChE inhibition to chlorpyrifos. EPA remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by CCCEH investigators. (Ref. 20 at pg. 43) Moreover, given the uncertainties, particularly in the exposure information available from CCCEH (single timepoints, lack of time varying exposure, lack of knowledge about application timing), uncertainties remain about the dose-response relationships from the epidemiology studies.

Finally, there are several lines of evidence for actions of chlorpyrifos distinct from the classical mode of action of AChE inhibition. This information has been generated from model systems representing different levels of biological organization and provide support for molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling), and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Among the many *in vitro* studies on endpoints relevant to the developing brain available for chlorpyrifos, only three have identified outcomes in picomole concentrations, including concentrations lower than those that elicit AChE inhibition *in vitro*. However, as is the case for many other developmental neurotoxicants, most of these studies have not been designed with the specific goal of construction or testing an adverse outcome pathway. Thus, there are not sufficient data available to test rigorously the causal relationship between effects of chlorpyrifos at the different levels of biological organization in the nervous system. (*Id.* at pgs. 27 through 31)

Due to the complexity of nervous system development involving the interplay of many different cell types and developmental timelines, it is generally accepted that no single *in vitro* screening assay can recapitulate all the critical processes of neurodevelopment. As a result, there has been an international effort to develop a battery of new approach methodologies (NAMs) to inform the DNT potential for individual chemicals. This DNT NAM battery is comprised of *in vitro* assays that assess critical processes of neurodevelopment, including neural network formation and function, cell proliferation, apoptosis, neurite outgrowth, synaptogenesis, migration, and differentiation. In combination the assays in this battery provide a mechanistic understanding of the underlying biological processes that may be vulnerable to chemically-induced disruption. It is noteworthy, however, that the quantitative relationship between alterations in these neurodevelopmental processes and adverse health outcomes has, to date, not been fully elucidated. Moreover, additional assays evaluating other critical neurodevelopmental processes such as myelination are still being developed. (Ref. 23)

In September 2020, EPA convened a FIFRA SAP on developing and implementing NAMs using methods such as *in vitro* techniques and computational approaches. Included in that consideration was use of the DNT NAM battery to evaluate OP compounds as a case study. These methods

presented to the 2020 FIFRA SAP provide a more systematic approach to evaluating pharmacodynamic effects on the developing brain compared to the existing literature studies. Initial data from the NAM battery were presented to the SAP for 27 OP compounds, including chlorpyrifos and its metabolite, chlorpyrifos-oxon, and, when possible, compared to *in vivo* results (by using *in vitro* to *in vivo* extrapolation). On December 21, 2020, the SAP released its final report and recommendations on EPA's proposed use of the NAMs data. (Ref. 24) The advice of the SAP is currently being taken into consideration as EPA develops a path forward on NAMs. The Agency is continuing to explore the use of NAMs for the OPs, including chlorpyrifos, and intends to make its findings available as soon as it completes this work.

2. Reregistration and Registration Review

In 2006, EPA completed FIFRA section 4 (7 U.S.C. 136a–1) reregistration (a program under which EPA reregisters older pesticides that continue to meet the standard for registration) and FFDCA tolerance reassessment (21 U.S.C. 346a(q)) for chlorpyrifos and the OP class of pesticides. EPA concluded that process by determining that those tolerances were safe and should be left in effect. That decision relied on an endpoint based on 10% RBC AChE inhibition. (Ref. 25)

Given ongoing scientific developments in the study of the OPs generally, in March 2009 EPA announced its decision to prioritize the FIFRA section 3(g) (7 U.S.C. 136a(g)) registration review of chlorpyrifos by opening a public docket and releasing a preliminary work plan to complete the chlorpyrifos registration review by 2015. Despite the ambitions of that original work plan, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated, and thus, chlorpyrifos is currently still undergoing registration review, which must be completed by October 1, 2022. (7 U.S.C. 136a(g)(1)(A)(iv)) For information about the ongoing registration review process for chlorpyrifos, see *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0850.*

Reflecting that complexity, the Agency has engaged in extensive and ongoing analyses of the available science since initiating registration review in 2009, including multiple human health risk assessments and drinking water assessments, development of a new model for deriving points of departure to assess risks of chlorpyrifos, development of a framework for incorporating human epidemiology information into risk assessments as well as conducting an in-depth epidemiology and literature review, and in the process convening the FIFRA SAP at least six times. The following lays out the major milestones of the chlorpyrifos registration review process.

In 2011, EPA released its preliminary human health risk assessment (2011 HHRA) for the registration review of chlorpyrifos. (Ref. 18) The 2011 HHRA used 10% RBC AChE inhibition from laboratory rats as the critical effect (or PoD) for extrapolating risk. It also used the default 10X uncertainty factors for inter- and intra-species extrapolation. The 10X FQPA safety factor was reduced to 1X with a note to the public that a WOE analysis evaluating available epidemiological studies would be forthcoming. Also, in 2011, EPA released its Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment. (Ref. 26) This assessment provided estimated drinking water concentrations (EDWCs) based on Tier I groundwater and Tier II surface water model simulations for registered uses of chlorpyrifos and considered monitoring data from several different programs. Based on data demonstrating the impacts of drinking water treatment on chlorpyrifos, EPA concluded that chlorpyrifos in drinking water would convert to chlorpyrifos-oxon, a metabolite, when going through chlorinated drinking water treatment systems. Based on modeling results, EDWCs for chlorpyrifos and chlorpyrifos-oxon generated from surface water sources provided higher estimates of the potential exposure to either of these chemicals in drinking water than those from groundwater.

In 2014, following the development of the PBPK–PD model and 2012 SAP's review of EPA's epidemiology review, EPA released a revised human health risk assessment (2014 HHRA). (Ref. 20) Using the chlorpyrifos PBPK–PD model for deriving human PoDs for RBC AChE inhibition, which obviated the need for the inter-species extrapolation factor and allowed for data-derived intra-species extrapolation factors (as described in Unit II.B.1.b.i.), the revised risk assessment identified highly refined PoDs that accounted for gender, age, duration and route-specific exposure considerations. In addition, the revised risk assessment retained the 10X FQPA SF, based on EPA's WOE analysis concerning the potential for neurodevelopmental outcomes that followed a draft of EPA's Epidemiologic Framework (Ref. 19), and incorporated recommendations from the 2012 SAP. Also in 2014, EPA released its Updated Drinking Water Assessment for Registration Review ("2014 DWA"). (Ref. 27) As an update to the 2011 DWA, the 2014 DWA included several additional analyses focusing on: (1) Clarifying labeled uses, (2) evaluating volatility and spray drift, (3) revising aquatic modeling input values, (4) comparing aquatic modeling and monitoring data, (5) summarizing the effects of drinking water treatment, and (6) updating model simulations using current exposure tools. The additional analyses did not change the exposure assessment conclusions reported in the preliminary DWA. The 2014 HHRA, taken together with the Agency's drinking water assessment, identified estimated aggregate risks exceeding the level of concern for chlorpyrifos.

In 2016 EPA issued a revised human health risk assessment using a dose-reconstruction approach to derive the PoD based on the neurodevelopmental effects observed in the CCCEH study based on advice from the 2016 SAP. (Ref. 28) Although the 2016 HHRA found that risks from food alone exceeded the safe level for chlorpyrifos, EPA also issued a revised drinking water assessment (2016 DWA). (Ref. 29) This refined drinking water assessment served to combine, update, and complete the work presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. Even with the additional refinements, the results were consistent and suggested potential exposure to chlorpyrifos or chlorpyrifos-oxon in finished drinking water based on labeled uses. The assessment noted that depending on the drinking water level of concern, measured concentrations of chlorpyrifos and chlorpyrifos-oxon may exceed the level of concern in some locations across the country, which warranted comparison of EDWCs to the established drinking water level of concern. EPA issued a Notice of Data Availability seeking public comment on the 2016 HHRA and 2016 DWA. (81 FR 81049, November 17, 2016) (FRL–9954–65)

In September 2020, EPA issued the "Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review" (2020 HHRA) (Ref. 2) and the "Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (2020 DWA) (Ref. 30). In the 2020 HHRA, EPA utilizes the same endpoint and PoDs as those used in the 2014 HHRA. This was done because the Agency concluded that the

unresolved nature of the science addressing neurodevelopmental effects warranted further evaluation of the science during the remaining time for completion of registration review. Due to the uncertainties concerning neurodevelopmental effects, the 2020 HHRA retained the default 10X FQPA safety factor; the 2020 HHRA also presented potential risk estimates at a reduced 1X FQPA safety factor to reflect the range of estimates possible, although it did not adopt or explain why the 1X FQPA safety factor would be safe for infants and children. While in the 2020 HHRA the Agency determined that risks from exposures to chlorpyrifos residues in food combined with residential exposures were not of concern, drinking water exposures significantly add to those risks. The 2020 DWA built upon the analysis in the 2016 DWA but focused on a subset of currently registered chlorpyrifos uses for high benefit crops to growers in specific areas of the country, *i.e.*, alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat. This assessment utilized new surface water model scenarios (*i.e.*, soil, weather, and crop data), integrated the entire distribution of community water system percent cropped area (PCA) adjustment factors and state-level percent crop treated (PCT) data, and considered the quantitative use of available surface water monitoring data. The 2020 DWA noted that concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water were not likely to exceed the drinking water level of comparison (DWLOC) even with the retention of the 10X FQPA safety factor for the subset of uses considered; however, that assessment noted that adding additional uses could change estimated drinking water concentrations, which could ultimately result in changes to the risk conclusion relative to the drinking water level of comparison(s).

In December 2020, EPA released the "Proposed Interim Decision for the Registration Review of Chlorpyrifos" (2020 PID) for a 60-day public comment period (85 FR 78849, December 7, 2020) (FRL–10017–1). The 2020 PID concluded that "[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern." (Ref. 31 at pg. 19) However, the 2020 PID also noted that if one considered only the uses that result in EDWCs below the DWLOC, then aggregate exposures would not be of concern. (*Id.*) Accordingly, the 2020 PID proposed to limit applications of chlorpyrifos in this country to only 11 uses in certain regions of the United States; EPA had focused its review on those 11 geographically limited uses due to potential benefits from those uses and concluded that the EDWCs for those uses alone were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos, although as a proposal, it was not a final Agency determination and could be subject to change following public comment and stakeholder interest, perhaps in an Agency determination on a different subset of uses. Along with comments on the 2020 PID, EPA invited comments on the benefits assessments, the 2020 HHRA, draft ecological risk assessment, and 2020 DWA. EPA extended the 60-day comment period by 30 days, which then closed on March 7, 2021. EPA is currently reviewing public input and will respond to comments prior to issuing an interim decision.

3. Scientific Issues and SAPs

As noted previously, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated. The OPs have presented EPA with numerous novel scientific issues that the Agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration in 2006. (*Note:* The SAP is a federal advisory committee created by FIFRA section 25(d), 7 U.S.C. 136w(d), and serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides. EPA may convene an SAP meeting to present significant regulatory, science, or policy matters involving pesticides and request that the SAP provide comments, evaluations, and recommendations on the matters submitted for its review.)

These FIFRA SAP meetings, which have included the review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, and the evaluation of a chlorpyrifos-specific PBPK–PD model, have resulted in significant developments in EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. In particular, and partly in response to issues raised in the 2007 Petition (discussed in Unit III.B. of this document), EPA has conducted extensive reviews of available data to evaluate the possible connection between chlorpyrifos and adverse neurodevelopmental effects and to assess whether the neurodevelopmental effects could be used to determine PoDs for assessing chlorpyrifos. On this particular topic, EPA has convened multiple FIFRA SAP meetings.

In 2008, the Agency presented to the FIFRA SAP a preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action. (Ref. 32) The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the PoDs but noted that despite some uncertainties, the CCCEH epidemiologic studies "is epidemiologically sound" and "provided extremely valuable information" for evaluating the potential neurodevelopmental effects of chlorpyrifos.

The 2010 FIFRA SAP favorably reviewed EPA's 2010 draft epidemiology framework. (Ref. 33) This draft framework, titled "Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments in Pesticides," ("Epidemiologic Framework") described the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. As suggested by the 2010 FIFRA SAP, EPA did not immediately finalize the draft framework but instead used it in several pesticide evaluations prior to making revisions and finalizing it. EPA's Office of Pesticide Program's (OPP) finalized this Epidemiologic Framework in December 2016. (Ref. 19)

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to RBC AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the United States, including those from the CCCEH, Mount Sinai, and University of California, Berkeley. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies.

The 2012 FIFRA SAP described the Agency's epidemiology review as "very clearly written, accurate" and a "very thorough review." (Ref. 21 at pgs. 50–52, 53) It went further to note that it "believes that the [Agency's] epidemiology review appropriately

concludes that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7 through 9 years, and attention and behavior problems at 3 and 5 years of age. . . .'' The 2012 FIFRA SAP concluded that the RBC AChE inhibition remained the most robust dose-response data, though expressed concerns about the degree to which 10% RBC AChE inhibition is protective for neurodevelopmental effects, pointing to evidence from epidemiology, *in vivo* animal studies, and *in vitro* mechanistic studies, and urged the EPA to find ways to use the CCCEH data.

Taking that recommendation into consideration, the Agency prepared a proposal for using cord blood data from the CCCEH epidemiology studies as the source of data for the PoDs, which it presented to the FIFRA SAP in April 2016. The 2016 SAP did not support the ''direct use'' of the cord blood and working memory data for deriving the regulatory endpoint, due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations, and lack of raw data from the epidemiology study. (Ref. 22) Despite its critiques of uncertainties in the CCCEH studies, the 2016 FIFRA SAP stated that it ''agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition (*i.e.*, toxicity at lower doses).'' (*Id.* at pg. 18)

B. FFDCA Petition and Associated Litigation

1. 2007 Petition Seeking Revocation of Chlorpyrifos Tolerances

As described previously, in 2006, EPA issued the Reregistration Eligibility Decision (RED) for chlorpyrifos, which concluded that chlorpyrifos was eligible for reregistration as it continued to meet the FIFRA standard for registration. In September 2007, Pesticide Action Network North America (PANNA) and Natural Resources Defense Council (NRDC) (collectively, the Petitioners) submitted to EPA a petition (the Petition) seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA. (Ref. 34) That Petition raised several claims regarding EPA's 2006 FIFRA reregistration decision for chlorpyrifos and the active registrations in support of the request for tolerance revocations and product cancellations. Those claims are described in detail in EPA's earlier Order denying the Petition (82 FR 16581, April 5, 2017) (FRL–9960–77).

2. Agency Responses and 2017 Order Denying Petition

Ultimately, EPA denied the Petition in full on March 29, 2017 (82 FR 16581, April 5, 2017) (FRL–9960–77). Prior to issuing that Order, however, EPA issued two interim responses and a proposed rule in response to the Petition.

EPA provided the Petitioners with two interim responses on July 16, 2012, and July 15, 2014, which denied six of the Petition's claims. EPA made clear in both the 2012 and 2014 responses that, absent a request from Petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request, and EPA therefore finalized its response to those claims in the March 29, 2017 Order Denying Petition.

As background, three of the Petition's claims all related to the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% RBC AChE inhibition). Because the claims relating to the potential for neurodevelopmental effects in children raised novel, highly complex scientific issues, EPA originally decided it would be appropriate to address these issues in connection with the registration review of chlorpyrifos under FIFRA section 3(g) and decided to expedite that review, intending to finalize it in 2015, well in advance of the October 1, 2022 registration review deadline. (Ref. 35) EPA decided as a policy matter that it would address the Petition claims regarding these matters on a similar timeframe. (82 FR 16581 at 16583)

As noted earlier in this Unit, the complexity of these scientific issues precluded EPA from finishing its review according to EPA's original timeline, and the Petitioners brought legal action in the Ninth Circuit Court of Appeals to compel EPA to either issue an Order denying the Petition or to grant the Petition by initiating the tolerance revocation process. The result of that litigation was that on August 10, 2015, the Court ordered EPA to ''issue either a proposed or final revocation rule or a full and final response to the administrative [P]etition by October 31, 2015.'' (*In re Pesticide Action Network N. Am.*, 798 F.3d 809, 815 (9th Cir. 2015))

In response to that Court's order, EPA issued a proposed rule in 2015 to revoke all tolerances for chlorpyrifos (80 FR 69080, November 6, 2015) (FRL–9935–92) (2015 proposed rule), based on its unfinished registration review risk assessment. EPA acknowledged that it had had insufficient time to complete its drinking water assessment and its review of data addressing the potential for neurodevelopmental effects. Although EPA noted that further evaluation might enable more tailored risk mitigation, EPA was unable to conclude, based on the information before EPA at the time, that the tolerances were safe, since the aggregate exposure to chlorpyrifos exceeded safe levels.

On December 10, 2015, the Ninth Circuit issued a further order, in response to additional legal challenge by Petitioners, requiring EPA to take final action on its proposed revocation rule and issue its final response to the Petition by December 30, 2016. *In re Pesticide Action Network N. Am.*, 808 F.3d 402 (9th Cir. 2015). In response to EPA's request for an extension of the deadline in order to be able to fully consider the July 2016 FIFRA SAP report regarding chlorpyrifos toxicology, the Ninth Circuit ordered EPA to complete its final action by March 31, 2017. *In re Pesticide Action Network of North America* v. *EPA*, 840 F.3d 1014 (9th Cir. 2016). Following that Court's order, EPA published a Notice of Data Availability (NODA), seeking comment on EPA's revised risk assessment and water assessment and reopening the comment period on the proposal to revoke tolerances. (81 FR 81049, November 17, 2016) (FRL–9954–65)

On March 29, 2017, the EPA issued the 2017 Order Denying Petition. (82 FR 16581, April 5, 2017) (FRL–9960–77) The specific responses are described in full in that 2017 Order Denying Petition (and summarized again in the Agency's denial of objections. (84 FR 35555, July 24, 2019) (FRL–9997–06) EPA's 2017 Order Denying Petition did not contain a determination concerning the safety of chlorpyrifos. Rather, EPA concluded that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. EPA therefore denied the remaining Petition claims, concluding that it was not required to complete—and would not complete—the human

health portion of the registration review or any associated tolerance revocation of chlorpyrifos without resolution of those issues during the ongoing FIFRA registration review of chlorpyrifos.

3. Objections and EPA's Denial of Objections

In June 2017, several public interest groups and states filed objections to the 2017 Order Denying Petition pursuant to the procedures in FFDCA section 408(g)(2). Specifically, Earthjustice submitted objections on behalf of the following 12 public interest groups: Petitioners PANNA and NRDC, United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens (LULAC), Learning Disabilities Association of America, National Hispanic Medical Association and Pineros y Campesinos Unidos del Noroeste. Another public interest group, the North Coast River Alliance, submitted separate objections. With respect to the states, New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submitted a joint set of objections. (Ref. 34), These objectors asserted that EPA erred in not making the requisite safety finding in denying the Petition and that EPA should revoke all tolerances because the available record supported a conclusion that the tolerances were unsafe.

On July 18, 2019, EPA issued a final Order denying all objections to the 2017 Order Denying Petition and thereby completing EPA's administrative denial of the petition (2019 Order Denying Objections to Petition Denial) (84 FR 35555, July 27, 2019) (FRL–9997–06). Again, the 2019 Order Denying Objections to Petition Denial did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA denied the objections on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the Petitioners' burden to present evidence supporting the request for revocation.

4. Judicial Challenge to 2019 Order Denying Objections To Petition Denial and 2021 Ninth Circuit Order

On August 7, 2019, the objectors (LULAC Petitioners) and States petitioned the Ninth Circuit for review of the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial. The LULAC Petitioners and States argued that EPA was compelled to grant the 2007 Petition and revoke chlorpyrifos tolerances because: (1) EPA lacked authority to maintain chlorpyrifos tolerances without an affirmative finding that chlorpyrifos is safe; (2) EPA's findings that chlorpyrifos is unsafe in the Agency's 2014 and 2016 risk assessments compel revocation of the chlorpyrifos tolerances; and (3) The Petition provided a sufficient basis for EPA to reconsider the question of chlorpyrifos's safety and was not required to prove that a pesticide is unsafe.

On April 29, 2021, the Ninth Circuit issued its decision, finding that when EPA denied the 2007 Petition to revoke chlorpyrifos tolerances, it was essentially leaving those chlorpyrifos tolerances in effect, which, the Court noted, the FFDCA only permits if EPA has made an affirmative determination that such tolerances were safe. (*League of United Latin Am. Citizens (LULAC)* v. *Regan,* 996 F.3d. 673 (9th Cir. 2021)) Although EPA argued that it was not compelled to reconsider its safety determination because the 2007 Petition had failed to meet the threshold requirement of providing reliable evidence that the tolerances were unsafe, the Court found that the Petition provided the necessary "reasonable grounds," which triggered EPA's duty to ensure the tolerances were safe. (*Id.* at pg. 695) Since the 2017 Order Denying Petition and 2019 Order Denying Objections to Petition Denial failed to make any safety determinations for chlorpyrifos, the Court concluded that EPA violated the FFDCA by leaving those tolerances in place without the requisite safety findings. (*Id.* at pgs. 678, 695 and 696 (declaring that EPA's action was a "total abdication of EPA's statutory duty under the FFDCA")) Moreover, in light of the record before the Court, including the 2016 HHRA indicating that the current chlorpyrifos tolerances were not safe, the Court found EPA's denial of the 2007 Petition to be arbitrary and capricious. (*Id.* at pg. 697) Based on the available record, the Court concluded that EPA must grant the Petition and issue a final rule modifying or revoking the tolerances under FFDCA section 408(d)(4)(A)(i). (*Id.* at pg.701)

The Court recognized that, since the litigation had commenced, EPA had been continuing to evaluate chlorpyrifos in registration review and had issued the 2020 PID and convened another FIFRA SAP; the Court noted that such information could be relevant to a safety determination. (*Id.* at pg. 703) The Court allowed that if the new information could support a safety determination, EPA might issue a final rule modifying chlorpyrifos tolerances rather than revoking them. But the Court warned that EPA was to act "immediately" and not engage in "further factfinding." (*Id.*) The Court chided that taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition" was an "egregious delay" and "EPA's time is [ ] up." (*Id.*) As a result, the Court ordered EPA to: (1) Grant the 2007 Petition; (2) Issue a final rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances, provided that such modification is supported by a safety finding, and (3) Modify or cancel related FIFRA registrations for food use in a timely fashion. (*Id.* at 703 and 704) Since the mandate was issued on June 21, 2021, the deadline for issuing the final rule was August 20, 2021, less than four months from the date the Court issued its decision.

IV. The Final Rule

As noted in the previous Unit, the Ninth Circuit directed EPA to act on the 2007 Petition by granting it and issuing a final rule concerning the chlorpyrifos tolerances. The Court allowed that that rule could either revoke all tolerances or modify tolerances, as long as EPA issued, concurrently with such modification, a determination that such modified tolerances were safe. The Court, impatient with EPA's failure to comply with the FFDCA when it left chlorpyrifos tolerances in place without the requisite safety finding, directed EPA to issue that final rule very quickly, *i.e.,* 60 days after the issuance of the mandate.

Given the limited window for issuing the rule and the Court's directive not to engage in additional fact-finding or further delay, the Agency focused in its rulemaking on the data and completed assessments available at the time and whether they were adequate to support a safety finding for the chlorpyrifos tolerances. EPA did not conduct additional analyses or engage in any additional fact-finding or scientific review, due to the limited time. Thus, the rule was based on available information that EPA had already reviewed and incorporated into risk assessments and/or regulatory documents.

The most recent risk assessments and regulatory documents were the 2020 HHRA (Ref. 2), 2020 DWA (Ref. 30), and the 2020 PID (Ref. 31). These documents were not in the record before the Ninth Circuit, although as noted previously, the Court allowed that the new information could be used in support of

a safety finding as appropriate. Thus, the Agency considered, in addition to other previously developed documents on chlorpyrifos as cited in the final rule (Ref. 1), whether the 2020 documents would support a safety finding for the chlorpyrifos tolerances.

EPA's final rule follows the Agency's practice of assessing risk described in Unit II.B. of this document. Relying on the Agency's existing analyses on chlorpyrifos, EPA examined the toxicological profile of chlorpyrifos to identify potential hazards and identify PoDs for assessing risk. The Agency considered the appropriate uncertainty factors, including the appropriate FQPA safety factor, for setting the level of concern. EPA also examined potential exposures of chlorpyrifos in food and drinking water, as well as from uses that might result in exposure to residues in residential settings. Finally, EPA aggregated all anticipated exposures to determine if the existing tolerances would meet the safety standard of the FFDCA. The rest of this Unit summarizes the analysis and conclusions of the 2021 final rule. For further detail, see Ref. 1.

In the 2021 final rule, EPA described the two primary toxicological effects associated with chlorpyrifos: Acetylcholinesterase inhibition and neurodevelopmental effects. These effects are discussed in greater detail in Unit III.A.1.b. of this document. As EPA noted, the mode of action of chlorpyrifos of affecting the nervous system through inhibition of AChE is well-established, as well as its use as the basis for PoD for assessing risks from chlorpyrifos as well as other OPs. In addition, EPA acknowledged and addressed the extensive body of information studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos. EPA recognized that available data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain and acknowledged the observed associations between prenatal chlorpyrifos exposure and neurodevelopmental outcomes in the epidemiological data. But EPA also noted that due to uncertainties in the data, including the lack of specific exposure information, EPA was precluded from being able to make a causal linkage between chlorpyrifos exposure and the outcomes found in the epidemiological studies. As a result, while there is a lot of information about the potential association between chlorpyrifos and neurodevelopmental outcomes in infants and children, there was insufficient information at the time of the final rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes.

As a result, EPA relied on the RBC AChE inhibition results from laboratory animals to derive PoD, consistent with the 2006 chlorpyrifos RED, the 2006 OP cumulative risk assessment, and other single chemical OP risk assessments. To account for the unresolved scientific uncertainties associated with the potential for neurodevelopmental effects—and to be protective of those effects—the Agency retained the default 10X FQPA safety factor. As noted earlier, EPA is required to apply this tenfold margin of safety to account for potential pre- and postnatal toxicity, unless it has reliable data to support a determination that a different margin of safety would be protective. (21 U.S.C. 346a(b)(2)(C)) EPA explained that the Agency's WOE analysis indicates there is qualitative evidence of a potential effect on the developing brain associated with chlorpyrifos exposures; however, uncertainties remain about the levels at which those neurodevelopmental outcomes may occur. Therefore, EPA retained the 10X FQPA safety factor in recognition of the fact that despite extensive analysis of the available data, the science concerning neurodevelopmental effects remains unresolved and thus presents an uncertainty concerning the potential pre- and postnatal toxicity. EPA did not believe it had sufficient reliable data to determine that a lower safety factor would be protective of infants and children.

To assess risk, EPA estimated exposures to chlorpyrifos from approved uses. As the FFDCA requires, EPA examined exposures for chlorpyrifos uses that resulted in residues of chlorpyrifos in or on food, in drinking water, and in residential (or non-occupational) settings. EPA's assessment of dietary (food only) exposures relied on the Agency's Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate exposure by combining data on human consumption amounts with residue values in food commodities. These food-only exposure assessments were highly refined, based both on field trial data and monitoring data.

In drinking water, EPA estimated exposures of chlorpyrifos and chlorpyrifos-oxon, a metabolite of chlorpyrifos. The most recent drinking water assessment that examined all approved uses of chlorpyrifos was conducted in 2016; thus, the Agency relied on that assessment in evaluating the safety of the chlorpyrifos tolerances. While a more recent drinking water assessment had been conducted in 2020, that newer assessment only evaluated a subset of the approved uses and thus was incomplete for purposes of assessing the aggregate exposures of chlorpyrifos. Based on the 2016 drinking water assessment then, EPA evaluated estimated concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water resulting from approved uses of chlorpyrifos.

There are few remaining uses of chlorpyrifos that result in residential or non-occupational exposures. EPA evaluated those uses and used estimated exposures from use on golf courses in the overall aggregate risk assessment since golf course uses result in the highest estimated exposures among remaining residential (non-occupational) uses.

In accordance with the requirements of the FFDCA, EPA considered aggregate exposures of chlorpyrifos in all food, drinking water, and residential settings. EPA used a DWLOC approach, in which EPA compared estimated drinking water exposures to a DWLOC, *i.e.*, a value corresponding to the maximum amount of chlorpyrifos exposures that may be present in drinking water without resulting in aggregate exposures of chlorpyrifos that would result in unsafe exposures. Where the estimated drinking water concentrations for chlorpyrifos exceed the DWLOC, the Agency concluded that aggregate exposures would be unsafe because the chlorpyrifos residues in drinking water, when combined with food and residential exposures, would exceed safe levels of chlorpyrifos exposure. For chlorpyrifos and chlorpyrifos-oxon, the Agency calculated DWLOCs for acute and steady-state exposures for several population subgroups. (Ref. 2 at pgs. 15, and 44 through 47)

As noted in the final rule, EPA's assessment concluded that exposures to chlorpyrifos from food and residential exposures individually or together did not exceed EPA's levels of concern. However, the Agency found that when combined with the exposures in drinking water from all registered uses of chlorpyrifos, the aggregate exposure to chlorpyrifos exceeded safe levels. The estimated drinking water concentrations calculated in the 2016 drinking water assessment exceeded the DWLOC. The Agency recognized that the 2020 PID proposed a subset of uses that might result in exposures below the Agency's level of concern if uses were eliminated and significant changes to the labels were made, including use cancellations

and geographic limitations, among others. However, as no registration or label changes had been effectuated such that EPA could rely on them at the time of the final rule, EPA assessed aggregate exposures expected from all registered uses.

Ultimately, EPA concluded that, based on the information before the Agency and taking into consideration all the registered uses for chlorpyrifos at the time, it was unable to determine that the chlorpyrifos tolerances were safe, since aggregate exposures to chlorpyrifos exceeded safe levels. Therefore, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. The prepublication copy of the final rule was posted on the EPA website on August 18, 2021, and the final rule published in the **Federal Register** on August 30, 2021 (Ref. 1). The final rule became effective on October 29, 2021. EPA provided a grace period of six months to ease the transition for growers and accommodate international trade considerations, by setting an expiration date for the chlorpyrifos tolerances of February 28, 2022.

The final rule provided that, pursuant to FFDCA section 408(g), 21 U.S.C. 346a, any person could file an objection to any aspect of the regulation, request a hearing on those objections, and requests for stay of the final rule. The objections, requests for hearing, and requests for stay received are summarized in Units V. and VI. of this document.

V. Objections, Requests for Hearing, and Requests for Stay

The Agency received several filings of objections, four requests for hearing on those objections, and several requests seeking a stay or extension of the rule. EPA briefly summarizes the objections, hearing requests, and stay requests, and responds to them in the next three units of this document.

Individual objections were filed by the following: The Amalgamated Sugar Company; the American Crystal Sugar Company; the American Farm Bureau Federation; the American Soybean Association; the California Citrus Quality Council; the Cherry Marketing Institute; the Coalition of Organophosphate (OP) Registrants; Gharda Chemicals International, Inc.; the Michigan Vegetable Council. Inc.; the Minor Crop Farmer Alliance; the Republic of Colombia; the Southern Minnesota Beet Sugar Cooperative; and 99 independent growers of soybean, corn, wheat, cotton, rice, alfalfa, and sugarbeet. Several entities also filed objections jointly in response to the final rule as follows: American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, Sugarbeet Associations) CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) (collectively, CLA/RISE); two sugarbeet farmers filed a joint objection; numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders signed on to a set of objections (collectively, the Agricultural Retailers Association, *et al.*).

The Agency has grouped the objections submitted into the following five categories:

(i) *Objections to the scope of EPA's final rule revoking tolerances.* Several Objectors objected to the final rule revoking all chlorpyrifos tolerances. Rather than revoke all tolerances, the Objectors assert that EPA should have modified tolerances by retaining the tolerances for those 11 high-benefit crops identified in the 2020 PID. Some of those objectors also argued that EPA had an obligation to harmonize its tolerance revocations with action under FIFRA (*e.g.,* canceling uses) in order to allow for the retention of the 11 tolerances identified in the PID. Finally, a number of Objectors requested that EPA retain "import tolerances" for chlorpyrifos commodities, on the grounds that those tolerances would not contribute to drinking water exposures, which are driving risks.

(ii) *Retention of the 10X FQPA safety factor.* Several objectors assert that EPA should not have retained the 10X FQPA safety factor due to scientific uncertainties tied to epidemiological data that objectors believe is invalid, incomplete, and unreliable. Objectors argue that EPA should have reduced the FQPA safety factor to 1X based on the rest of the available data for assessing the toxicity of chlorpyrifos.

(iii) *Objections related to drinking water.* Several objectors assert that EPA erred in relying on the 2016 Drinking Water Assessment (DWA), instead of the more refined 2020 DWA for assessing drinking water exposures. Objectors believe the Agency's approach is highly conservative and inaccurate. In addition, Gharda asserts that the Agency erred in assessing chlorpyrifos-oxon in the aggregate assessment of chlorpyrifos.

(iv) *Procedural considerations.* A number of objectors argue that EPA has failed to provide adequate due process by not addressing comments submitted on the 2015 proposed rule to revoke chlorpyrifos tolerances, and in the chlorpyrifos registration review process. Moreover, an objector raised due process concerns with the delayed opening of the Agency's Federal eRulemaking Portal for submitting objections electronically. Finally, some objectors argued that the Agency failed to provide meaningful opportunity for interagency input under Executive Order 12866.

(v) *Objections that, as a matter of law, do not provide a basis for leaving the tolerances in place.* Several Objectors requested that EPA rescind the final rule due to the impacts on growers and the environment from the loss of the pesticide. One objector believes that EPA improperly considered occupational exposure in the final rule based on an Agency press statement. Other objectors assert that the final rule is improper because it deviates from an unspecified Codex Alimentarius international standard of 0.05 mg/kg for chlorpyrifos. Some objectors assert that the implementation timeline specified by EPA was too short and that the final rule should have provided guidance for chlorpyrifos products in the channels of trade and considered the implications for existing stocks of chlorpyrifos. Finally, Gharda objects that the final rule violates their substantive due process rights.

Four objectors also included requests for evidentiary hearings. Three of these requesters—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—each request evidentiary hearings to demonstrate that the best available science, including the 2020 PID, supports a finding that chlorpyrifos tolerances can remain in effect for soybeans, sugarbeets, and Michigan tart cherries, respectively. Gharda submitted the fourth request for an evidentiary hearing on its objection that the chlorpyrifos-oxon was not relevant to the Agency's aggregate risk assessment. While Gharda believes the Agency has all the evidence necessary to make this determination, it still requests a hearing "[t]o the extent that EPA believes that a fact issue is presented by this data."

Finally, EPA received written requests to stay the effective date of the final rule from several objectors. The Sugarbeet Associations and Gharda both argue that the criteria set out in the FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35 require that EPA stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. Several other Objectors

do not specifically address the regulatory criteria set forth at 21 CFR 10.35, but request that EPA stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. Some objectors simply request an extension of the timeframe for implementation of the rule.

VI. Response to Requests for Hearing

EPA denies each of the four requests for evidentiary hearing on objections. Three objectors requested an evidentiary hearing on their objection that EPA should have retained tolerances for certain crops based on the conclusions of the 2020 PID; these requests are denied for failure to make a sufficient evidentiary proffer. Gharda also requested a hearing on its objection to EPA's assessment of chlorpyrifos-oxon exposures in drinking water; this request is denied as unnecessary for the purpose of receiving evidence and because the likely factual issue has no material impact on Agency's decision to revoke tolerances. EPA's substantive responses to the underlying objections follow in the next Unit, *i.e.,* Unit VII.C.1. and VII.C.3.b., respectively. Under EPA's regulations, EPA may treat these objections as a group and rule on them only after ruling on the request for an evidentiary hearing on that objection. 40 CFR 178.30(c)(2) Therefore, EPA is addressing these hearing requests before responding to objections in the next Unit.

A. The Standard for Granting an Evidentiary Hearing

EPA has established regulations governing objections to tolerance rulemakings and tolerance petition denials and requests for hearings on those objections. (40 CFR part 178; 55 FR 50282, December 5, 1990) (FRL–3688–4)) Those regulations prescribe both the form and content of hearing requests and the standard under which EPA is to evaluate requests for an evidentiary hearing.

As to the form and content of a hearing request, the regulations specify that a hearing request must include: (1) A statement of the factual issues on which a hearing is requested and the requestor's contentions on those issues; (2) A copy of any report, article, or other written document "upon which the objector relies to justify an evidentiary hearing;" (3) A summary of any other evidence relied upon to justify a hearing; and (4) A discussion of the relationship between the factual issues and the relief requested by the objection. (40 CFR 178.27)

The standard for granting a hearing request is set forth in 40 CFR 178.32. That section provides that a hearing will be granted if EPA determines that the "material submitted" shows all of the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought. (40 CFR 178.32(b))

This provision essentially imposes four requirements upon a hearing requestor. First, the requestor must show it is raising a question of fact, not one of law or policy. Hearings are for resolving factual issues, not for debating law or policy questions. Second, the requestor must demonstrate that there is a genuine dispute as to the issue of fact. If the facts are undisputed or the record is clear that no genuine dispute exists, there is no need for a hearing. Third, the requestor must show that the disputed factual question is material, *i.e.,* that it is outcome determinative with regard to the relief requested in the objections. Finally, the requestor must make a sufficient evidentiary proffer to demonstrate that there is a reasonable possibility that the issue could be resolved in favor of the requestor. Hearings are for the purpose of providing objectors with an opportunity to present evidence supporting their objections as the regulation states, hearings will not be granted on the basis of "mere allegations, denials, or general descriptions of positions or contentions." (40 CFR 178.32(b)(2))

The Court in *National Corn Growers Ass'n* v. *EPA* noted that the FFDCA and EPA's regulations "establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact." (613 F.2d 266, 271 (DC Cir. 2010)) In addition, the Court applied a "necessarily deferential" standard of review in determining whether an issue was material, looking to whether the agency "has given adequate consideration to all relevant evidence in the record." (*Id.* at pgs. 271 and 272) "Mere difference in the weight or credence given to particular scientific studies . . . are insufficient" to overturn an agency conclusion regarding whether an objection raises a material issue of fact. (*Id.* at pg. 271)

EPA's hearing request requirements are based heavily on FDA regulations establishing similar requirements for hearing requests filed under other provisions of the FFDCA (53 FR 41126, 41129, October 19, 1988) (FRL–8372–5). FDA pioneered the use of summary judgment-type procedures to limit hearings to disputed material factual issues and thereby conserve agency resources. FDA's use of such procedures was upheld by the Supreme Court in 1972, (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973)), and, in 1975, FDA promulgated generic regulations establishing the standard for evaluating hearing requests (40 FR 22950, May 27, 1975). It is these regulations upon which EPA relied in promulgating its hearing regulations in 1990.

Unlike EPA, FDA has had numerous occasions to apply its regulations on hearing requests. FDA's summary of the thrust of its regulations, which has been repeatedly published in the **Federal Register** in Orders ruling on hearing requests over the last 24 years, is instructive on the proper interpretation of the regulatory requirements. That summary states:

> A party seeking a hearing is required to meet a threshold burden of tendering evidence suggesting the need for a hearing.' [ ] An allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.
>
> A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. [ ] FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. [ ] Stated another way, a hearing is justified only if the objections are made in good faith and if they 'draw in question in

a material way the underpinnings of the regulation at issue.' Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy.

(49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007 (citations omitted) EPA has been guided by FDA's application of its regulations in this proceeding.

Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996. Although the statute had been silent on this issue previously, the FQPA added language specifying that when a hearing is requested, EPA "shall . . . hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections" (21 U.S.C. 346a(g)(2)(B)). This language grants EPA broad discretion to determine whether a hearing is "necessary to receive factual evidence" to objections (H.R. Rep. No. 104–669, at pg. 49 (1996)).

B. American Soybean Association, Sugarbeet Associations, and Cherry Marketing Institute Hearing Requests

1. Summary of Hearing Request

Three Objectors—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—requested evidentiary hearings based on their objections that EPA erred in revoking tolerances covering chlorpyrifos residues for their particular commodity, *i.e.*, soybean, sugarbeet, and cherry, respectively. (Refs. 36 through 38) These Objectors root this claim in statements made in the 2020 PID, in which EPA proposed a subset of 11 registered uses for retention as an option to mitigate dietary risks from uses of chlorpyrifos. The 2020 PID noted that if uses were limited in accordance with that proposal, EPA would be able to determine that such uses would "not pose potential risks of concern." Because, at the time of the final rule, uses were not so limited, EPA revoked all tolerances. These Objectors assert that such a conclusion was inconsistent with the conclusions in the 2020 PID and thus not supported by factual evidence. As a result, these Objectors request a hearing on that objection to dispute the underlying factual basis for EPA's decision to revoke all tolerances and, in particular, for their tolerance of interest.

Specifically, the American Soybean Association notes that soybeans were included among the 11 high-benefit crop uses of chlorpyrifos that the 2020 PID described as "not pos[ing] potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X." (Ref. 36 at pg. 4) In addition, the American Soybean Association asserts that EPA has determined "elsewhere in its administrative record" that it is reasonably certain soybean uses will not pose harm from aggregate dietary exposures. (*Id.*) Therefore, the American Soybean Association challenges EPA's determination in the final rule that soybean uses of chlorpyrifos might pose dietary risks of concern as factually inaccurate and contrary to the finding in the 2020 PID, and requests an evidentiary hearing "to dispute this underlying factual inaccuracy." (*Id.*) Similarly, the Sugarbeet Associations argue that EPA's decision to revoke tolerances for the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID is arbitrary and capricious and request an evidentiary hearing "to demonstrate that the best available science, including the 2020 PID, supports a finding that tolerances for sugarbeets can remain in effect." (Ref. 37 at pg. 6) Lastly, the Cherry Marketing Institute argues that EPA's decision to revoke tolerances for chlorpyrifos in the Michigan tart cherry industry due to dietary risks is factually inaccurate, in light of EPA's identification of tart cherries among the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID. (Ref. 38 at pg. 2) The Cherry Marketing Institute allege that an unspecified "drinking water assessment and a dietary assessment" provide that the Michigan tart cherry industry's use of chlorpyrifos meets FFDCA safety standards. (*Id.* at pg. 1) The Cherry Marketing Institute therefore requests an evidentiary hearing "to further convey [its] concerns with EPA's determination" to revoke chlorpyrifos tolerances. (*Id.* at pg. 2)

2. Denial of Hearing Request

The evidentiary hearing requests submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute do not meet the regulatory standard for granting an evidentiary hearing request set forth in 40 CFR 178.32 and are therefore denied.

As noted previously, the purpose for holding hearings is "to receive factual evidence." (21 U.S.C. 346a(g)(2)(B); 53 FR 41126 at 41129 ("Hearings are for the purpose of gathering evidence on disputed factual issues . . . .")) Therefore, at a bare minimum, a requestor must identify evidence relied upon to justify a hearing and either submit copies of that evidence or summarize it. (40 CFR 178.27)

None of these Objectors proffers any factual evidence to support their request for an evidentiary hearing. Other than offering that the Agency's determinations in the final rule were inconsistent with the 2020 PID, these Objectors refer to a hearing as an opportunity to dispute the Agency's factual conclusions regarding the risks posed by the use of chlorpyrifos on their particular commodity. As noted previously, "[a]n allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one." (49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007) (citing *Georgia Pacific Corp* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)) The statute requires that the objector identify actual evidence; however, the Objectors point to no additional factual evidence that they would offer for review in this evidentiary hearing. Failing to identify any factual evidence that the Objectors would like to be considered in a hearing, the Objectors' hearing request fails to proffer the requisite evidence.

Even viewed in the most favorable light, these Objectors merely proffer the Agency's own statements in its risk assessments and the 2020 PID and unspecified references to statements "elsewhere in the administrative record." As a result, EPA concludes that this submission is sufficiently lacking to be considered an evidentiary proffer. Given that the purpose of a hearing is to gather or receive evidence, proffering evidence already considered and relied upon by EPA is not grounds for holding a hearing. Furthermore, EPA has already considered and found inadequate the evidence in the record to support retaining individual tolerances without a change in registrations, and it is difficult to understand, how, as a matter of law, this same evidence would justify the opposite conclusion, given the same underlying facts. At bottom, these objectors' proffer fails to "identify" evidence which would, if established, resolve an issue in the objectors' favor.

Moreover, the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute have all failed to demonstrate that there is a "genuine and substantial issue of fact for resolution at a hearing." (40 CFR 178.32(b)(1)) Whether EPA was arbitrary and capricious in revoking the soybean, sugarbeet, and cherry tolerances is a question of law, not of fact. Contrary to what these objectors assert, EPA does

not assess safety of tolerances based upon the risks posed by use on a single commodity. Under the FFDCA, EPA is required to assess aggregate exposures, *i.e.,* exposure to the pesticide from use on that particular commodity, as well as use on all other commodities, contributions to drinking water from all registered uses, and exposures in non-occupational settings. Furthermore, to the extent there is a factual question here, it is not in dispute. EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document. The problem is that at the time of the final rule, the Agency did not have a basis for assuming that uses would be limited in accordance with the 2020 PID mitigation proposal. Thus, as a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time of the final rule. Ultimately, this issue comes down to whether EPA properly interpreted its obligation under the FFDCA in assessing aggregate exposure to chlorpyrifos, and that is ultimately a question of law and not one of fact. Hearings are not granted on legal questions. (40 CFR 178.32(b)(1)) Accordingly, the hearing requests of the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute are denied.

EPA responds to the objection concerning whether EPA was justified in revoking all chlorpyrifos tolerances in Unit VII.C.1.a. of this document.

C. Gharda Chemicals International, Inc. Hearing Request

1. Summary of Hearing Request

In a footnote in a section of its objections alleging that EPA failed to adequately consider certain relevant scientific information, Gharda says, "Gharda respectfully submits that EPA has all of the scientific data at its disposal to find that chlorpyrifos oxon is not relevant to EPA's aggregate exposure assessment under the FFDCA. To the extent that EPA believes that a fact issue is presented by this data, Gharda respectfully requests a hearing." (Ref. 39 at pg. 34) Although the first sentence of Gharda's footnote indicates that Gharda does not believe that a hearing is necessary, which should settle the matter, the second sentence introduces some ambiguity that compels a response as a matter of completeness. So, as discussed later in this document, EPA considers whether an evidentiary hearing on Gharda's objection to EPA's assessment of chlorpyrifos-oxon is warranted and determines that it is not.

On its face, Gharda's request for a hearing fails to proffer any evidence that Gharda believes warrants an evidentiary hearing. The specific request refers simply to "scientific data", which is so vague as to not be an evidentiary proffer at all. Nevertheless, taking into consideration the whole of Gharda's objection concerning the assessment of chlorpyrifos-oxon, EPA notes that Gharda references two documents: (i) A drinking water study submitted to EPA by Corteva in December 2020 (*Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days* (MRID 51392601) ("Corteva Oxon Study")) and (ii) A Declaration of Dr. Richard Reiss, dated October 21, 2021 and included as an exhibit attached to Gharda's Objections to the final rule, offering opinions on the meaning of the Corteva Oxon Study ("Reiss Declaration"). (*Id.* at pg. 32) Also mentioned within the same section of Gharda's submission as its objection relating to chlorpyrifos-oxon are two other documents: (i) Comments filed by Dow AgroSciences LLC (DAS) (now doing business as Corteva Agriscience) on January 17, 2017 on the *Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment* (81 FR 81049) and its accompanying assessments, including the 2016 DWA; and (ii) A Response to Objections document filed by DAS on April 18, 2019 regarding objections submitted by PANNA, NRDC, and others to EPA's March 29, 2017 Order denying the 2007 Petition. (*Id.* at 31) Because Gharda refers to these documents only in the context of challenging the Agency's use of the 2016 DWA in general and not with regard to the chlorpyrifos-oxon objection specifically, EPA concludes that Gharda is not proffering those documents in support of its objection on the assessment of chlorpyrifos-oxon.

Gharda points to the Corteva Oxon Study as support for its objection that the chlorpyrifos-oxon was not relevant to, and should not have been included in, EPA's aggregate risk assessment. Gharda asserts, quoting from the Reiss Declaration, that the Corteva Oxon Study found "(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure," and therefore nullified EPA's assumption in the 2020 DWA "that chlorpyrifos oxon is more toxic that the parent chlorpyrifos for drinking water exposure purposes." (*Id.* at pg. 32) As a result, Gharda argues that this study shows that "drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos." (*Id.* at pgs. 32 and 33) According to Gharda, EPA has received this study but has failed to review it. Gharda argues that EPA's failure to consider this study means that the final rule rests on incomplete information and is arbitrary and capricious. (*Id.* at pgs. 33 through 34) Therefore, giving Gharda the benefit of the doubt, EPA finds that the Corteva Oxon Study is being proffered by Gharda for the Agency's consideration in determining whether a factual issue is raised that warrants an evidentiary hearing. Similarly, because Gharda relies heavily on the Reiss Declaration for its allegations concerning the Corteva Oxon Study, EPA finds that Gharda is proffering that declaration as evidence as well.

2. Denial of Hearing Request

EPA denies Gharda's hearing request under both its broad discretionary authority found in FFDCA section 408(g)(2) and under the regulatory standard in 40 CFR 178.32. As an initial matter, the equivocating and vague nature of Gharda's hearing request makes it difficult to discern whether Gharda has submitted a request for an evidentiary hearing that meets even the basic form and content criteria of EPA's regulations. (40 CFR 178.27) First, EPA's regulations require a specific request for an evidentiary hearing and a statement of the factual issue on which the hearing is requested. (40 CFR 178.27(a) and (b)) While Gharda "respectfully requests a hearing," it is only to the extent EPA finds a factual issue warranting one. (Ref. 39 at pg. 34) Gharda asserts many things in this particular objection concerning what Gharda believes is EPA's failure to consider relevant scientific data, including failure to consider the Corteva Oxon Study, which Gharda asserts would support a conclusion that chlorpyrifos-oxon in drinking water is not relevant for chlorpyrifos risk assessment purposes. That is not a clear statement of the factual issue on which EPA should evaluate the request for a hearing. (40 CFR 178.27(b)) Moreover, as discussed previously, it is difficult to discern exactly what evidence Gharda is proffering—"all scientific data" in EPA's files or just the Corteva Oxon Study. (40 CFR 178.27(c)) Finally, Gharda makes no attempt to "include a discussion of the relationship between

the factual issues and the relief requested by the objection." (40 CFR 178.27(e)) Gharda seems to be arguing that if the chlorpyrifos-oxon was not relevant to the Agency's assessment, it would somehow change the outcome of the final rule, but Gharda fails to explain how consideration of that study would ultimately impact the Agency's conclusions concerning the safety of chlorpyrifos. In order to evaluate this "hearing request", EPA has had to discern from context what the factual issue is and what Gharda specifically hopes to accomplish with this evidence. This is contrary to EPA's regulations, which place the burden of presenting evidence upon which the objector relies to justify an evidentiary hearing on the objector, not on EPA. (40 CFR 178.27(c) and (d)) It appears that Gharda in its comment is trying to flip the burden for demonstrating whether an evidentiary hearing is necessary onto EPA; as such EPA believes that Gharda has failed to meet a threshold burden of submitting a hearing request that meets the basic criteria for such submissions under 40 CFR 178.27.

Significantly, by its own terms, Gharda does not believe that a hearing is necessary for the Agency to receive factual evidence, since the Agency already "has all of the scientific data at its disposal" to evaluate this objection. (Ref. 39 at pg. 34) As noted previously, FFDCA directs EPA to "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections" (21 U.S.C. 346a(g)(2)(B)) This language was added to the FFDCA by the FQPA in 1996, after EPA promulgated its evidentiary hearing regulations, and EPA views it as providing broad discretion to evaluate whether a hearing is necessary, even if the requirements in 40 CFR 178.32 are met. EPA does not interpret this language as requiring it to hold a hearing in any instance where factual evidence relevant to a material issue of fact is proffered (essentially the standard set forth in 40 CFR 178.32); rather, EPA construes the statutory language as requiring it to hold a hearing only where it determines a hearing is necessary to receive such proffered evidence. In other words, a party wishing to obtain a hearing must not only satisfy the requirements of 40 CFR 178.32, it must also show that an evidentiary hearing is necessary for the presentation of proffered evidence to the Agency.

In this particular instance, Gharda states that EPA already has all the scientific data necessary to evaluate this issue and thus does not believe that a hearing is necessary to address the relevance of the oxon issue. EPA agrees. Because EPA already has the Corteva Oxon Study in its files, EPA has determined that a hearing is not necessary to receive that evidence. This conclusion is bolstered by EPA's determination that ultimately, consideration of this study would not materially impact EPA's conclusions regarding the safety of chlorpyrifos, since (as discussed later in this unit) EPA could not support a safety finding for chlorpyrifos based on consideration of only the chlorpyrifos (and not the oxon) concentrations in drinking water.

Moreover, in examining the evidentiary proffer of the Reiss Declaration, EPA concludes that a hearing would not be appropriate for receiving that evidence. "An evidentiary hearing will not be granted on the basis of mere allegations . . . or general descriptions of positions and contentions. . . ." (40 CFR 178.32(b)(2)) The Reiss Declaration contains a composite of conclusory statements of interpretation of the Corteva Oxon Study, with no elucidation of how Dr. Reiss arrived at those conclusions. (Ref. 39 at pgs. 113 through 132) One paragraph simply refers to a "prior study" to illustrate an example of the oxon causing lower levels of brain AChE inhibition than chlorpyrifos, but no citation to that study is provided. (*Id.* at pg. 120, paragraph 26) Paragraph 27, which Gharda quotes for its objections, concludes that the Corteva Oxon Study "found (a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure." (*Id.* at pg. 121, paragraph 27) But that is it. There is no explanation of how Dr. Reiss came to those conclusions based on the study or what information provided in the study that supports these conclusions. Therefore, with regard to the Corteva Oxon Study, EPA finds that a hearing is not warranted to receive the Reiss Declaration, since the statements contained therein appear to contain mere allegations and conclusions.

In applying the criteria for granting a hearing, EPA looks first to the question of whether there is a genuine and substantial issue of fact. (40 CFR 178.32(b)(1)) As noted previously, Gharda has failed to provide a clear statement of the factual issue to be resolved at an evidentiary hearing. However, EPA recognizes Gharda's assertion that chlorpyrifos-oxon is not relevant for risk assessment purposes due to the lack of toxicity allegedly demonstrated in the Corteva Oxon Study is at odds with EPA's assessment of chlorpyrifos-oxon residues in drinking water and in the aggregate risk assessment. Whether there is valid scientific data supporting a different conclusion about the toxicity of chlorpyrifos-oxon is likely to be a factual question, rather than one of law or policy.

Nevertheless, EPA's hearing regulations also require that the "[r]esolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action request." (40 CFR 178.32(b)(3)) Under this prong, Gharda's request for a hearing fails. As noted previously, Gharda has failed to provide a discussion of how resolution of this factual issue would assist in granting the relief of their objection. For that matter, Gharda has not even clarified how their objection (*i.e.*, failure to consider relevant scientific information) supports a change to the Agency's safety determination in the final rule.

Assuming *arguendo* that Gharda (and Dr. Reiss) has correctly interpreted the Corteva Oxon Study and assuming also that chlorpyrifos-oxon is less toxic than chlorpyrifos and is not therefore the relevant exposure measurement for assessing risks of chlorpyrifos in drinking water as EPA had assumed, Gharda's request for an evidentiary hearing still fails. This is because this assumption would not ultimately change the outcome of the final rule; EPA would still be unable to conclude that the chlorpyrifos tolerances were safe because the estimated concentrations of chlorpyrifos itself (rather than chlorpyrifos-oxon) in drinking water still exceed the relevant DWLOC.

In the 2020 PID, EPA calculated a DWLOC for both chlorpyrifos and chlorpyrifos-oxon. The DWLOCs used for comparison to residues of chlorpyrifos in drinking water in the final rule were associated with chlorpyrifos-oxon, as that was considered the residue of concern: 4.0 ppb for steady-state exposures and 23 ppb for acute exposures. Based on the 2016 DWA, EPA determined that there were likely to be estimated concentrations of chlorpyrifos-oxon in drinking water that exceeded those DWLOCs. As indicated in Unit II.B.1.d., where the concentrations of pesticide in drinking water exceed the DWLOC, the Agency concludes that the aggregate exposures are not safe. If, as Gharda asserts, the chlorpyrifos-oxon residues are not relevant, there would still be exposures to chlorpyrifos in drinking

water, and EPA would need to consider whether those exposures to chlorpyrifos would be safe. The DWLOCs calculated for chlorpyrifos were 17 ppb for steady-state exposures and 100 ppb for acute exposures. (Ref. 31 at pg. 15) Relative to the DWLOCs for chlorpyrifos-oxon, the DWLOCs for chlorpyrifos are larger, providing slightly more room in the risk cup for residues of chlorpyrifos, relative to chlorpyrifos-oxon. Nevertheless, the 2016 DWA indicates that for the majority of HUC regions assessed, the estimated concentrations of chlorpyrifos alone in drinking water still exceed the higher DWLOC of 17 ppb, *i.e.,* Table 25 of the 2016 DWA indicates that the range of chlorpyrifos concentrations in drinking water have the potential to exceed the DWLOC for all HUC regions except one (HUC 16b). (Ref. 29 at pgs. 73–74) As long as there are certain vulnerable watersheds where the concentrations of chlorpyrifos exceed the maximum amount allowed for residues in drinking water to ensure that aggregate chlorpyrifos exposures stay below safe levels, the Agency cannot make a safety finding to support the chlorpyrifos tolerances. Thus, Gharda has failed to raise a material factual issue for which an evidentiary hearing would be appropriate. "An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought." (40 CFR 178.32(b)(3))

The absence of a material issue of fact here is fatal to Gharda's request for a hearing. As noted previously, the Corteva Oxon Study, even if it supported Gharda's assertion that chlorpyrifos-oxon residues were not relevant for EPA's risk assessment, does not ultimately support a finding that the chlorpyrifos tolerances are safe. Therefore, EPA concludes that a hearing is not justified to receive that evidence for the purposes of evaluating Gharda's claim concerning the consideration of chlorpyrifos-oxon in the Agency's risk assessment. This conclusion also reinforces EPA's earlier determination that a hearing is not necessary to receive the evidence since the study is already in the Agency's files. Furthermore, because the Reiss Declaration offers nothing more than conclusory statements about how to interpret the Corteva Oxon Study, it also fails to provide a basis for determining that the chlorpyrifos tolerances are safe and changing the final rule. Conclusory statements indicating a potential difference of scientific interpretation of a study that, even in the most favorable light, is not outcome determinative, does not create a material issue of fact. (*See National Corn Growers Ass'n,* 613 F.3d at 274 (finding that "[m]ere differences in the weight or credence given to particular scientific studies" would not be a sufficient basis to overturn an Agency conclusion that there is no material issue of fact)) Therefore, EPA has determined that Gharda has failed to proffer evidence warranting an evidentiary hearing on its objection concerning the Agency's assessment of chlorpyrifos-oxon.

D. Summary of Reasons for Denial of Hearing Requests

EPA is denying the requests for evidentiary hearing submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute because those entities failed to proffer any evidence for which a hearing would be appropriate. The statute clearly states that a hearing is appropriate when "necessary to receive material evidence." (21 U.S.C. 346a(g)(2)(B)) Moreover, these Objectors ultimately disagree with EPA's application of the FFDCA statutory standard for assessing exposures, which is a legal question, rather than a factual one, and thus not appropriate for a hearing. (40 CFR 178.32(b)(1))

EPA is denying Gharda's request for an evidentiary hearing for lack of necessity since, as Gharda concedes, EPA already has the evidence proffered and for lack of materiality, since even if Gharda's factual assertions are correct and supported by the evidence proffered, those issues are not determinative with regard to the Agency's conclusions in the final rule, *i.e.,* they would not provide a basis for leaving the chlorpyrifos tolerances in place at this time.

VII. Response to Objections

A. Overview

EPA denies each of the objections to the final rule. As noted in Unit V. of this document, EPA received several objections from many different entities, including trade associations, farm bureaus, individual growers, and registrants. EPA has grouped these objections into five different categories, which are described later in this unit. After a brief description of each objection or objection subissue, EPA responds to each in this unit.

B. Denial of Objections Not Properly Filed

As a preliminary matter, EPA notes that several parties submitted documents to the Federal eRulemaking Portal that are styled as objections but that do not comply with the requirements of 40 CFR 178.25. As EPA noted in the final rule—and as required in EPA's regulations—objections must be submitted in writing and filed with the Office of the Hearing Clerk in accordance with the procedures in 40 CFR 178.25. While the regulations specify that objections are to be mailed or hand-delivered to the Hearing Clerk, due to the pandemic the Office of Administrative Law Judges (OALJ), where the Office of the Hearing Clerk is housed, is directing parties to file electronically. (Ref. 40) The final rule provided instructions for filing online as well as what to do in the event that online filing was not available. (Ref. 1 at pgs. 48315–16)

The following parties did not submit their objections to the Office of the Hearing Clerk either through the OALJ e-filing system or through mail or hand delivery as required by 40 CFR 178.25(b): The Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador. (Refs. 41 through 45) EPA also notes that the National Association of Wheat Growers submitted two sets of objections: One as a standalone document, which was not properly filed with the Office of the Hearing Clerk (Ref. 46), and one as a signatory to objections submitted by numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders (which EPA is referring to as the Agricultural Retailers Association, *et al.* objections (Ref. 47)), which was properly filed with the Office of the Hearing Clerk. EPA's regulations require EPA to deny each objection that is found not to conform with 40 CFR 178.25. (40 CFR 178.30(a)(1)) As a result, EPA denies the previously-described objections that were not submitted to the Office of the Hearing Clerk and will not be considering them in this Order.

C. Responses to Specific Issues Raised in Objections

1. Objections to the Scope of EPA's Final Rule Revoking Tolerances

One theme running through several objections was an assertion that EPA's revocation of all chlorpyrifos tolerances was unlawful and unnecessary. Some Objectors argued that EPA should have

retained some of the chlorpyrifos tolerances, rather than revoking them all, based on EPA's mitigation proposal in the 2020 PID to limit uses to 11 high-benefit crops in certain geographic locations. Relatedly, some Objectors believed that EPA should have coordinated the tolerance revocations with actions under FIFRA to cancel uses in order to avoid revoking all tolerances. Finally, some Objectors asserted that EPA should have retained import tolerances since imported commodities would not contribute to drinking water exposures, which were driving risk concerns. These objections and EPA's responses are discussed in further detail in this sub-unit.

a. EPA's Proposal for Limiting Uses to 11 High-Benefit Crops in the 2020 Proposed Interim Decision (PID) for Chlorpyrifos

i. Objection. Nearly all Objectors assert that revoking all chlorpyrifos tolerances was unlawful and unnecessary based on statements in the 2020 PID where EPA proposed a subset of chlorpyrifos tolerances for retention, provided certain restrictions were implemented. (The objections, requests for hearing on objections, and stay requests submitted in response to the final rule are available at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.) Some Objectors' claims are general, asserting that EPA should have retained all 11 tolerances, and some are specific to their own commodity of interest (*e.g.,* the American Soybean Association focuses on EPA's determination in the 2020 PID as it relates to soybeans, specifically). (Ref. 36 at pg. 4) In each case, however, these Objectors rely on EPA's proposed finding in the 2020 PID to demonstrate that EPA's record contains sufficient information to determine that at least some tolerances and uses satisfy the FFDCA safety standard. The objectors conclude that, therefore, revocation of all tolerances was inconsistent with the FFDCA requirement to consider aggregate exposure from all "anticipated dietary exposures".

The Objectors point to the Ninth Circuit's April 29, 2021, decision for support that EPA was not required to revoke all chlorpyrifos tolerances. The Objectors note that the Court gave EPA the option to "either revoke all chlorpyrifos tolerances or modify chlorpyrifos tolerances," as long as the modification was supported by a safety determination, as well as a direction to "modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of [FFDCA 408(a)]." (*LULAC,* 996 F.3d at 703–04) Consequently, the Objectors assert that EPA should have modified tolerances by retaining the 11 uses rather than revoking all.

ii. Denial of objection. EPA denies this objection. The Objectors' claim is primarily based on a misunderstanding of the FFDCA's requirement to consider aggregate exposure, a misreading of the 2020 PID, and a disregard of the facts at the time of the final rule. When one corrects for each of those factors, it is clear that EPA's revocation of all chlorpyrifos tolerances was entirely consistent with the Agency's obligations under the FFDCA.

Before diving into the rationale for why the Objectors' argument is legally flawed, it is worth providing context for the PID, or proposed registration review decision. Under EPA's regulations, a proposed (interim) registration review decision lays out the Agency's proposed findings, identifies proposed risk mitigation measures or other remedies as needed, identifies any missing or needed data, specifies proposed labeling changes, and identifies any anticipated deadlines. (*See* 40 CFR 155.58(b)) EPA publishes notice of the availability of this proposed decision and provides for at least a 60-day comment period. (40 CFR 155.58(a)) After consideration of those comments, EPA will issue an interim or final registration review decision, which can be very similar to the proposed decision or incorporates changes based on those comments. (40 CFR 155.58(c)) As noted in Unit II.A., the purpose of registration review is to determine whether the registered pesticide continues to meet the standard for registration. Where EPA identifies potential unreasonable risks from use of a pesticide, EPA considers whether there are any options or measures for reducing or mitigating those risks that would enable the pesticide to meet the standard for registration. Where such mitigation measures are available, EPA will propose those in the proposed registration review decision in conformance with its regulations. But consistent with the nature of any proposal, the findings in the proposed decision are just proposals and subject to change based upon public comment or other developments that may occur before the final decision is issued.

For the 2020 PID for chlorpyrifos, EPA followed the process laid out in its regulations. EPA summarized the findings of its aggregate risk assessment and concluded that "[w]*hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos,* aggregate exposures are of concern. *If considering only the uses that results in DWLOCs below the EDWCs,* aggregate exposures are not of concern." (Ref. 31 at pg. 19 (emphases added)) In other words, EPA found that the universe of currently registered chlorpyrifos uses presented aggregate exposures that exceeded the Agency's determined safe level of exposure. As a result, EPA proposed mitigation to address the dietary and aggregate risks of concern that were posed by use of chlorpyrifos as currently registered. (*Id.* at pg. 40)

To mitigate these risks, EPA proposed that chlorpyrifos applications be limited to the following 11 specific uses in only those specific geographic areas where the estimated concentrations of chlorpyrifos in drinking water from those uses were lower than the DWLOC, *i.e.,* the maximum amount of chlorpyrifos residues that could be present in water and still ensure that aggregate exposures would be safe: Alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and spring and winter wheat. (*Id.* at pgs. 40 and 41) For this mitigation proposal to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos that contribute to aggregate exposures (*i.e.,* food, drinking water, and residential exposures) would need to be cancelled and the labels for products containing the identified subset of uses would need to be amended to ensure that applications would be limited to those specifically identified geographic areas. Moreover, some revisions to labeled application rates would also be required since the conclusions in the 2020 PID that drinking water contributions were safe in these areas from these uses was based on usage data rather than maximum labeled application rates. It is also important to emphasize that the act of proposing to limit chlorpyrifos applications to this subset of uses did not, in fact, automatically result in the elimination of all uses beyond those identified uses; that would require separate actions under FIFRA to cancel uses and to amend labels, which has not occurred.

EPA proposed this particular list of uses as critical and high-benefit uses of those uses currently registered for chlorpyrifos. (Ref. 30, Attachment 2) Although the "reasonable certainty of no harm" standard in the FFDCA, which is strictly a risk-based standard, allows no consideration of benefits, except in one very limited circumstance not relevant here (*see* 21 U.S.C. 346a(b)(2)(B)), FIFRA's "unreasonable adverse effects" standard incorporates a consideration of economic costs or benefits, which EPA took into

consideration when identifying this proposed list of retainable uses as part of the FIFRA registration review process. But this is likely not the only combination of uses that could have resulted in safe levels of aggregate exposure. To conserve resources (and because previous analyses had indicated risks of concern when considering all chlorpyrifos uses), EPA's 2020 DWA focused solely on the areas where these particular crops were grown that had the highest benefit to growers to determine if there were areas where the EDWCs were below the DWLOC; it is possible that a different set of crops and a different range of geographic areas could also result in safe aggregate exposures. The Agency expressly noted that it would "consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if any other limited uses may be retained." (Ref. 31 at pg. 40) The 2020 PID was made available for public comment, and the Agency did, in fact, receive hundreds of comments, although none committed to making changes to the chlorpyrifos registrations necessary to implement the 2020 PID as proposed, nor were any requests for voluntary cancellation of registered uses submitted under FIFRA in response to the 2020 PID.

Turning now to the legal standard, as noted in Unit II.A., FFDCA section 408(b)(2)(A)(i) permits EPA to leave tolerances in place only if the Agency can determine that the tolerance is safe. If the Agency determines that the tolerances, which must be based on aggregate exposures, are not safe (or cannot determine that tolerances are safe), the Agency must modify or revoke them. (21 U.S.C. 346a(b)(2)(A)(i); see also *LULAC,* 996 F.3d at pgs. 693–94 (concluding that when EPA receives a petition raising substantive questions concerning safety, FFDCA provides no middle ground in which EPA can leave tolerances in place if EPA is unwilling or unable to make a safety finding)) The FFDCA also defines safe as requiring EPA to determine that "there is a reasonable certainty that no harm will result from *aggregate exposure* to the pesticide chemical residue, including *all anticipated dietary exposures and all other exposures for which there is reliable information.*" (21 U.S.C. 346a(b)(2)(A)(ii) (emphases added)) Congress understood the phrase "aggregate exposure" to include dietary exposures under all tolerances for the pesticide chemical residue, H.R. Rep. 104–669(II) at 1279, and codified that understanding among the factors EPA must consider when establishing, modifying, leaving in effect, or revoking tolerances. (21 U.S.C. 346a(b)(2)(D)(vi)) In FFDCA section 408(b)(2)(D)(vi), EPA must consider "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue,* and exposure from other non-occupational sources." (*Id.* (emphasis added))

The requirement to consider "aggregate exposure" was added to the FFDCA through the FQPA amendments in 1996. (Food Quality Protection Act of 1996, Pub. L. 104–170) Prior to the enactment of the FQPA, when assessing risk, EPA treated exposures from different pathways as independent events and made no concerted effort to evaluate potential exposures simultaneously. In reality, however, exposures to pesticides do not occur as single, isolated events, but rather as a series of sequential or concurrent events that may overlap or be linked in time and space. Congress, in enacting the FQPA, was concerned with ensuring that the Agency's assessments under the FFDCA would be strictly health-protective and risk-based, and as a result, made a number of significant amendments to the FFDCA, including the new risk-only safety standard, the FQPA children's safety factor, and, of most relevance here, a new requirement for EPA to consider exposures in the ag ate rather endently. owing the of the FQPA, EPA developed guidance on how to conduct aggregate exposure and risk assessment. (Ref. 14) That guidance describes the aggregate exposure and risk assessment as involving "the analysis of exposure to a single chemical by multiple pathways [food, drinking water, residential] and routes of exposure [oral, dermal, inhalation] . . . . All potential, relevant routes of exposure are analyzed with an aggregate exposure assessment." (*Id.* at pg. 4) That guidance also defines aggregate risk as "[t]he likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to a single substance." (*Id.* at pg. 72) In describing how EPA intends to conduct such aggregate risk assessments, EPA states that "[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide," which are determined by looking to labeled allowable use patterns. (*Id.* at pgs. 24, 44 and 45) Moreover, the guidance directs that aggregate exposure and risk should be estimated for major identifiable subgroups of the population, which the Agency typically does through considerations of demographics (*e.g.,* age, gender, racial/ethnic background) and temporal (season) and spatial (geographics) characteristics of potentially exposed individuals. (*Id.* at pgs. 12, 24)

The Aggregate Exposure Guidance describes an approach for assessing aggregate exposures that recognizes such exposures to hypothetical individuals in the population: "(1) may occur by more than one route (*i.e.,* oral, dermal and/or inhalation); (2) may originate from more than one source and/or pathway (*i.e.,* food, drinking water, and residential); (3) may occur within a time-frame that corresponds to the period of exposure required in an appropriately designed toxicity study to elicit an adverse toxicological effect; (4) should occur at a spatially relevant set of locations that correspond to an individual's potential exposure; and (5) should be consistent with the individual's demographic and behavioral attributes." (*Id.* at pg. 26) In practice, this means that the Agency might consider whether different populations of individuals are more or less likely to eat different kinds of food over different time periods; whether pesticide concentrations in drinking water vary temporally due to the growing season calendar or spatially due to the nature of applications generally being localized or regional; and/or whether different populations are likely to use or be exposed to pesticides in non-occupational settings. Generally, EPA would utilize upper-end estimates to ensure protection for the most vulnerable populations, unless other factors warranted a different approach.

From there, the Agency assesses the aggregate exposure through relevant routes of exposure for hypothetical individuals among these major identifiable subgroups (including food, drinking water, and residential exposures to which that individual is likely exposed), taking into consideration the various factors for co-occurrence of exposures in the various exposure pathways. (*Id.* at pg. 26) Where risks from aggregate exposures exceed safe levels, EPA will examine whether refinements can be made to the assessment. (*Id.* at pg. 13)

In the final rule, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance. That

assessment considered exposure through oral, dermal, and inhalation routes of exposure that could result from exposures in food, drinking water, and residential uses. Taking into consideration the registered use patterns for chlorpyrifos, EPA assessed the universe of potential exposures from all currently approved uses of chlorpyrifos because no formal steps had been taken to limit those uses.

In demanding that EPA retain tolerances for the 11 uses, the Objectors essentially argue that EPA should have presumed that individuals would only be exposed to chlorpyrifos from the 11 uses because EPA proposed those 11 uses as an option for mitigation in the 2020 PID proposal. However, that argument ignores the premise in the PID that the safety finding for those uses is contingent on all other uses being cancelled and the remaining 11 uses being restricted both geographically and with lowered use rates. Exposures from those uses alone could not reasonably be considered as "anticipated" since they did not yet (nor did EPA have reason to believe that they would) reflect the exposures people would be exposed to in the real world. The FFDCA requires EPA to determine whether tolerances *are* safe, requiring consideration of aggregate exposures, including "anticipated dietary exposures"; it does not allow EPA to leave tolerances in place if they *would be* safe at some unspecified time in the future based on certain mitigation that may not be implemented.

At the time of the final rule, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: No uses had been cancelled, nor had any labels been revised to geographically limit applications or limit maximum application rates. Although there were discussions with registrants and indications of a willingness to mitigate uses (see discussion in next sub-unit), the Agency had not received prior to the issuance of the final rule from registrants any formal requests under FIFRA for voluntary cancellation or applications to amend labels, to which the Agency could point as directionally supportive for a conclusion that exposures would at some future time be limited to that subset of chlorpyrifos applications. Until such uses cease—or at least until EPA has a reasonable basis to believe that they will cease—the Agency could not ignore the exposures from those uses. In sum, the 2020 PID proposal, without more, is just a proposal; it does not support an EPA assumption that aggregate exposures would be limited to that subset of uses instead of an assessment based on the actual registered uses and ongoing real-world applications of chlorpyrifos.

While the Objectors claim that EPA could have modified tolerances, as per the Court's order, by leaving in place only those identified in the 2020 PID, doing so, without accompanying registration actions under FIFRA, would have put EPA in the position of picking "winners and losers" among the tolerances. While, under FIFRA, EPA might be able to make an argument that some uses contribute relatively lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment whereas others may not, considerations of those relative benefits is not a factor for consideration under the FFDCA when determining which tolerances are safe or not. As noted previously, the 2020 PID proposal reflected one possible subset of uses that might warrant retention based on economic considerations. In circumstances where aggregate exposures exceed safe levels, there are potentially multiple variations of the potential subset of tolerances that might meet the safety standard and that EPA did not analyze. As such, EPA's general policy is to defer to the pesticide registrant and the public to determine which of the various subsets of tolerances are of sufficient importance to warrant retentions since not all parties might agree on the particular combination that should be retained. For example, one comment submitted on the 2020 PID requested that EPA retain tolerances on cranberries (Ref. 48), which was not listed among the 11 uses in the PID. Without some reasonable basis to believe that the uses would be limited as had been proposed, EPA did not have a basis to assume anticipated exposures would be limited to that particular subset of uses for purposes of modifying the tolerances.

Some Objectors made this same argument but focused more specifically on their crop of interest (*e.g.*, cherry, citrus, soybean, sugarbeet). These objectors assert that EPA could not have revoked the specific commodity tolerance because that crop was included in the list of crops EPA proposed to retain and thus EPA did not have a basis for concluding that those tolerances themselves were unsafe. However, the Agency does not assess tolerances for each crop in a vacuum; whether one tolerance is safe depends on whether aggregate exposure from that tolerance and all other tolerances in effect are safe. (21 U.S.C. 346a(b)(2)(D)(vi)) The consequence of the FFDCA requirement for EPA to assess the safety of tolerances as an aggregate is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels. At the time the final rule was issued, there were over 80 tolerances in effect, which the Agency was required to consider in its aggregate exposure assessment, unless there had been a reasonable basis to exclude exposures from those tolerances. The list in the 2020 PID was only a proposed mitigation measure, necessary because the aggregate exposures from chlorpyrifos, which included exposures from use of chlorpyrifos on these three commodities, exceeded safe levels.

It is also worth noting that tolerances themselves are broadly applicable rules that regulate the amount of pesticide residues on a food commodity. As such, they are not limited in geographic scope, and the Agency must be able to determine that all aggregate exposures from any registered uses (including all relevant geographic areas) that would be covered by a particular tolerance would be safe. For example, the tolerance covering residues of chlorpyrifos on cherry applies to the pesticide residues on the crop regardless of the location of application. In practice, this means that EPA needs to be able to determine that use of chlorpyrifos in any place permitted by the FIFRA label would be safe. For cherries, EPA's 2020 PID proposal only concluded that use on cherry could be safe in Michigan, if the other aforementioned mitigation measures were implemented; whether cherry use could be safe in other areas was not assessed. In order to conclude that cherry use was safe based on the 2020 PID proposal, the labels would need to restrict chlorpyrifos use to cherries only in Michigan. Since the uses on cherry were not so restricted under FIFRA at the time of the final rule, EPA could not assume that chlorpyrifos would be used only in the limited geographical regions without some progress being made on the label revisions.

In conclusion, while the 2020 PID proposed that there is at least one subset of chlorpyrifos uses that could be safe if additional restrictions were adopted and all other uses contributing to aggregate exposures were cancelled under FIFRA, that is not a basis for maintaining tolerances when the Agency does not have a reasonable basis to believe that the registrations would be so amended. Based on the factual realities at the time of the final rule, EPA was required to consider aggregate exposures resulting from approved labelling and all currently registered

uses. The Objectors' claim incorrectly relies on the proposal in the 2020 PID as a basis for limiting the aggregate exposure assessment, and the request to limit EPA's safety assessment to a subset of actual exposures based on a proposal would reflect an incorrect application of the statutory standard under the FFDCA. EPA recognizes that the practice of identifying mitigation measures to address risks of concern in the proposed or interim decisions in registration review is common, and the expectation is that registrants will make adjustments to retain registrations. However, this is not always the case; some registrants may suggest alternative means of mitigating risks, which the Agency then needs to evaluate, or may refuse due to a disagreement with the Agency's underlying rationale for its decision. When mitigation measures are not implemented (or it is unclear that such risks will be mitigated), the risks that EPA initially identified remain. Therefore, the objection is denied.

b. Coordination With FIFRA Under FFDCA Section 408(l)(1)

i. Objection. Objectors assert that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA. The Sugarbeet Associations and Gharda argue that EPA had a statutory duty under section 408(l)(1) of the FFDCA to harmonize the chlorpyrifos tolerance revocation with necessary actions under FIFRA. (Refs. 37 and 39) They argue that EPA offers no explanation for why it was not practicable for EPA to cancel the FIFRA registrations and revoke tolerances for the food uses for which EPA would be unable to make a safety finding while maintaining the registrations and tolerances that the 2020 PID proposed for retention. The Sugarbeet Associations also argue that because the Ninth Circuit also ordered EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion," EPA's failure to harmonize its revocations with FIFRA actions is therefore also inconsistent with the Court's order. (Ref. 37 at pg. 7) Gharda acknowledges that EPA did engage in negotiations with registrants to attempt this harmonization but alleges that EPA was acting in bad faith in those negotiations and disregarded Gharda's commitment to modify its registration. (Ref. 39 at pgs. 28 through 31) The Minor Crop Farmers Alliance notes that EPA did not follow "its traditional FIFRA/FQPA sequencing of taking the necessary tolerance actions only after first finalizing its decision in a cancellation action under Section 6 of FIFRA." (Ref. 49 at pg. 4) Finally, CLA/RISE requests guidance on how EPA intends to harmonize the tolerance revocation under FIFRA to reduce confusion among growers and industry. (Ref. 50)

ii. Denial of objection. EPA denies this objection on the following legal and factual grounds. FFDCA 408(l)(1) states that "[t]o the extent practicable . . . , in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA]." (21 U.S.C. 346a(l)(1)) While the statutory language includes the word "shall," this provision clearly contemplates that there may be circumstances in which coordination is not practicable and thus such coordination is not required. Even when such coordination would be practicable, the statute does not require that this coordination be concurrent or occur in any predetermined order.

EPA has previously opined on this provision in a final rule revoking carbofuran tolerances in which this same comment was raised. (See 74 FR 23046, 23069–70, May 15, 2009 (FRL–8413–3)) In that rule, EPA found that the requirement to "coordinate" is a direction to ensure that the substance of actions taken under FIFRA and the FFDCA are consistent, and that the Agency make a determination as to the proper order of action under the two statutes. It cannot be read as a requirement that actions under FIFRA precede actions under the FFDCA, or that any particular order for EPA actions is necessarily required. Accordingly, there is no support for the notion that, as a matter of law, the Agency lacks the legal authority to revoke pesticide tolerances under the FFDCA that do not meet the safety standard of that statute unless the Agency has first canceled—or simultaneously cancels—associated pesticide registrations under FIFRA.

In this instance, the Ninth Circuit itself prioritized EPA's taking action on the chlorpyrifos tolerances above the action necessary under FIFRA, when it set a very short and specific deadline for addressing pesticide tolerances (*i.e.*, within 60 days of the issuance of the mandate) and allowed flexibility for EPA to "modify or cancel related FIFRA registrations for food use in a timely fashion." (*LULAC*, 996 F.3d at 703–04) Under the Court's timeframe, it was not practicable for EPA to take action under FIFRA to cancel registered food uses of chlorpyrifos concurrently with the final rule. Cancellation of uses under FIFRA section 6(b) requires several steps, including drafting a notice of intent to cancel, interagency coordination and SAP review, as well as possible administrative hearings, and can take several years to complete. (See 7 U.S.C. 136d(b)) Even the process to obtain and act on voluntary cancellation requests can be a time-consuming process with statutorily set comment periods before a cancellation can be ordered. (7 U.S.C. 136d(f))

In any event, in this particular instance, EPA did attempt to harmonize its tolerance revocation actions with cancellation actions under FIFRA. As the Minor Crop Farmer Alliance pointed out, EPA traditionally, as part of the registration review process, identifies the relative risks and benefits of particular uses and works with registrants to eliminate uses that no longer meet the FIFRA standard, including for safety risks. Under that approach, EPA and the registrant(s) can mutually agree on terms for the smooth phase-out of the product, and the product or use cancellations can be coordinated with tolerance revocations under the FFDCA. After the Ninth Circuit's decision was issued, EPA engaged in discussions with the four registrants of technical chlorpyrifos products (*i.e.*, those that are used to manufacture the chlorpyrifos pesticide products sold to end users) to discuss possible voluntary use cancellations and label restrictions, although EPA did not initiate any discussions with the dozens of registrants of end-use products. (Ref. 51) Despite the progress made in those discussions, no registrant submitted under FIFRA a request for voluntary cancellation of any uses or application to amend existing chlorpyrifos labels to reduce application rates and geographically limit uses. One of those registrants, Gharda, asserts that EPA acted in bad faith in the negotiations with Gharda and disregarded a commitment from Gharda to modify its registration. EPA disagrees with Gharda's characterization of the negotiations.

Prior to the issuance of the final rule, EPA entered into discussions with Gharda, as well as several other registrants, in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. EPA held several meetings with each of the technical registrants, including Gharda, to discuss their interests and concerns as EPA considered its response to the Court's directive to issue a final rule. (*Id.*) The meetings with Gharda occurred on May 27, June 3, June 17, June 24, July

14, and August 16, 2021. As Gharda's objection filing indicates, there was an extensive amount of back-and-forth between EPA and Gharda concerning restrictions to the current registrations and an attempt to work out mutually agreeable terms (*e.g.*, uses to be retained, geographic limitations on uses, retention of import tolerances, timing for phase-out of existing uses) to provide a reasonable basis for assuming aggregate exposures could be limited to the 11 uses proposed for retention in the 2020 PID.

Gharda asserts, in its objection, that EPA disregarded a written commitment to voluntarily cancel uses and therefore, the Agency's decision to revoke all tolerances was arbitrary and capricious. (Ref. 39 at pgs. 28 and 29) EPA acknowledges that Gharda submitted two such letters to the Agency; however, the question is whether those letters provided a legal basis for any EPA regulatory determination, *e.g.*, whether to retain tolerances for the 11 uses assessed in the PID. EPA concludes that they did not.

On their face, Gharda's letters fall far short of actually requesting voluntary cancellation of their registered uses. Gharda's first letter says that it is "willing to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users." Gharda requests that any agreement with EPA to voluntarily cancel uses include several key terms, including further discussion of the geographic restrictions set forth in the PID as to the 11 crops, allowing use on crops in addition to the 11 uses in the PID, phase-out schedules that would allow some uses to continue until 2026 (5 years after the Court ordered EPA to issue a final rule revoking or modifying tolerances), additional existing stocks orders that would allow additional time for phase-out, retention of all import tolerances, etc. (Ref. 39 at Exhibit B to Gharda's objection, Letter from Gharda to EPA (May 12, 2021)) Gharda's second letter states that "Gharda commits to voluntarily cancel all currently approved agricultural uses of chlorpyrifos other than uses for the 11 high-benefit agricultural crops in select regions that the Agency has identified [in the PID] . . . . subject to [several] conditions." Those conditions included allowing use on cotton in Texas (which the Agency had not determined would be safe under the limited conditions presented in the 2020 PID), existing stocks terms that allowed for sale of all finished Gharda technical product in the United States and overseas to be processed and sold until stocks were exhausted, retention of all "import tolerances," and allowing food treated with chlorpyrifos to clear the channels of trade. (*Id.* at Exhibit C, Letter from Gharda to EPA (June 7, 2021)) As Gharda's objection filing indicates, there were several other emails exchanged in which terms continued to be negotiated, and Gharda continued to seek agreement on various terms prior to submission of a voluntary cancellation request. (*Id.* at Exhibits D through J)

Contrary to Gharda's assertions, a conditional proposal does not provide a sufficient basis for EPA to conclude that uses will be cancelled and exposures will be reduced. By their terms the letters simply indicate an intent to keep discussing the issue and a willingness to initiate the process to cancel uses provided other conditions can be agreed upon. The implication in Gharda's letter was that if agreement could not be reached on the other conditions, then no such voluntary cancelation request would be forthcoming. And as indicated previously, Gharda's proposal was initially contingent upon EPA allowing use on crops beyond the 11 identified in the PID, which EPA had not assessed and proposed to find safe if other conditions were met. Although Gharda's subsequent email traffic indicated a willingness to drop those additional uses, given the Agency's safety concerns with the tolerances, EPA continued to express a concern about whether an extended existing stocks period would be considered consistent with the Ninth Circuit's order.

Typically, a formal request for voluntary cancellation of a pesticide registration or registered uses would involve the submission of a letter requesting cancelation of a product or uses and would also, in the case of deletions of certain uses, need to be accompanied with applications to amend relevant labels. (See *https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use*) While Gharda's letters indicate a willingness to continue negotiations with EPA, they do not constitute an actual request to cancel uses and thus do not provide a sufficient basis for EPA to conclude that aggregate exposures to chlorpyrifos would be limited to the 11 geographically limited uses identified in the 2020 PID proposal.

It should also be noted that Gharda's voluntary cancellation request alone would not be sufficient to support a conclusion that all registered uses would be cancelled since other products are registered for those uses as well. Other registrants would have also needed to submit voluntary cancellation requests and label amendments, and as indicated previously, that has not happened.

Unlike negotiations that are typically conducted as part of registration review, this situation involved a tight deadline for a final Agency rulemaking and thus a very short period of time to resolve differences and allow EPA to develop a final rule that incorporated any such resolution. In light of the Ninth Circuit's impending deadline for issuing a final rule and the lack of a mutually agreeable resolution to the remaining issues in a timely manner, it simply was not practicable for EPA to continue negotiating these terms.

While it is understandable for Gharda to be disappointed, Gharda erroneously asserts now, based on the lack of resolution in time for the final rule to be completed by the Court's deadline, that EPA's rule is arbitrary and capricious. This simply is not true. Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question. As noted in the denial of the previous objection, EPA determined that the tolerances were not safe, based on the assessments EPA had completed at the time and aggregate exposures resulting from the uses in place at the time of the final rule.

It is worth noting that, although the Agency/registrant negotiations prior to the final rule ended without resulting in use cancellations or label amendments under FIFRA, any registrant is authorized at any time, without prior EPA consent, to take initiative and submit a request to voluntarily cancel uses on its registration or to submit an application seeking amendments to its label to restrict uses. Upon submission of such a request, EPA would consider that request and publish a notice of receipt of a voluntary cancellation request, and for situations like chlorpyrifos, take into consideration whether that request would have an impact on the Agency's ability to support a safety finding, in light of uses remaining on other registered products. For chlorpyrifos, however, no such submissions were submitted to with the Agency prior to the issuance of the final rule. While there were communications from Gharda indicating an intent to amend registrations and cancel uses, with an extended existing stocks period to allow for continued sale and distribution of their chlorpyrifos inventory, no formal steps were taken

under FIFRA to put those processes in action.

c. Import Tolerances

i. Objection. Gharda, the Agricultural Retailers Association, *et al.,* and CLA/RISE argue that EPA should have retained import tolerances (*i.e.,* tolerances covering pesticide residues for commodities that are imported into the United States) for chlorpyrifos commodities. (Refs. 39, 47 and 50) These Objectors assert that because EPA's final rule noted that food exposures and non-occupational exposures do not exceed levels of concern—rather, risks are driven by exposures to chlorpyrifos in drinking water—EPA could conclude that import tolerances, which would not contribute to drinking water exposures, would be safe. The Objectors assert that there is no science-based reason to revoke tolerances as they apply to food imported with chlorpyrifos residues. CLA/RISE cites to EPA's guidance entitled, "Pesticides; Guidance on Import Tolerances & Residue Data for Imported Food" ((65 FR 35069, June 1, 2000) (FRL–6559–3)), and legal precedent for support for the retention of import tolerances. (Ref. 50)

ii. Denial of objection. This objection is denied because, as a matter of law, where aggregate exposures from pesticide use exceed safe levels, EPA cannot leave tolerances in place, even if those tolerances just cover residues in imported foods.

As a legal matter, tolerances established under the FFDCA apply to pesticide residues in or on food moving through interstate commerce, regardless of whether those residues came from use of a domestically registered pesticide or from application of a pesticide overseas to a food that is then imported into the United States. As a matter of law, EPA does not separately establish "import tolerances" that apply exclusively to imported commodities. The term "import tolerance" is a term of convenience that refers to tolerances for pesticide residues in an imported food where there is no corresponding U.S. registration for that pesticide on that particular commodity; however, there is no statutory or regulatory distinction between a tolerance covering pesticide residues in imported commodities and tolerances covering pesticide residues from use of a pesticide product registered in the United States. Once established, that tolerance would cover pesticide residues in that particular commodity, regardless of how residues came to be present in the food.

It is correct that imported food treated with a pesticide would only contribute to aggregate exposures through the residues that are present on the imported commodity. Imported foods do not result in additional drinking water and residential contributions to exposure because the pesticides are used overseas, not domestically. Nevertheless, the pesticide residues on the imported food must be aggregated with all the other food, drinking water, and residential exposures to that pesticide that occur in the United States, as part of the safety determination and consideration of aggregate exposures for that pesticide. If the domestic uses of that particular pesticide already exceed safe levels, EPA would not be able to approve the new import tolerance, even if the relative contributions from the imported commodities was very minor because the safety assessment of that tolerance requires a consideration of "aggregate exposures" from all other tolerances in effect.

For chlorpyrifos, since domestic use of chlorpyrifos in accordance with currently approved labeling results in aggregate exposures that exceed safe levels, due to drinking water concerns, all tolerances, including those covering imported commodities, are unsafe and must be revoked. Until domestic use ceases—or EPA has a reasonable basis to believe that it will cease—the risks from drinking water need to be assessed in EPA's risk assessment. Once domestic uses are cancelled and aggregate exposures are reduced below the Agency's levels of concern for safety, EPA could consider whether risks from exposures in or on imported food would be safe. Again, this is a consequence of the requirement under the FFDCA to consider aggregate exposures from all uses; when one tolerance is unsafe, all are equally unsafe until aggregate exposures have been reduced to levels that are below the Agency's level of concern.

CLA/RISE cite EPA's *Guidance on Import Tolerances* to encourage EPA to consider and approve requests to retain import tolerances. This guidance, however, does not provide a legal basis for retaining import tolerances under the current circumstances. Rather the guidance document describes how EPA may consider requests for modifying or maintaining tolerances to allow the continue import of food treated with a pesticide, where "domestic uses are canceled . . . for any other reason (other than dietary risk)" as long as EPA can make the required safety finding. (65 FR at 35072) For chlorpyrifos, no domestic uses have been cancelled to date, which precludes EPA from making the required safety finding.

CLA/RISE also point to the D.C. Circuit Court's decision in *National Corn Growers Ass'n* v. *EPA,* 613 F.3d 266, as instructive here. In that case, the Court ordered EPA to reinstate import tolerances for the pesticide carbofuran because the Agency had received requests for retaining those tolerances and because EPA had concluded that exposure from imported foods alone was safe. (*Id.* at pg. 275)

This present case is distinguishable in that for the carbofuran situation, the import tolerances at issue had no domestic registrations for the commodities covered by those tolerances. This fact was specifically identified by footnotes to the tolerances for those commodities. For chlorpyrifos, there are no specifically designated import tolerances, although the Agency notes that there is a tolerance for chlorpyrifos on banana, for which there are no U.S. registrations. To the extent there were requests for retention of import tolerances prior to the issuance of the final rule, such requests were to leave *all* current tolerances in place, in order to accommodate chlorpyrifos use in other countries on any of the commodities for which tolerances were set. Because those uses would overlap with domestic uses, the Agency could not exclude other non-food exposures associated with those uses until those domestic uses were cancelled.

EPA recognizes that the Republic of Colombia, in its objections, requested the retention of the banana tolerance; however, EPA denies that request since EPA is unable, at this time with the existing domestic uses still being registered, to make a safety finding for the banana tolerance. While after *National Corn Growers Ass'n* was decided, the import tolerances were reinstated for commodities that had no domestic uses, that reinstatement occurred after the other domestic uses that had resulted in unsafe aggregate exposure levels had been cancelled, thus obviating the need to tackle a potential aggregate exposure issue involving residues from both domestic and imported food. (*See* Carbofuran; Product Cancellation Order ((74 FR 11551, March 18, 2009) (FRL–8403–6)) (announcing FMC Corporation's voluntary cancelation of its carbofuran registrations for all but six crops); Carbofuran; Reinstatement of Specific Tolerances and Removal of Expired Tolerances ((80 FR 21187, Apr. 17, 2015) (FRL–9925–70)) (EPA reinstatement of import tolerances for carbofuran for banana; coffee, bean, green; rice, grain; and sugarcane, cane))

Here, all registrations of chlorpyrifos remain intact and uses in accordance with the labels are still contributing to drinking water concentrations that result in aggregate exposures exceeding safe levels. Therefore, for chlorpyrifos, the Agency cannot make the safety finding for leaving tolerances in place to accommodate imports until sufficient uses are cancelled that reduce aggregate exposures to acceptable levels.

2. Retention of the 10X Food Quality Protection Act (FQPA) Safety Factor

a. Objection

Several Objectors (Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.*, Minor Crop Farmer Alliance, California Citrus Quality Council, and Coalition of OP Registrants) claim that EPA acted unlawfully in retaining the 10X FQPA safety factor based on the epidemiology data. (Refs. 37, 39, 47, 49, 52 and 53) Objectors assert that the epidemiological data was invalid and unreliable and should not been considered nor should it have been relied upon to introduce "scientific uncertainties" into the Agency's assessment of chlorpyrifos. In light of the alleged defects with the epidemiological studies, the Objectors assert EPA had no basis to retain the 10X FQPA safety factor, given the balance of toxicity data on chlorpyrifos.

b. Denial of Objection

As an initial matter, EPA points out that the Objectors have failed to identify an issue that supports a retention of the chlorpyrifos tolerances or changing the EPA's final rule, even if what the objectors assert is correct. Even if the Agency agreed that the epidemiological data should not have been considered by the Agency or that available data support a reduction of the FQPA safety factor to 1X, as indicated in the 2020 PID, EPA would not have been able to determine that chlorpyrifos tolerances were safe without some uses being cancelled and other uses being modified.

The 2020 PID provided estimates of potential risks based on retention of the 10X FQPA safety factor and on a reduced FQPA safety factor of 1X. The previous sub-unit discussed the need to cancel all uses besides the 11 uses identified for retention and the need for label amendments to geographically restrict applications and to reduce maximum application rates, if EPA retained the 10X FQPA safety factor. For the 1X scenario, EPA concluded that "the majority of labeled chlorpyrifos uses result in drinking water concentrations below the DWLOC." (Ref. 31 at pg. 41) The "majority," however, is not all, and thus, EPA noted that three uses still resulted in EDWCs above the DWLOC (peppers, trash storage bins, and wood treatment), and six uses would need to be restricted to certain states and application rates adjusted consistent with assessed usage data in order to ensure that concentrations of chlorpyrifos in drinking water did not exceed safe levels. (*Id.*) In other words, uses as registered at the time EPA issued the 2020 PID—and at the time of the final rule—still resulted in aggregate exposures that were not safe under a scenario in which EPA applied a 1X FQPA safety factor. Since some uses would result in exposures of chlorpyrifos that exceeded the Agency's safe levels, EPA would not have been able to determine that the tolerances were safe, even with the FQPA safety factor being reduced to 1X. If EPA had had a reasonable basis to assume that such uses resulting in exceedances would cease, EPA may have been able to aggregate only those uses that were expected to continue. As there was no such basis at the time the final rule was issued—and, indeed at this time, there is still no such basis, EPA was required to look at aggregate exposures from all currently registered uses, as those exposures were anticipated to continue. Therefore, since the Objectors have failed to state a claim upon which the relief they seek (leaving the tolerances in place) can be granted, this objection is denied.

Notwithstanding this denial, EPA disagrees with the assertions made by Objectors with regard to the Agency's decisions to rely on the epidemiological data and retain the 10X FQPA safety factor as discussed in this unit. For ease of addressing this claim, EPA is breaking this objection into two subissues: (1) Whether it was reasonable for EPA to use the epidemiology data as part of its weight-of-the evidence analysis for assessing the potential pre- and postnatal toxicity relating to neurodevelopmental effects and (2) Whether EPA had "reliable data" to support a different margin of safety to protect infants and children based on the available record.

c. Background

Before responding to these objections, it is helpful to provide some background on the FQPA safety factor EPA used in the final rule to clarify the statutory standard, and to provide some background on EPA's FQPA safety factor policy.

i. Final rule. In the final rule, EPA retained the 10X FQPA safety factor due to uncertainty around the levels at which potential neurodevelopmental outcomes may occur in infants and children exposed to chlorpyrifos. The decision was based on the Agency's weight-of-evidence (WOE) analysis, which took into consideration the totality of available information on the toxicity of chlorpyrifos and the potential for neurodevelopmental outcomes associated with chlorpyrifos exposure. That information included laboratory animal studies, epidemiological studies, and available mechanistic data, as described in Unit III.A.1.b. of this document.

In essence, the WOE analysis concluded that there was qualitative evidence of a potential effect on the developing brain; however, due to insufficient clarity on the levels at which these neurodevelopmental outcomes occur relative to levels at which cholinesterase inhibition occurs, the science addressing neurodevelopmental outcomes remained unresolved in a manner sufficient to quantify these effects. Due to the remaining uncertainties, EPA was unable to conclude at the time of the final rule that a different safety factor would be sufficient to protect infants and children from potential pre- and postnatal toxicity related to neurodevelopmental effects. (Ref. 1 at pg. 48327)

ii. FFDCA section 408(b)(2)(C) and EPA's FQPA safety factor policy. Through the FQPA, Congress significantly amended the FFDCA, to establish a new stringent health-based standard ("reasonable certainty of no harm") and add a new provision providing heightened protections for infants and children. (21 U.S.C. 346a(b)(2)(C)) That provision directs EPA to consider available data on, among other things, the "special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals." (21 U.S.C. 346a(b)(2)(C)(i)(II)) Moreover, EPA is required to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide. (21 U.S.C. 346a(b)(2)(C)(ii)(I)) When making that safety determination for infants and children, EPA is required to apply, in the case of threshold effects, an additional tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)) This provision

permits a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." (*Id.*) Thus, EPA interprets this provision as establishing a presumption in favor of applying the default 10X safety factor, which can be departed from only if reliable evidence show that a different factor would be protective of infants and children.

In 2002, EPA issued guidance on how OPP intends to make determinations regarding the FQPA safety factor when developing risk assessments for pesticides ("FQPA Policy Paper") (Ref. 9) While not binding, that document provides helpful background and clarification on the process for determining the appropriate FQPA safety factor. Ultimately, the decision to retain the default 10X FQPA safety factor or use a different factor depends on level of confidence in the risk assessment and the degree of concern for any susceptibility or residual uncertainties in the toxicity and exposure databases. (*Id.* at 50) A lower level of confidence and a higher degree of concern will support retention of the default 10X FQPA safety factor. Because the chlorpyrifos 10X FQPA safety factor decision relates primarily to the concern for potential pre- and postnatal toxicity, this discussion focuses on those aspects of the guidance, although it also covers concerns related to the completeness of the toxicity and exposure databases.

Before making any determination on the FQPA safety factor, OPP will review all available and relevant toxicological data and determine whether the chemical has any potential to cause adverse effects in infants and children, *i.e.*, potential pre- and postnatal toxicity or special susceptibility. (*Id.* at pg. 8) The FQPA Policy Paper states, "In general terms, there is increased susceptibility or sensitivity when data demonstrate unique effects (*e.g.*, a different pattern of effects of concern) or adverse effects in the young that are of a type similar to those seen in adults, but occur either at doses lower than those causing effects in adults, occur more quickly, or occur with greater severity or duration than in adults." (*Id.* at pg. 30) If the toxicity data indicate no concern for pre- and postnatal toxicity or special susceptibility, then the presumption for the 10X factor should be treated as obviated with respect to the potential for pre- and postnatal toxicity. In contrast, if the toxicity data indicate pre- and postnatal toxicity, then OPP will assess the level or degree of concern for the potential for those effects, taking into consideration the degree to which the traditional uncertainty factors provide protection for infants and children. (*Id.* at pg. 29)

EPA typically uses a WOE approach for making judgments about the degree of concern for potential pre- and postnatal toxicity, in the context of the entire database, taking into consideration the quality and adequacy of the data, and the consistency of responses induced by the chemical across different studies. (*Id.* at pg. 30) The FQPA Policy Paper notes that this integrative approach is important because "for example, positive animal findings may be diminished by other key data (*e.g.*, toxicokinetic or mechanism of toxicity information), or likewise, a weak association found in epidemiological studies may be bolstered by experimental findings in animal studies." (*Id.* at pg. 31) Moreover, it is important to consider other factors concerning the biological responses observed in the young relative to the adult effects, such as "progression, severity, recovery time or persistence, and dose-response . . . . For example, there would be greater concern for effects that were irreversible and of a greater potential consequence to the young compared to observed effects in adults that are of a transient and minimal nature, even when they occur at the same dose." (*Id.* at pg. 33) The FQPA Policy Paper notes that "[w]hen sufficient human data are available to judge that an adverse developmental outcome is related to exposure, the degree of concern increases," although "sufficient human evidence is very difficult to obtain." (*Id.*) Another factor influencing the degree of concern is the relationship between dose and response. Where the dose-response relationship is well-characterized, there is a lower degree of concern, whereas in cases where the opposite is the case, the degree of concern may increase. (*Id.* at pg. 34) Finally, mechanistic data can be helpful in evaluating the degree of concern. (*Id.*)

In some cases, concerns regarding pre- and postnatal toxicity can be addressed by calculating a protective reference dose or margin of exposure based on relevant endpoints in the offspring or through the use of traditional uncertainty factors. (*Id.* at pg. 35) OPP risk assessors will consider whether the developmental and offspring effects are well-characterized in the toxicity database and if other appropriate uncertainty factors are already applied for calculating a protective RfD; if so, then "there would normally be no need for an additional FQPA safety factor to address potential pre- and postnatal toxicity." (*Id.*) However, in some instances, "data may raise uncertainties or a high concern for infants or children which cannot be addressed in the derivation of an RfD or MOE". (*Id.* at pg. iv) If so, "those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor . . . ." (*Id.* at pg. 35)

If there is a high level of confidence that the combination of the hazard and exposure assessments is adequately protective of infants and children, then the presumption in favor of the additional 10X default FQPA safety factor would be obviated and the risk assessor should recommend that a different FQPA safety factor be applied . . . . Conversely, if the risk assessor finds evidence of pre- or postnatal toxicity or problems with the completeness of the toxicity or exposure databases and these uncertainties have not been adequately dealt with in the toxicity and/or exposure assessments (through use of traditional uncertainty factors or conservative exposure assumptions), then the default additional 10X safety factor should be retained." (*Id.* at pgs. 51 and 52)

If the degree of concern for the potential pre- or postnatal uncertainty is high, the default 10X FQPA safety factor will typically be retained, unless there is "reliable data" to account for and describe the level of uncertainty regarding the potential for pre- or postnatal toxicity. (*Id.* at pg. 30) "If the uncertainty can be addressed by reliable data, the risk assessor should recommend use of a different FQPA safety factor . . . to protect the safety of infants and children." (*Id.*) In the FQPA Policy Paper, EPA explains that "reliable data" must "be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action." (*Id.* at pg. A–5) As part of determining whether a different margin of safety would be safe, the paper indicates that the risk assessment should focus on whether the "combination of data and reasonable scientific judgment," taking into account relevant information and data, would lead to a conclusion that the "hazard or exposure . . . will not be underestimated." (*Id.* at pg. A–8)

d. Reliance on Epidemiological Data

i. Objection subissue. The Objectors assert that EPA's retention of the 10X FQPA safety factor to account for scientific uncertainties in the epidemiological data was unlawful. Citing the lack of underlying data and EPA's inability to reproduce or verify the conclusions of the studies, the Objectors claim that the epidemiological data are incomplete, invalid, and unreliable. As a result, Objectors argue

that the "scientific uncertainties" in those epidemiological data cannot be used to justify retention of the 10X FQPA safety factor. Gharda also asserts that the FFDCA does not allow application of the 10X FQPA safety factor based on unreliable epidemiological studies, "particularly where a 10X safety factor results in the elimination of many important crop uses." (Ref. 39 at pg. 48) In essence, the Objectors are arguing that EPA acted arbitrarily and capriciously in considering the epidemiological studies in its WOE analysis.

ii. Denial of objection subissue. To the extent the Objectors are arguing that EPA cannot, as a matter of law, rely on epidemiological studies where the underlying raw data is unavailable or EPA cannot independently verify or reproduce the studies' conclusions, that objection is denied. There is no requirement for epidemiological studies to be supported by the raw data before the Agency can rely on them. On the contrary, a rule promulgated in January 2021, which would have required EPA to give heightened consideration to studies for which underlying data were publicly available, was judicially vacated one month after its issuance. (*EDF* v. *EPA*, 515 F. Supp. 3d 1135 (D. Mt. Jan. 27, 2021); 86 FR 29515, June 2, 2021 (FRL–10024–32–ORD) (removal of regulatory provisions from Code of Federal Regulations))

Significantly, the idea that these epidemiological studies are unreliable without the raw data was soundly rejected by the Ninth Circuit as applied to the chlorpyrifos studies. In a departure from its previous statements about the epidemiological studies, in the 2019 Denial Order and in the attendant litigation, EPA argued that the epidemiological data was invalid, incomplete, and unreliable due to the lack of underlying data and thus should not be considered by the Agency in assessing chlorpyrifos. The Ninth Circuit rejected EPA's reasoning as follows:

"[W]hile the EPA might reasonably conclude that divergences from international protocols and lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCA requires the EPA to consider the "information" that is "available" and to make a safety determination based on that information. In this case, live animal studies showing sex-linked, neurotoxic harms from *in utero* chlorpyrifos exposure are available—even if such studies are supposedly not perfectly aligned with (unspecified) international standards. And peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available—even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: Speculation. Such speculation "runs counter to the evidence before the agency," so it cannot form the basis for denying the 2007 Petition." (*Id.* pgs. 699 and 700 (citations excluded))

Moreover, in its recent framework document concerning the use of epidemiology studies, EPA recognizes that it is quite common and understood that certain information may be unavailable in epidemiology studies or suffer some limitations that may impede their use in quantitative risk assessment. (Ref. 19 at pgs. 10 and 16) That does not mean EPA cannot rely on these studies or use them to inform risk assessment. Often, such studies can "provide insight into the effects cause by actual chemical exposures in humans and thus can contribute to problem formulation and hazard/risk characterization." In addition, epidemiological data "can guide additional analyses or data generations . . . , identify potentially susceptible populations, identify new health effects, or confirm the existing toxicological observations." (*Id.* at pg. 4) Epidemiology studies "have the potential to help inform multiple components of the risk assessment", *e.g.,* qualitative comparisons between outcomes in epidemiologic studies to those in *in vitro* and animal studies to evaluate the human relevance of animal findings or assessing the biological plausibility of epidemiologic outcomes. (*Id.* at pg. 16)

Turning to the epidemiology studies themselves, there is extensive evidence in the record to support EPA's scientific decision to include those studies as part of its WOE analysis. Until its statements in the 2019 Denial Order and attendant litigation, which was rejected by the Ninth Circuit, EPA had concluded that the three prospective cohort studies (CCCEH, Mt. Sinai, and CHAMACOS, as described in Unit III.A.1.b.ii. of this document) were "strong studies which support a conclusion that chlorpyrifos likely played a role in these [neurodevelopmental] outcomes." (Ref. 20 at pg. 33) Having considered the strengths and limitations of the studies, EPA concluded that the observed positive associations between *in utero* chlorpyrifos exposures and adverse neurodevelopmental effects were unlikely the result of errors in the design of the study. (*Id.*) While EPA did identify limitations in the studies, overall, EPA found the studies to be sound and worthy of consideration as part of a WOE analysis of available data concerning the potential pre- and postnatal toxicity of chlorpyrifos.

Under EPA's Epidemiologic Framework, "human health characterizations involve the consideration of all available and relevant data, including but not limited to human studies/epidemiology . . . ." (Ref. 19 at pg. 12) In evaluating epidemiology studies for use in pesticide risk assessment, EPA considers the "quality of epidemiologic research, sufficiency of documentation of the study (study design and results), and relevance to risk assessment." (*Id.* at pg. 21) EPA will take into consideration various aspects of the study, including, but not limited to, adequacy of the exposure assessment, sample population and statistical power of the study, reliability of identifying affected individuals, adequacy of method for identifying confounding variables, characterization of systematic biases, among others. (*Id.* at pgs. 22 through 36)

For the epidemiology studies incorporated into EPA's WOE analysis, EPA fully evaluated and characterized the strengths and limitations of those studies consistent with its Framework Document. (Ref. 20 at pgs. 32–49) Despite limitations in the studies, EPA found "considerable strengths in study design, conduct, and analyses demonstrated" in the three cohort studies, including using prospective birth cohorts as a strong study design; using several methods for measuring pesticide exposure; using well-established, validated analytical tools for ascertaining developmental outcomes; measuring, analyzing, and adjusting for potentially confounding variables. Balancing those strengths against the limitations (one-time measure of exposure to assess prenatal exposure, lack of assessment of influence of mixtures, and small sample size, as well as lack of understanding of a critical window of exposure), EPA concluded that "these data present an informative body of evidence with some notable consistencies across studies." (*Id.* at pg. 34)

Therefore, there is no merit to the Objectors' claim that it was unlawful for EPA to rely on the epidemiological studies in its assessment of chlorpyrifos. There is no requirement for the underlying data to be made available before EPA can rely on these studies,

and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children.

e. Whether There Are "reliable data" Supporting a Different FQPA Safety Factor

i. Objection subissue. By objecting to the retention of the 10X FQPA safety factor, the Objectors appear to assert that EPA had "reliable data" to support a different margin of safety than the default 10X FQPA safety factor. However, most Objectors (Sugarbeet Associations, Gharda, Minor Crop Farmer Alliance) argue that because the epidemiological data is allegedly unreliable, the data should not be utilized. (Refs. 37, 39, and 49) Thus, removing the epidemiological data from consideration erases "uncertainties" and removes the need to retain the default safety factor. As EPA has demonstrated, the epidemiological studies have been evaluated and have been determined to support the conclusion of a potential effect on the developing brain associated with chlorpyrifos exposure.

The Coalition of OP Registrants assert that the toxicological profile of chlorpyrifos and other OPs indicates that the acetylcholinesterase inhibition endpoint is protective of the neurodevelopmental effects and thus the 10X FQPA safety factor was unnecessary to protect infants and children. (Ref. 53) Moreover, although noting that work concerning the New Approach Methodologies (NAMs) is ongoing, the Coalition of OP Registrants and the Agricultural Retailers Association, *et al.*, assert that NAMs would also support the position that the acetylcholinesterase inhibition endpoint would be protective of adverse neurodevelopmental effects. (Refs. 47 and 53)

ii. Denial of objection subissue. As noted previously, the FQPA amended the FFDCA to include an additional tenfold margin of safety to ensure the protection of infants and children. EPA may use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." (21 U.S.C. 346a(b)(2)(C)) Thus, the presumption is to retain the 10X FQPA safety factor, unless there are reliable data to support a conclusion that a different safety factor will protect infants and children, taking into consideration potential pre- and postnatal toxicity and any residual uncertainties in the toxicity and exposure databases. Rather than requiring EPA to justify why the default factor is retained, the statute puts the burden on EPA to ensure that there are "reliable data" supporting a conclusion that a different safety margin would be protective for infants and children. Contrary to Gharda's implication, the FFDCA provides no flexibility for EPA to consider impacts on registrants or users of a pesticide when determining whether the available data is sufficiently reliable; this determination, much like the "reasonable certainty of no harm" standard is a purely risk-only standard, intended to ensure protection of infants and children from the harmful impacts of a pesticide.

As discussed in the FQPA Policy Paper, where there is a high degree of concern for potential pre- and postnatal toxicity, where data raise uncertainties or a high concern for infants or children that cannot be addressed through traditional uncertainty factors or other tools, those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor. (Ref. 9 at pg. 35) If there are "reliable data" that can account for the uncertainty regarding the potential for pre- or postnatal toxicity, a different FQPA safety factor may be appropriate. (*Id.* at pg. 30) As noted previously, "reliable data" must "be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action" and would lead to a conclusion that the "hazard or exposure . . . will not be underestimated." (*Id.* at pgs. A–5 and A–8)

As noted previously and in the final rule, acetylcholinesterase inhibition remains the most robust quantitative dose-response data in the chlorpyrifos toxicity database and thus, has been and continues to be the critical effect for quantitative risk assessment. Based on its historic experience and confirmation from the 2008 and 2012 SAPs, EPA used acetylcholinesterase inhibition as the endpoint for assessing chlorpyrifos risks. Despite the robustness of that dataset, the Agency's WOE analysis indicates that there is qualitative evidence of an association with potential effects on the developing brain and chlorpyrifos exposure. As EPA noted in the final rule and in the 2020 PID, despite several years of study, the science addressing neurodevelopmental effects remained unresolved. In the face of that uncertainty, and given the potential concerns for neurodevelopmental effects in infants and children, the Agency could not conclude that a different margin of safety would be safe to infants and children. The data considered at the time of the final rule did not resolve the uncertainty about the levels at which these effects may occur.

The purpose of the FQPA safety factor is to ensure the protection of infants and children against special susceptibilities identified in the toxicological database, including the potential for neurodevelopmental effects and effects occurring *in utero*. While the Agency's extensive database on the impacts of chlorpyrifos on acetylcholinesterase is well-established, the additional data—including animal studies, mechanistic studies, as well as epidemiological studies—concerning the special susceptibility of infants and children and the potential for neurodevelopmental effects raised additional questions, and residual uncertainties remain about the levels at which those effects may occur. Those uncertainties could not be ignored. In the face of unresolved uncertainties, EPA cannot determine that a different safety factor would ensure the safety of infants and children with regard to these effects. At the time of the final rule, EPA did not have sufficient "reliable data" to identify a different safety factor that would assure protection of infants and children.

At the time of the final rule, EPA acknowledged that ongoing work to develop NAMs may inform the assessment of the developmental neurotoxicity potential for chemicals, including chlorpyrifos and other OPs. EPA noted that it had convened a FIFRA SAP in September 2020 regarding the use of NAMs, and the SAP released its report and recommendations on EPA's proposed use of the NAMs data in December 2020. (Refs. 23 and 24) In the final rule, EPA stated that the advice of the SAP was being taken into consideration and thus "analysis and implementation of NAMs for risk assessment of chlorpyrifos is in progress and was unable to be completed in time for use in this rulemaking." (Ref. 1 at pg. 48325) For purposes of the final rule then, EPA did not consider the NAMs data among the information available to inform its decision on the safety of chlorpyrifos.

As noted previously, the FFDCA permits the use of a different safety factor only if EPA has "reliable data" to support a determination that a different factor would be safe for infants and children. (21 U.S.C. 346a(b)(2)(C)) At the time of the final rule, under pressure to finalize a rule by a tight court-ordered deadline from a court that found EPA's delays to be "egregious" and a "total abdication" of its statutory duty, EPA relied heavily on data already reviewed. EPA did not conduct any new risk assessments for chlorpyrifos or

incorporate any new data after the Court's decision was issued.

Courts have recognized that court-imposed deadlines can become a "substantive constraint on what an agency can reasonably do." (*San Luis & Delta-Mendota Water Authority* v. *Jewell,* 747 F.3d 581, 606 (9th Cir. 2014); *see also Am. Iron and Steel Inst.* v. *EPA,* 115 F.3d 979, 1006–07 (D.C. Cir. 1997) (recognizing that EPA was not required to stop process due to new evidence; "mentioning the new evidence" in the guidance and subsequently announcing use of that new evidence satisfied the requirement to deal with the new evidence "in some reasonable fashion")) In this case, EPA did recognize the NAMs data and its relevance, but because the Agency's path for incorporating NAMs into risk assessments was not finalized by the Court's deadline, EPA did not consider the NAMs data in the context of chlorpyrifos nor incorporate that data into any of its risk assessments or risk management decisions.

Although the Objectors suggest that the NAMs data may support the conclusion that the AChE endpoint is protective of the potential for neurodevelopmental effects in infants and children and thus obviate the need to retain the 10X FQPA safety factor, at this time, such conclusions are merely speculative. EPA's work on responding to the SAP report and developing a path forward for incorporation of the NAMs data into risk assessment is ongoing; EPA has not yet finalized its approach. When EPA's analysis is complete, EPA will proceed, as appropriate, with its use of the NAMs data in accordance with that evaluation.

f. Conclusion

In summary, EPA's inclusion of the epidemiological studies in its WOE was reasonable and consistent with sound science and its FQPA Policy Paper and Epidemiological Framework. Moreover, given the uncertainties surrounding the potential for neurodevelopmental effects, EPA's retention of the default 10X FQPA safety factor was consistent with the standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children. In any event, as EPA explained at the beginning of this section addressing the objection concerning the retention of the 10X FQPA safety factor, the question of what FQPA safety factor to apply is ultimately not outcome determinative in light of aggregate chlorpyrifos exposures resulting from registered uses. Even if EPA were to reduce the FQPA safety factor to 1X, the currently registered uses still result in aggregate risks of concern, and thus would not change the Agency's determination that the tolerances were unsafe and needed to be revoked. Therefore, this objection is denied.

3. Objections Related to EPA's Assessment of Drinking Water Exposures

The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association, *et al.,* submitted objections concerning EPA's assessment of drinking water exposures. (Refs. 37, 39, and 47) Essentially, there were two objections related to drinking water: (1) Whether EPA had a rational basis for relying on the April 14, 2016, Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2016 DWA) (Ref. 29) in the final rule instead of the September 15, 2020 Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2020 DWA) (Ref. 30) and (2) whether it was reasonable for EPA to assess exposures to chlorpyrifos-oxon, a metabolite of chlorpyrifos that forms in drinking water, in its drinking water assessment. Both of these objections are denied for the reasons discussed in the following unit.

a. Reliance on 2016 DWA

i. Objection. For the objection concerning reliance on the 2016 DWA, the Objectors claim that because EPA had conducted a more updated and refined drinking water assessment in 2020, the Agency could no longer rely on the 2016 DWA, which the Objectors allege no longer reflected the "best available science." (Ref. 37 at pg. 10) The Objectors identify no substantive problems with the analysis of the 2016 DWA itself but believe that it fails solely because it did not incorporate the following refinements that were used in the 2020 DWA: (a) New surface water modeling scenarios, (b) Presentation of the entire distribution of community water systems percent cropped area (PCA) adjustment factors and integration of state-level crop-treated data using percent crop treated (PCT) factors, and (c) Quantitative use of surface water monitoring data. (Ref. 47 at pg. 7) Gharda further claims that EPA could not rely on the 2016 DWA because EPA has failed to take into consideration comments submitted in response to the 2016 DWA. (Ref. 39 at pgs. 31 and 32) Gharda cites Dow AgroSciences LLC's Comments on the 2016 Notice of Data Availability, Revised Human Health Risk assessment and Refined Drinking Water Assessment for Chlorpyrifos and Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (Ref. 39). Again, Gharda points to no specific deficiencies about the 2016 DWA identified in the Dow comments on the 2016 DWA and Dow Response to Objections; rather, Gharda simply summarizes the Dow submissions as commenting that the 2016 DWA is "an overly conservative, screening-level estimate that far over-estimates real world exposures and ignores science-based refinements submitted by" Dow (now Corteva) and asserting that the 2016 DWA was "incomplete and unrefined." (*Id.* at pgs. 31 and 32) In addition, Gharda states that there were "significant limitations" in the 2016 DWA, although those limitations seem, again, tied to the absence of the refinements in the 2020 DWA. (*Id.* at pg. 32)

ii. Background. As described in Unit II.B.1.c.ii.(d), EPA takes a tiered approach to assessing drinking water. Lower tiered assessments are more conservative based on the defaults or upper-bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations. (Ref. 13)

Over the years, EPA has conducted several drinking water assessments for chlorpyrifos and refined those assessments as new information and tools became available. In 2011, EPA completed a preliminary DWA. (Ref. 26) That assessment recommended use of surface water estimated drinking water concentrations (EDWCs) derived from modeling and concluded that a range of agricultural uses could lead to high levels of chlorpyrifos in surface water that could potentially be used by community water systems to supply drinking water. That assessment discussed the effects of drinking water treatment on chlorpyrifos and concluded that during the chlorination disinfection processes, chlorpyrifos can be readily converted to chlorpyrifos-oxon. Therefore, chlorpyrifos and its oxon were considered residues of concern in the preliminary assessment.

Taking into consideration public comments on the 2011 preliminary DWA, EPA updated that assessment in a 2014 DWA to include additional analyses focused on clarifying labeled uses, evaluating volatility and spray drift, revising aquatic modeling input values, comparing aquatic modeling and monitoring data, summarizing effects of drinking water treatment, updating model simulations, and proposing a

strategy to refine the assessment using community water system-specific drinking water intake percent cropped area (PCA) adjustment factors. (Ref. 27) This 2014 DWA confirmed the findings of the 2011 preliminary DWA, concluding that there were a number of uses that may result in exposures to chlorpyrifos-oxon in drinking water at unsafe levels, although the 2014 DWA also noted that additional analyses would be needed in order to finish identifying specific geographical areas where exposures may be of concern. (*Id.* at pgs. 8 and 9)

In 2016, EPA conducted a refined drinking water assessment that estimated drinking water concentrations based on modeling of all registered uses, as well as all available surface water monitoring data. That assessment considered several refinement strategies in a two-step process to derive exposure estimates for chlorpyrifos and chlorpyrifos oxon across the country. The first step was an assessment of potential exposure based on the current maximum label rates at a national level. This indicated that the EDWCs could be above the DWLOC. The second step considered model estimates, as well as measured concentrations, at a more localized level and more typical use scenarios. This built on the approach presented in the 2014 DWA for deriving more regionally specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos-oxon. The results of this second-step analysis also concluded that there were high levels of chlorpyrifos and chlorpyrifos-oxon in drinking water. (Ref. 29)

Following the completion of the 2016 DWA, EPA developed refinement strategies to examine those estimated regional/watershed drinking water concentrations to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At that time, EPA was anticipating that a more refined drinking water assessment might allow EPA to better identify where at-risk watersheds are located throughout the country for the purpose of supporting more targeted risk mitigation through the registration review process. The refinements better account for variability in the use area treated within a watershed that may contribute to a drinking water intake (referred to as PCA or percent use area when considering non-agricultural uses) and incorporate data on the amount of a pesticide that is historically applied based on user surveys within a watershed for agricultural uses (referred to as PCT). These refinement approaches underwent external peer review and were issued for public comment in January 2020. (Ref. 54) In addition, EPA used average application rates, average numbers of annual applications for specific crops, and estimated typical application timing at the state-level based on pesticide usage data derived from Kynetec, a statistically reliable private market survey database; publicly available survey data collected by the USDA; and state-specific scientific literature from crop extension experts.

The recently developed refinements were integrated into the 2020 DWA. (Ref. 30) Because of how high the estimated drinking water concentrations were in the 2016 DWA, it was not expected that the exposures for all uses could be refined to a safe level; therefore, the Agency decided to focus its refinements for the 2020 updated drinking water assessment on a subset of uses in specific regions of the United States. The purpose of the focus on this subset of uses was to determine whether, if these were the only uses permitted on the label, the resulting estimated drinking water concentrations would be below the DWLOC. The subset of uses assessed were selected because they were identified as critical uses by a registrant or high-benefit uses to growers by EPA. That subset of currently registered uses included alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat, confined to specific areas of the country. (*Id.* at Appendix A) The updated assessment applied the new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state level PCT data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information. The results of this analysis indicated that the EDWCs from this subset of uses limited to certain regions would be below the DWLOC. (*Id.* at pgs. 16 and 17)

It is important to emphasize that the 2020 DWA "focuse[d] on a subset of currently registered chlorpyrifos uses. . . . The exposure estimates reported in [the 2020 DWA] and associated conclusions drawn are solely for those uses. . . . Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s)." (*Id.* at cover memo) In other words, EPA recognized that the subset of assessed uses was only one combination of possible subsets that might be safe. Recognizing that in response to the Agency's proposal in the 2020 PID, registrants or growers could have advocated for a different subset of uses or to add different uses or geographic regions, EPA noted that additional analyses would need to be completed to determine the contributions to drinking water in those impacted regions and whether such uses would be safe.

iii. Denial of objection. The Objectors' primary argument is that EPA could not rely on the 2016 DWA (Ref. 29) because the subsequently developed refinements used in the 2020 DWA (Ref. 30) meant that the 2016 DWA, having been conducted without those refinements, did not represent the best available science. As EPA acknowledges in the background discussion, the 2020 DWA incorporated several refinements, including updated surface water scenarios, new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state-level PCT data, and a quantitative use of surface water monitoring data. (Ref. 30) The 2020 DWA represents one of, if not, the highest tiered, most refined drinking water assessment EPA has conducted to date. Nevertheless, the availability of the more refined 2020 DWA does not make it unlawful for EPA to rely on the 2016 DWA in the final rule, particularly where the 2020 DWA was confined to a scenario that did not exist at the time of the final rule.

In denying this objection, EPA finds the scope of the 2020 DWA to be determinative. As noted previously and in the final rule, the 2020 DWA evaluated only a subset of the currently registered uses. Specifically, the 2020 DWA evaluated only 11 of the over 50 agricultural use sites and non-agricultural use sites currently registered for chlorpyrifos. Moreover, those 11 uses were assessed only in specific geographic regions (not all geographic regions in which the pesticide is currently being used) based on typical use rates rather than maximum labeled application rates. The underlying presumption of the 2020 DWA was that chlorpyrifos would not be labeled for any other uses, including non-food uses, besides that limited subset. As such, it presented a highly refined evaluation of a particular subset of predicted uses only; it was not a complete and full assessment of the approved uses of chlorpyrifos and thus did not provide an accurate picture of aggregate exposures from all currently registered use patterns. Although the Sugarbeet Associations assert that EPA could have relied on the 2020 DWA

since it tracks the proposal in the 2020 PID, that argument fails for all the same reasons why EPA could not rely on the conclusions in the 2020 PID to retain the 11 uses, as explained in Unit VIII.C.1. Since the FFDCA, in requiring consideration of aggregate exposure, required EPA to evaluate food, drinking water, and residential exposures from all registered uses, EPA could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations, unless all other uses were canceled. Doing so would have presented an incomplete picture of potential drinking water contributions from currently registered uses. Thus, the 2016 DWA, which is the most recent EPA assessment of contributions to drinking water from all registered uses of chlorpyrifos—and not the 2020 DWA—represented the most recent, most robust "best available science" for use by the Agency for the uses on current labels.

EPA also disagrees with the Objectors' implication that the mere existence of new refinement methodologies somehow impacts the reliability of the 2016 DWA. At the time the 2016 DWA was issued, it represented the most refined drinking water assessment EPA's OPP had conducted. It applied all available refinement techniques available at that time, including, as discussed previously, using modeled estimates and measured concentrations to drill down to drinking water contributions on a regionally specific level. The subsequent development of additional tools to refine drinking water assessments that show risks of concern does not render the 2016 DWA overly conservative or otherwise scientifically invalid and unreliable. The Agency simply has additional tools and methods that can be applied to refine drinking water assessments where appropriate. The Agency's Drinking Water Framework notes that moving to the higher tiers that were used in the 2020 DWA "requires a large amount of resources and adds a great amount of complexity to the assessment." Therefore, rather than moving to the higher tiers automatically, "advancement to Tier 4 should be done in consultation with the interdivisional chemical team." (Ref. 13 at pg. 51)

The question then is whether it was reasonable for EPA not to apply the 2020 refinements to all the uses assessed in the 2016 DWA; EPA concludes that it was. Following the issuance of the 2016 DWA, in which EPA identified EDWCs from registered chlorpyrifos uses that exceeded safe levels, EPA met with representatives of Corteva, a chlorpyrifos registrant, about whether additional information about critical uses to growers could be used to refine the 2016 DWA as part of the ongoing work in registration review to assess uses of chlorpyrifos. (Ref. 51) Given the large number of uses and high estimates across various vulnerable watersheds throughout the country, EPA focused its resources to apply the refinement strategies on assessing whether a subset of uses that were identified by Corteva as critical and considered by EPA to present high benefits to chlorpyrifos users could result in EDWCs lower than the DWLOC.

Once EPA determined the appropriate subset of uses to evaluate, EPA dedicated extensive resources to apply the newly developed methodologies, including gathering PCT data from states in which the specific crops to be retained were grown, to those uses to determine if the resulting uses would result in estimated drinking water concentrations of chlorpyrifos below the Agency's relevant level of concern, *i.e.,* the DWLOC. This approach is consistent with the Agency's standard practice during registration review; for pesticides that pose risks of concern, EPA will typically consider whether any mitigation is available that would allow the pesticide to meet the registration standard, including the FFDCA safety standard. (*See* 40 CFR 155.53 and 155.56) For chlorpyrifos, for which the Agency had identified high levels of risk in 2016, EPA decided to focus on whether there was a mitigation package that would allow some uses of chlorpyrifos to be considered safe.

Starting with a hypothetical "blank label" with no registered uses and adding back just the 11 geographically and application rate limited uses, *i.e.,* assuming all other current uses did not exist, EPA assessed the subset of aforementioned uses applying the new refinement techniques. That analysis resulted in estimates of chlorpyrifos concentrations in drinking water below the DWLOC, which provided a basis for EPA to propose that subset of uses for mitigation of risk in the 2020 PID. For some areas, the estimated drinking water concentrations from combinations of those 11 uses were close to the DWLOC, so there was not much room in the risk cup for adding more uses. For example, EPA concluded that use of chlorpyrifos on alfalfa, sugarbeet, and soybean in the Upper Mississippi region (HUC–07) or on alfalfa, sugar beet, soybean, and spring and winter wheat in the Souris-Red-Rainy region (HUC–09), the estimated drinking water concentrations were 3.2 ppb and 3.3 ppb, respectively; for comparison, a concentration of 4.0 ppb or above would exceed safe levels of chlorpyrifos in those areas. (Ref. 31 at pg. 16) Because EPA was trying to evaluate a specific subset of uses for purposes of providing a mitigation option in the proposed registration review decision and because that evaluation indicated that that subset alone would not pose risks of concern, EPA did not engage in further refinements of other uses from the 2016 DWA to determine if other hypothetical uses could be safe. EPA, however, recognized the possibility that additional or different uses might be requested following that proposal and cautioned that, if so, additional assessment would need to be conducted to support risk management decisions for those other uses.

Thus, at the time the 2020 DWA was conducted, it was reasonable that EPA did not expand the application of refinements beyond the 11 uses assessed. It was also reasonable that EPA did not engage in refinements of the rest of the uses in the 2016 DWA in preparation of the final rule. As EPA has indicated throughout this Order, given the time constraints imposed on the Agency by the court-ordered deadline, EPA did not conduct any new risk assessments, including any new drinking water assessments to further refine the 2016 DWA for all registered uses. To apply the refinements to all currently registered uses would have required an extraordinary investment of resources and time, which EPA did not have in light of the Court's deadline. Consequently, EPA relied on the best available science it had available to assess the currently registered uses as required at the time of the final rule—the 2016 DWA. This objection is denied.

b. Assessing Chlorpyrifos-Oxon

In addition to opposing the use of the 2016 DWA in the final rule, the Agricultural Retailers Association, *et al.,* and Gharda assert that EPA's assessment of aggregate exposure should not have considered chlorpyrifos-oxon, a metabolite of chlorpyrifos.

i. Objection regarding lack of exposure. (A) Objection. The Agricultural Retailers Association, *et al.* note that the 2016 DWA stated that there were "no detections of chlorpyrifos-oxon degradates in any finished drinking water samples that people actually consume." (Ref. 47 at pg. 7) Thus, the Agricultural Retailers Association, *et al.* argue that it was arbitrary and capricious for EPA to assess the exposures of chlorpyrifos oxon in drinking water.

(B) Denial of objection. EPA has extensive reliable data supporting its

conclusion that chlorpyrifos-oxon will be present in at least some drinking water. It is well understood that chlorpyrifos rapidly oxidizes to form chlorpyrifos-oxon almost quantitatively (*i.e.*, nearly 100% conversion of chlorpyrifos into equal quantities of chlorpyrifos-oxon) during drinking water treatment with chlorination. While chlorination is the most common drinking water treatment, there are some areas that use different disinfection processes, such as those using chloramines, which are less effective at converting chlorpyrifos to its oxon, so, the resulting drinking water may contain combination of residues of chlorpyrifos and its oxon.

Currently, there are no data available on the removal efficiency of chlorpyrifos prior to chlorination or the removal efficiency of chlorpyrifos-oxon after formation. Stability studies indicate that once chlorpyrifos-oxon forms, little transformation is likely to occur between water treatment and consumption of the drinking water; the chlorpyrifos-oxon has been shown to be relatively stable following drinking water treatment (*i.e.*, with a half-life of 12 days). While some drinking water treatment procedures, such as granular activated carbon filtration and water softening, may reduce the amount of chlorpyrifos-oxon in drinking water, it is unlikely that these treatment processes completely remove chlorpyrifos-oxon from drinking water. In addition, these treatment methods are not typical practices across the country for surface water. For these reasons, it is reasonable for EPA to assume that drinking water will contain chlorpyrifos-oxon residues as a result of water treatment systems. (Ref. 26 at pgs. 2, 22 and 23)

The Agricultural Retailers Association, *et al.* point out that the 2016 DWA states that there have been no detections of chlorpyrifos oxon in finished water samples. (Ref. 47 at pg. 7; Ref. 29 at pg. 111) While it is correct that the 2016 DWA contains this statement, the lack of detections in finished water does not mean that chlorpyrifos-oxon is not present in some drinking water. There were several detections in the monitoring data of both chlorpyrifos and oxon in filtered and unfiltered surface water, and in surface water with known particulates (Ref. 29 at pgs. 97 through 113), so it is clear that chlorpyrifos and its oxon are present in at least some drinking water. Chlorpyrifos found in surface water that enters a drinking water treatment plant will be converted in most instances, as indicated previously, into chlorpyrifos-oxon before it leaves the plant and travels to consumers. There are several reasons why chlorpyrifos and chlorpyrifos-oxon may not have been detected in finished drinking water, including sample site location, sampling frequency, as well as drinking water treatment not involving chlorination that may lead to less oxon formation. There is insufficient data available to determine if the community water systems sampled for chlorpyrifos to date are located in watersheds vulnerable to chlorpyrifos contamination. (Ref. 29 at pg. 10) Due to the limitations of monitoring data, EPA cannot conclusively determine that chlorpyrifos-oxon will not be present in some drinking water, in light of the available science demonstrating conversion of chlorpyrifos to its oxon during chlorination, which occurs in the vast majority of major drinking water treatment systems throughout this country.

ii. Objection regarding lack of toxicity. (A) Objection. Gharda objects to EPA's assessment of chlorpyrifos-oxon residues in drinking water because Gharda believes that the "drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos." (Ref. 39 at pgs. 32 and 33) Gharda bases this conclusion on its interpretation of the Corteva Oxon Study, which Gharda asserts found "(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure," and therefore nullified EPA's assumption in the 2020 DWA "that chlorpyrifos oxon is more toxic than the parent chlorpyrifos for drinking water exposure purposes." (*Id.* at pg. 32) Gharda argues that EPA's failure to consider this study makes EPA's final rule arbitrary and capricious.

(B) Denial of objection. As noted throughout this document, in light of the time constraints imposed on EPA by the Court and the direction to avoid further delay and fact-finding 14 years after the petition to revoke the tolerances had been filed, EPA focused on information already assessed to determine whether the chlorpyrifos tolerances were safe. The Agency did not conduct any additional analyses of other data, including review of the Corteva Oxon Study, due to the time constraints that were imposed on the Agency by the Ninth Circuit's deadline. That study had not been incorporated into any Agency's risk assessments at the time of the final rule, given that this study was submitted to EPA in December 2020, after the Agency's risk assessments on chlorpyrifos had been finalized (in September 2020). Due to the ongoing status of registration review, the Agency has not yet determined whether—and if so, how—to integrate this study into any risk assessment. Therefore, the final rule was not arbitrary and capricious for failure to incorporate this study into the completed risk assessments.

In any event, as EPA indicated in Unit VII.C.2., Gharda has failed to demonstrate how EPA could conclude that the tolerances are safe, even if EPA were able to incorporate this study into its assessment and agreed that the oxon was not relevant for risk assessment purposes. Also as discussed in Unit VII.C.2., EPA has concluded that even assuming that chlorpyrifos-oxon is not more toxic than chlorpyrifos and thus should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe. Based on a comparison of 2016 DWA estimates of chlorpyrifos residues in drinking water to the chlorpyrifos DWLOC, registered uses of chlorpyrifos result in levels of chlorpyrifos in drinking water that would exceed safe levels of chlorpyrifos exposure. Therefore, this objection is denied for failure to demonstrate that using the Corteva Oxon Study would have a material impact on the Agency's safety finding.

4. Procedural Considerations

A number of objections were filed raising a variety of process claims: Failure to consider public comments on the Agency's 2015 proposal to revoke chlorpyrifos tolerances in response to the 2007 Petition and on the 2020 PID; delayed opening of the portal for submission of objections; and failure to comply with requirements for interagency coordination under Executive Order 12866. These objections are denied for the reasons discussed in this unit.

a. Prior Comments

i. Objection. The Sugarbeet Associations and CLA/RISE assert that the failure to consider and respond to the more than 90,000 comments on the 2015 proposed rule and the comments submitted in response to the 2020 PID is inconsistent with the principles of due process and transparency. (Refs. 37 and 50)

ii. Denial of objection. EPA denies this objection for lack of specificity and

relevance. EPA's regulations require that an objection "[s]pecify with particularity the provision(s) of the . . . regulation . . . objected to, the basis for the objection(s), and the relief sought." (40 CFR 178.25(a)(2)) The objection claiming that EPA must consider the 90,000 comments on a prior proposed rule fails to meet this test. Other than objecting to EPA's not having considered those prior comments, the objections do not specify a particular aspect of the final rule that is problematic. Neither do the objectors point to anything specifically raised in the comments on the 2015 proposed rule that would support a particular objection they have to the rule. Without something specific to address, these comments as a general matter are not relevant to the Agency's final rule, for the reasons articulated directly following this discussion in this document. For this reason, this objection is denied as not conforming to the required form of objections. (40 CFR 178.30(a)(1))

Moreover, EPA does not believe that responses to the comments submitted on the 2015 proposed rule are required before proceeding with this final action, due to the unique regulatory structure provided under the FFDCA. The FFDCA sets up three options for EPA in responding to a petition seeking revocation of tolerances: (1) To issue a final rule establishing, modifying or revoking a tolerance; (2) to issue a proposed rule subject to public comment and thereafter issue a final rule; or (3) to issue an Order denying the petition. (21 U.S.C. 346a(d)(4)(A)(i), (ii), (iii)) The 2015 proposed rule was issued in response to the 2007 Petition under the second option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(ii)) Based on comments submitted in response to that proposed rule, EPA conducted additional risk assessments, which were also released for public comment. (*See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment (81 FR 81049, November 17, 2016) (FRL–9954–65)) No formal responses to those comments were ever finalized, as soon thereafter, EPA abandoned the proposed rule and issued the 2017 Order Denying Petition under the third option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(iii)) EPA's final rule was issued under the first option provided by the statute—to issue a final rule establishing, modifying, or revoking a tolerance without public comment. In sum, the statute provides EPA with choices on how to act and does not constrain EPA's ability to follow any of the statutory paths.

After EPA denied objections to the 2017 Order Denying Petition in 2019, a lawsuit was filed, and the Ninth Circuit vacated the 2017 and 2019 Orders and directed EPA to "publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate." (*LULAC*, 996 F.3d at pg. 703) Notably, the court also specifically ordered EPA to issue a final rule either revoking or modifying chlorpyrifos tolerances under the first option provided in the statute, which provides for the issuance of a final rule "without further notice and without further period for public comment." (21 U.S.C. 346a(d)(4)(A)(i)) Since the Court directed EPA to proceed with a final rule without directing EPA to finalize the 2015 proposed rule, EPA interpreted the Court's mandate as requiring an independent final rule based on available information, not a finalization of the prior rule. The Court's strict deadline for finalizing the rule further suggests that the Court did not expect EPA to formalize responses to a large number of potentially stale comments. As such, EPA is not obligated to respond to comments on a rule that was never finalized.

With regard to the comments submitted in response to the 2020 PID, those comments were submitted in response to the separate registration review action. As a separate action, EPA is also not obligated to respond to those comments as part of its final rule. That registration review process for chlorpyrifos is ongoing, and EPA is still reviewing the comments received in connection with that process and was not in a position at the time of the final rule to have finalized its responses to those comments. It is also worth noting that, as alluded to earlier in Unit VIII.C.1.a. of this document, the scope of the registration review differs from that of the final rule, *i.e.*, registration review under FIFRA also includes consideration of environmental risks and benefits information that are not relevant to the Agency's final rule decision. As a result, several of the comments are not likely to be relevant to the final rule.

Finally, to the extent any objector believes that a comment on the 2015 proposed rule or the 2020 PID raises specific substantive challenges that should have been considered in the final rule, the FFDCA affords the exact due process they seek. Under the special administrative procedures provided in FFDCA section 408(g), "any *person* may file objections thereto with the *Administrator*, specifying with particularity the provisions of the regulation or Order deemed objectionable and stating reasonable grounds therefor." (21 U.S.C. 346a(g)(1)) Any objector can take advantage of the due process allowed by the FFDCA and submit any specific comments for Agency consideration as an objection to the final rule. Because of the opportunity to provide such objections directly to EPA as part of the objections process, there is no due process violation for not responding to comments on a proposed rule that was never finalized or to comments submitted on a separate regulatory action that remains ongoing.

b. Objections Portal

i. Objection. The American Soybean Association argues that the final rule failed to provide adequate procedural due process as a result of technical delays in opening the Federal eRulemaking Portal for submission of objections. (Ref. 36 at pgs. 3 and 4) The American Soybean Association states that on October 12, 2021, its staff discovered that the docket for the final rule was not open to accepting comments. The American Soybean Association speculates that having the objections portal disabled for any portion of the objections period could have prevented individual growers from being able to submit objections, thus denying them the right to object to the final rule.

ii. Denial of objection. EPA denies this objection. EPA's regulations require that objections be filed with the Hearing Clerk no later than 60 days following publication of the final rule in the **Federal Register** in accordance with EPA's regulations in 40 CFR part 178. (*See* 40 CFR 178.25(a)(6) and (7)) This mandatory requirement, including the direction to submit filings through the Office of Administrative Law Judges' electronic filing system, was clearly laid out in EPA's final rule, as the American Soybean Association notes. In addition to the mandatory filing of objections with the Hearing Clerk, EPA also requests that objectors submit their filed objections online (redacting any Confidential Business Information (CBI)) "for inclusion in the public docket". This additional step allows submitters to ensure the protection of any sensitive information in what is uploaded as part of the public docket for the action. This additional request does not include a deadline for submissions. The American Soybean Association objects only to the delayed opening of this latter online public docket.

While EPA concedes that there were technical issues with the opening of the

Federal eRulemaking Portal, this appears to be a harmless error as there is no legal consequence from the delay, and there is no indication that anyone was deprived of the opportunity to submit objections. Promptly upon receiving notice that the docket for the final rule was not open to accepting comments, and well before the close of the objection period on October 15, 2021, this issue was resolved by EPA. The American Soybean Association and over 100 other Objectors were able to submit their objections, hearing requests, and requests for stay without issue. While the American Soybean Association speculates that individual growers seeking to object might not have had the opportunity to do so, EPA did not receive any information suggesting that might be the case. On the contrary, EPA received dozens of submissions to the Federal eRulemaking Portal from individual growers, which were filed as both standalone objections (see the objections filed by individual growers Chris Hill, Willard Jack, Steve Kelley, Andrew Lance, Alan Meadows, and Joel Schreuers, Ref. 1) and included in a transmittal of 93 independent comment letters submitted by the Sugarbeet Associations (Ref. 37, Attachment 4).

c. Interagency Review Process

i. Objection. The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association argue that EPA failed to comply with Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993), and thus deprived other federal agencies an opportunity to provide feedback on the final rule. (Refs. 37, 39, and 47) The Objectors argue that the final rule is a "significant regulatory action" as defined in the Executive order, noting that EPA estimated a high-end annual economic benefit of chlorpyrifos of $130 million, based on higher-cost alternatives and pest damage. (Ref. 56 at pg. 39) The Agricultural Retailers Association, *et al.* and Gharda both argue in the alternative that the final rule meets the definition of a significant regulatory action in that it is "likely to adversely affect the entire agricultural economy, jobs, productivity, and our environment." (Ref. 39 at pgs. 47 and 48; Ref. 47 at pg. 4) In addition, Gharda and the Sugarbeet Associations assert that tolerance revocations are not covered by Office of Management and Budget's (OMB) guidance on Executive Order 12866, which excepts tolerance actions from OMB review, because that guidance excludes from the exemption only "those [tolerance actions] that make an existing tolerance more stringent." (Ref. 39 at pg. 47; Ref. 47 at pg. 12)

ii. Background. Executive Order 12866 provides that "significant regulatory actions" must be submitted for review to the Office of Information and Regulatory Affairs in OMB. A significant regulatory action is generally any regulatory action that is likely to result in a rule that might, among other things, have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. After the issuance of Executive Order 12866, OMB issued *Guidance for Implementing E.O. 12866,* which exempted tolerance actions under the FFDCA from Executive Order 12866 review, "except those that make an existing tolerance more stringent." (Ref. 55)

iii. Denial of Objection. As an initial matter, EPA notes that Executive Order 12866—like most, if not all, executive orders—explicitly says that it "does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person." (58 FR 51744) Thus, not submitting the final rule to OMB cannot constitute a violation of any law, such that a reviewing court could reasonably be expected to find that EPA's action was "not in accordance with law" under 5 U.S.C. 706(2)(A) or "without observance of procedure required by law" under 5 U.S.C. 706(2)(D). Therefore, this is not a judicially reviewable issue. Moreover, EPA notes that resolution of this particular objection has no bearing on any substantive issues with the final rule that are raised separately in other objections. Thus, this objection is denied.

In any event, EPA disagrees that the final rule revoking chlorpyrifos tolerances triggers the Executive Order 12866 interagency review requirements. EPA believes the OMB guidance regarding Executive Order 12866 and its application to pesticide tolerance actions can be interpreted to mean that a pesticide tolerance is made "more stringent," and thus subject to Executive Order 12866 requirements, when EPA does not make accommodations for affected parties to adjust to the impacts of the rule. With respect to the revocation of tolerances for chlorpyrifos, however, the final rule provided a meaningful period of time for affected parties to adjust to the rule's impact, in light of the identified safety concerns. Specifically, EPA provided six months between the publication of the final rule and its effective date, which far exceeds the 30-day effective date requirement contained in the Administrative Procedure Act. In addition, this approach is both consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures and, in the Agency's view, generous in light of the Agency's conclusion that chlorpyrifos tolerances were not safe. Finally, this approach is consistent with the Agency's approach for other pesticide tolerance revocations that EPA determined were not subject to Executive Order 12866; *see, e.g.,* EPA's revocations of tolerances for carbofuran in 2009 (74 FR 23045), butylate, clethodim, dichlorvos, dicofol, and isopropyl carbanilate, et al. in 2012 (77 FR 59120), and tebufenozide in 2017 (82 FR 53423).

For all the foregoing reasons, the objection regarding Executive Order 12866 and interagency review is denied.

5. Objections That, As a Matter of Law, Do Not Provide a Basis for Leaving Tolerances in Place

Many Objectors suggested that EPA's final rule was inappropriate on grounds that are immaterial to the question of whether tolerances can be maintained under the FFDCA. The FFDCA and EPA's regulations require that objections identify a particular aspect of the final rule deemed objectionable and specify with particularity the provision of the regulation objected to and the relief sought. (21 U.S.C. 346a(g)(2), 40 CFR 178.25(a)(2)) In addition, the objection must seek relief that is consistent with the FFDCA. (40 CFR 178.30(a)(2)) Objections that do not meet these conditions will be denied. The objections discussed in this sub-unit provide no reliable information pertaining to the FFDCA safety standard in section 408(b)(2) that could support leaving the tolerances in place. Because these complaints are meritless on their face, these objections are denied. EPA provides further discussion in this unit.

a. Economic and Environmental Impacts

i. Objection. A majority of Objectors, including the Agricultural Retailers Association, *et al.,* the Sugarbeet Associations, American Soybean Association, Cherry Marketing Institute, and 93 sugarbeet growers as part of a mass mailer, allege that the revocation of chlorpyrifos tolerances will have detrimental impacts on their crops due to increased pest pressure, force growers

to use more expensive and less efficacious alternatives, and result in harmful effects on the environment. (Ref. 1)

ii. Denial of objection. EPA appreciates that the revocation of chlorpyrifos tolerances will have an impact on growers who use the pesticide and the agricultural industry. Chlorpyrifos is a widely used pesticide that has been registered for many uses since 1965. As part of the registration review process under FIFRA, the Agency did evaluate the benefits of chlorpyrifos to growers by crop. (Ref. 56) EPA is aware that IPM and resistance management are critical pest management benefits of many pesticides, and where benefits considerations are permitted by law, the Agency takes these aspects into serious consideration. However, consideration of information on pesticidal benefits to growers or impacts on the environment from loss of a pesticide, while relevant considerations under FIFRA (*see* 7 U.S.C. 136(bb)), are not factors for consideration under the FFDCA, with one exception not applicable here. (*See* 21 U.S.C. 346a(b)(2)(B))

The safety standard under the FFDCA is strictly a human-health risk-based standard, which does not permit consideration of benefits or environmental information, in determining whether a tolerance is safe. Invariably, FFDCA section 408 directs EPA to consider factors relevant to the safety of the pesticide residue in food (aggregated with other sources of exposure to the pesticide residue), placing particular emphasis on human dietary risk. (*See, e.g.,* 21 U.S.C. 346a(b)(2)(B) (addressing an exception to the safety standard for pesticide residues as to which EPA "is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health"); 21 U.S.C. 346a(b)(2)(C) (requiring special safety findings as to "infants and children" regarding their "disproportionately high consumption of foods" and their "special susceptibility * * * to pesticide chemical residues"); 21 U.S.C. 346a(b)(2)(D)(iii) (requiring consideration of the relationship between toxic effects found in pesticide studies and human risk); 21 U.S.C. 346a(b)(2)(D)(iv), (vi), and (vii) (requiring consideration of available information on "dietary consumption patterns of consumers," "aggregate exposure levels of consumers," and the "variability of the sensitivities of major identifiable subgroups of consumers"); 21 U.S.C. 346a(b)(2)(D)(vi) (requiring consideration of "non-occupational" sources of exposure); 21 U.S.C. 346a(b)(2)(D)(viii) (requiring consideration of information bearing on whether a pesticide "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects"); 21 U.S.C. 346a(l)(2) and (3) (requiring revocation or suspension of tolerances where associated FIFRA registration is canceled or suspended "due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food")) Thus, under section 408, EPA has no discretion to insert economic or environmental considerations into its decisions on the chlorpyrifos tolerances.

Therefore, objections that EPA should have taken economic and environmental impacts into consideration in issuing the final rule are denied, as EPA has no authority to do so as part of its safety evaluation under the FFDCA.

b. Consideration of Occupational Exposure by EPA

i. Objection. Gharda and the Sugarbeet Associations assert that EPA unlawfully considered occupational exposures as a reason for revoking the tolerances. In support of this objection, they point to an EPA press release regarding the final rule dated August 18, 2021, which mentioned that the tolerance revocation will result in protections for farmworkers. (Ref. 37 at 13; Ref. 39 at 33)

ii. Denial of Objection. The August 18, 2021 press release announcing the publication of the final rule included statements that EPA was stopping the use of chlorpyrifos on food "to better protect human health, particularly that of children and farmworkers," and that ending the use of chlorpyrifos on food "will help to ensure children, farmworkers, and all people are protected" from potentially dangerous consequences of chlorpyrifos. (Ref. 57) Based on these statements alone, the Objectors argue that these references to farmworkers suggest that EPA impermissibly considered occupational exposures in its decision to revoke chlorpyrifos tolerances. However, the Objectors' arguments are not supported by the final rule itself, which specifically affirms that the FFDCA standard does not include occupational exposures to workers and which explicitly and repeatedly emphasizes that EPA's review included food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but did not include occupational exposures to workers. (*See, e.g.,* Ref. 1 at pgs. 48318, 48332 through 48333) The fact that the press release cited by the Sugarbeet Associations discusses the potential for incidental benefits to farmworkers from the final rule does not mean that such potential benefits were considered by EPA in the final rule. The Objectors' claim is meritless and is denied.

c. Compliance With Relevant International Standards

i. Objection. The Republic of Colombia objects to the final rule on the basis that the final rule's revocation of chlorpyrifos tolerances deviates from the Codex Alimentarius (Codex) international standard of 0.05 mg/kg for chlorpyrifos. (Ref. 58) Colombia requests that EPA reconsider the final rule's revocation of chlorpyrifos tolerances in light of the Codex MRL for chlorpyrifos, which it alleges is based on conclusive scientific evidence, although Columbia does not provide that scientific evidence with its objection for EPA to consider. In addition, Colombia requests that EPA consider, in its assessment of chlorpyrifos tolerances, the factors identified for consideration under Article 5, paragraphs 2 and 3 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Those paragraphs require Members to the SPS Agreement to "take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest—or disease—free areas; relevant ecological and environmental conditions; and quarantine or other treatment" and "relevant economic factors." (Ref. 59 at art. 5, paragraphs 2, 3)

ii. Denial of objection. The Codex is a collection of internationally adopted food standards and related texts published by the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. (*See https://www.fao.org/fao-who-codexalimentarius/en/*) The Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, establishes Codex Maximum Residue Limits (MRLs) for pesticide products, which are similar to tolerances in that they set the limit for allowable pesticide residues in food. Although the Objector seems to be referring to a single universal Codex MRL of 0.05 mg/kg for chlorpyrifos residues, in actuality, Codex has promulgated several MRLs ranging from 0.01 mg/kg to 20 mg/kg for chlorpyrifos

residues on a variety of commodities. (Ref. 60) It is unclear why Colombia is pointing the Agency to a generic MRL of 0.05 mg/kg.

The FFDCA requires consideration of Codex MRLs when EPA is making a decision to *establish* a tolerance. (21 U.S.C. 346a(b)(4)) Notably, the statute does not require the same consideration in revoking tolerances. That is because revocation is required when a tolerance is unsafe, (21 U.S.C. 346a(b)(2)(A)(i)), regardless of whether another international body, including Codex, is maintaining the same determination. In the final rule, EPA determined that current tolerances for chlorpyrifos are not safe under FFDCA and must therefore be revoked. Columbia has not provided any reliable information to support a reconsideration of that conclusion.

As far as the request to consider the factors under Article 5, paragraph 2 of the SPS Agreement is concerned, EPA reiterates its earlier arguments, that it is bound by its domestic statute, which requires that unsafe tolerances be revoked (21 U.S.C. 346a(b)(2)(A)(i)) and which does not permit consideration of environmental or economic factors. (See Unit VIII.C.5.a.) EPA does not have discretion to retain tolerances, based on consideration of the factors listed in SPS Agreement, where the Agency has determined those tolerances do not meet the FFDCA safety standard. For these reasons, the Republic of Colombia's objection with respect to the Codex MRLs and the SPS Agreement is denied.

d. Implementation Timeframe

i. Objection. While EPA received many requests for an extension of the phase-out period, this section address the single objection asserting that the Agency's six-month expiration date for the tolerances was unlawful. The requests EPA received for extensions of the tolerance expiration date are addressed in Unit IX, along with other requests seeking a stay of the final rule.

Seeking a "gradual, multi-year phase-out of crop uses" to mitigate economic injury to itself and growers, Gharda argues that EPA's selection of a six-month grace period was arbitrary and capricious because it did not provide for use in another growing season nor sufficient time for Gharda, distributors, or growers to phase out their inventories and exhaust existing stocks of chlorpyrifos. (Ref. 39 at 40) Nor, Gharda alleges, does the SPS Agreement requirement for a "reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force" mandate that EPA select six months as the reasonable interval. (*Id.* at 38)

ii. Denial of objection. Section 408(g)(1) of the FFDCA states that a rule issued under section 408(d)(4) of the FFDCA, which the final rule revoking chlorpyrifos tolerances was, "shall take effect upon publication", unless otherwise specified in the rule. (21 U.S.C. 346a(g)(1)) The Agency's authority to specify a different effective date or to set an expiration date for the tolerances is entirely discretionary. Moreover, there is no requirement in the FFDCA for EPA to accommodate, through delays in the effective date or any other way, economic hardships and transitions away from a pesticide that the Agency has found to be unsafe and for which tolerances must be revoked. Indeed, the FFDCA is entirely focused on whether the tolerance is safe, and so it would subvert the intent of the statute to allow all tolerances the Agency has deemed unsafe to remain effective for significant periods of time.

As stated in the final rule, EPA set a six-month expiration date for the chlorpyrifos tolerances, rather than requiring revocation immediately, to accommodate the SPS Agreement requirement to "allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force." (Ref. 59 at Annex B, paragraph 2) The World Trade Organization (WTO) has interpreted the phrase "reasonable interval" to mean normally a period of not less than six months, although shorter durations could be justified under "urgent circumstances." (Ref. 61 at paragraph 3.2) In the SPS Agreement, there are some procedural exceptions allow for urgent health concerns. (Ref. 59 at Annex B, paragraph 5; *see also* Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes,* WTO Doc, WT/DS406/AB/R (April 4, 2012) (finding that deviations from the TBT Agreement requirement to provide "reasonable interval" may be justified in cases of urgent safety or health concerns))

In light of EPA's inability to conclude that chlorpyrifos tolerances meet the FFDCA safety standard, the Agency determined that a six-month expiration date for the chlorpyrifos tolerances would provide a reasonable interval for importers and growers to adapt to the change in regulation. EPA also notes that the Ninth Circuit's decision directed EPA to act "immediately," and chastised EPA for its "egregious delay" in publishing a sufficient response to the 2007 Petition, which "exposed a generation of American children to unsafe levels of chlorpyrifos." (*LULAC,* 996 F.3d. at 703) It simply was not tenuous to leave tolerances in place to allow for additional growing season(s), given the Agency's lack of a safety finding for the chlorpyrifos tolerances in light of the Ninth Circuit's expressed impatience with EPA's delay in acting on the 2007 Petition and the accelerated timeframe provided by the Ninth Circuit for the issuance of the final rule. Consequently, EPA determined that six months was a reasonable period to accommodate growers and importers while minimizing any continued harm.

For these reasons, Gharda's objection with respect to the implementation timeframe of the final rule is denied.

e. Existing Stocks

i. Objection. The following Objectors argue that the final rule should have addressed the treatment of existing stocks of chlorpyrifos products and seek additional clarification on how existing stocks will be addressed: The Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.,* CLA/RISE, and the Michigan Vegetable Council. (Refs. 37, 39, 47, 50, and 62) These Objectors allege that the revocation of the tolerances is likely to leave millions of gallons of chlorpyrifos in the hands of growers or in storage in the United States and that the lack of clarity from EPA regarding the use and/or disposal of these existing stocks of chlorpyrifos places a financial and logistical burden on users and retailers and could inadvertently lead to inappropriate disposal of chlorpyrifos products. Several Objectors argue that guidance published by EPA on its website after publication of the final rule titled "Frequent Questions about the Chlorpyrifos 2021 Final Rule" (Ref. 63), fails to clarify this issue, and that the legal status of products with labels and registrations that contain both food and non-food uses remains unclear.

Gharda also argues that EPA, in issuing the final rule without concurrently addressing existing stocks in the final rule or issuing an existing stocks order pursuant to FIFRA section 6(a)(1) (7 U.S.C. 136d(a)(1)), has abdicated its responsibility under FIFRA to ensure the safe, lawful, and orderly phase-out and disposal of chlorpyrifos products. (Refs. 39 at 41 through 45) Gharda asserts that an existing stocks order is necessary to allow end users and others wishing to return existing stocks to the manufacturers or pursue other safe disposal options to avoid violating FIFRA. Gharda also asserts that because the practical effect of the final rule is to render previously registered products unregistered, EPA would have no

enforcement authority over misuse of those pesticides.

ii. Denial of objection. As an initial matter, EPA notes that while the Objectors use the term "existing stocks," existing stocks is a FIFRA term that applies to products that have been released for shipment upon cancellation of a registered pesticide. (*See* Existing Stocks of Pesticide Products; Statement of Policy, 56 FR 29362, June 26, 1991 (FRL–3846–4)) Since the final rule does not cancel any pesticide registrations, it has not created any "existing stocks" under FIFRA.

Nevertheless, EPA reads the majority of objections on this particular issue to be seeking clarity and guidance for users of chlorpyrifos on what to do with chlorpyrifos products that have been purchased but cannot be used on food crops following the expiration of the tolerances. As such, these objections are more akin to comments and requests concerning implementation of the final rule, than objections to the final rule itself; thus, they are denied as objections for failure to raise particular concerns with the final rule that can be resolved under the FFDCA. Nevertheless, EPA recognizes the confusion among the agricultural industry as a result of the final rule and the fact that tolerances will be revoked before any registrations for chlorpyrifos products are cancelled under FIFRA. Consequently, EPA will continue to update the FAQ page to provide guidance to assist growers and the agricultural industry with the implementation of this final rule.

Turning to Gharda's objection next, EPA denies that it has somehow abdicated its responsibilities under FIFRA by taking action to revoke unsafe tolerances under the FFDCA. EPA finds that Gharda is essentially making the same argument that EPA rejected in Unit VIII.C.1.b. Gharda's argument boils down to an assertion that EPA was required to take action concurrent with the final rule to cancel chlorpyrifos registrations under FIFRA, to provide for the use and disposition of existing stocks in that cancellation order, and then to revoke tolerances consistent with the existing stocks provisions of that cancellation order; thus, for the same reasons articulated in that previous Unit, Gharda's objection is denied. As noted previously, nothing in the FFDCA compels EPA to take action under FIFRA to cancel pesticide registrations and provide for existing stocks concurrently with or prior to revoking tolerances for that same chemical. Moreover, there is no requirement in the FFDCA, when revoking a tolerance, to resolve questions regarding existing stocks in the final rule itself.

Gharda appears to conflate the EPA's issuance of a rule revoking tolerances under the FFDCA with EPA's cancellation of registered pesticides under FIFRA. Gharda argues that because EPA's revocation of the tolerances under the FFDCA essentially renders the product unregistered, EPA was obligated to address the issue of existing stocks under FIFRA. However, Gharda misstates the effect of the final rule. The revocation of tolerances does not have the effect of rendering the chlorpyrifos products unregistered. Registered products only become unregistered once they are cancelled under FIFRA section 6. (7 U.S.C. 136d) EPA has no authority to issue a cancellation order under the FFDCA, only under FIFRA, and as discussed in Unit VIII.C.1.b., EPA is not required to cancel pesticides under FIFRA prior to taking action to revoke tolerances under the FFDCA. Because the actual remedy Gharda is seeking with this objection—a cancellation order with instructions on how to handle existing stocks—is only available under FIFRA, this is not a proper objection to the final rule.

f. Channels of Trade

i. Objection. The American Soybean Association and Willard Jack (an individual grower) submitted objections arguing that the final rule fails to provide adequate guidance for food or feed treated with chlorpyrifos that is or will be in the channels of trade when the tolerances are set to expire on February 28, 2022. (Refs. 36 and 64) The Objectors express concern that growers will be adversely impacted by this rule due to a lack of guidance and the potential of having adulterated food seized by the FDA.

ii. Denial of objection. To the extent this objection asserts that lack of guidance is a fatal flaw with the final rule, this objection is denied. This issue does not provide a basis for reversing the Agency's position on the safety of chlorpyrifos and changing the final rule. Nevertheless, EPA recognizes the need for guidance for farmers and food processors following the revocation of the chlorpyrifos tolerances. As EPA indicated in the final rule, section 408(l)(5) of the FFDCA governs commodities treated with pesticides and in the channels of trade following the tolerance revocations. Under that provision, chlorpyrifos residues in or on food in the absence of a tolerance will not render that food adulterated, as long as it is shown to the satisfaction of the U.S. Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. (21 U.S.C. 346a(l)(5))

The FDA, which is responsible for enforcing tolerances and implementing this provision, has developed guidance for growers and food processors for foods treated with chlorpyrifos. (Ref. 65) That guidance, which covers residues of chlorpyrifos in human food commodities, clarifies the FDA's planned enforcement concerning those foods containing chlorpyrifos residues after the tolerances expire. Animal feed items, which are regulated by FDA's Center for Veterinary Medicine, and various livestock commodities, which are regulated by USDA, are not covered by this guidance. EPA intends to work with those other agencies to assist with questions of compliance as they arise.

g. Substantive Due Process Concerns

i. Objection. Gharda argues that it and other registrants have a fundamental property right in their chlorpyrifos registrations, which is protected by the substantive due process doctrine provided for under the U.S. Constitution. (Ref. 39 at 36 through 37) Gharda claims that the economic value of its chlorpyrifos registration for food use crops is dependent on having tolerances for chlorpyrifos in place. Gharda argues that because the Agency revoked those tolerances "without a reasoned explanation or valid scientific basis, and in disregard of scientific data," the Agency improperly deprived Gharda of economic value of its registration and violated its substantive due process rights.

ii. Denial of objection. Whether Gharda has a substantive due process right to its registrations and the revocation of tolerances somehow infringes that right is immaterial to the question EPA must answer when leaving a tolerance in place—whether the tolerance is safe. The FFDCA is clear: When a tolerance is not safe, it must be modified or revoked. Whether the revocation of that rule has implications for registrants of products or growers of crops is outside the scope of considerations in the FFDCA. Since nothing about this objection provides information bearing on the safety of chlorpyrifos, this objection is denied.

In any event, EPA disagrees with Gharda's claim that the final rule has infringed substantive due process rights.

"To state a substantive due process claim, a plaintiff must allege: (1) That it had property or a property interest; (2) the government deprived it of that property interest; and (3) the government's actions fall so far beyond the outer limits of legitimate governmental action that no process could cure the deficiency. . . . [S]ubstantive due process concerns governmental action which is so arbitrary and irrational, so unjustified by any circumstance or governmental interest, as to be literally incapable of avoidance by any pre-deprivation procedural protections or of adequate rectification by any post-deprivation . . . remedies. . . . Thus, a substantive due process claim is warranted only where *no process* could cure the deficiencies in the governmental action." (*Syngenta Crop Protection, Inc.* v. *EPA*, 444 F.Supp.2d 435, 447 (M.D.N.C. 2006) (internal citations and quotations omitted)) EPA disagrees that Gharda has a property interest in the food uses here since "there is no property interest in using property in a manner that is harmful to the general public." (*American Vanguard Corp.* v. *United States*, 142 Fed. Cl. 320, 328 (Jan. 28, 2019) (citing *Mitchell Arms, Inc.* v. *United States*, 7 F.3d 212 (Fed. Cir. 1993))) Moreover, Gharda has failed to allege any activity by EPA that would implicate the "outer limits of legitimate governmental action" or that is "so arbitrary and irrational, so unjustified by any circumstance or governmental interest," as to be incapable of remedy. Gharda alleges no activity that is "so arbitrary or irrational" other than a general claim that the final rule is "without a reasoned explanation or valid scientific basis, and in disregard of scientific data."

EPA notes that the final rule includes significant explanation for its finding that EPA is unable to determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos residues for which there is reliable information. For example, the final rule includes, among other key information, an overview of the numerous human health risk assessments EPA has conducted and FIFRA SAPs that were convened to discuss chlorpyrifos, a detailed summary of EPA's risk assessment for chlorpyrifos, EPA's hazard assessment of chlorpyrifos, EPA's exposure assessment for chlorpyrifos, and EPA's process for assessing aggregate risk based on the aforementioned assessments. To the extent that this assertion is intended to refer to or incorporate Gharda's other objections—such as Gharda's argument that EPA's explanation for not retaining the eleven uses proposed for retention in the 2020 PID or fails to consider the Corteva oxon study—EPA has already provided responses to those more detailed objections elsewhere in this Order.

In any event, it cannot be said that EPA taking action to revoke an unsafe tolerance under its statutory mandate to ensure that pesticide residues in food are safe for public consumption is outside the bounds of a legitimate governmental action. Congress tasked EPA specifically with the responsibility to ensure that tolerances are only left in place if they are safe and to revoke or modify tolerances if they are not. (*See* 21 U.S.C. 346a(b)(2)(A)) Upon concluding that aggregate exposures were not safe, EPA revoked the tolerances in accordance with the statutory mandate, which is clearly within the bounds of a legitimate government action to ensure that residues of pesticides in or on food are safe for consumption. It is necessarily the case that when EPA revokes a tolerance on the basis of dietary risks for pesticides that are registered under FIFRA, there are going to be impacts to the registrants of those pesticides. Leaving tolerances in place to avoid impacts to pesticide registrants would be inconsistent with the FFDCA. Finally, Gharda is not without process for curing any deficiencies in EPA's actions, including procedures afforded by FIFRA, the APA, and judicial review. Therefore, Gharda's claim that its substantive due process rights have been infringed by EPA's final rule fails.

D. Summary of Reasons for Denying Objections

EPA is denying the objections submitted by the Objectors for several reasons. EPA is denying the objections of the Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador, because these parties did not submit their objections to the Office of the Hearing Clerk, as required by 40 CFR 178.25(b). As discussed in Unit VIII.A. of this document, EPA grouped the other Objectors' objections into five different substantive categories and addressed each in turn.

Regarding the first category—objections to the scope of the final rule—EPA is denying the objections asserting that revoking all chlorpyrifos tolerances was unlawful and unnecessary in light of the proposal in the 2020 PID for limiting uses to 11 high-benefit crops, because the FFDCA requires that EPA assess aggregate exposure based on all currently registered uses of chlorpyrifos, not on a hypothetical subset of those uses. EPA also denies the objections arguing that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA, because FFDCA 408(l)(1) does not require that actions under FIFRA precede or occur concurrently with actions under the FFDCA, and because in any event it was not practicable for EPA to first modify of cancel any registrations in light of the Ninth Circuit's deadline for issuing a final rule. Lastly, EPA denies the objections arguing that EPA should retain import tolerances for chlorpyrifos commodities, because EPA is unable to make the safety finding for leaving in place tolerances for imports until enough uses are canceled to reduce aggregate exposures to acceptable levels.

Regarding the second category—objections to the retention of the 10X FQPA safety factor—EPA is denying the objections that EPA's final rule was arbitrary and capricious for retaining the 10X FQPA safety factor. As an initial matter, EPA has determined that whether the Agency retains the 10X FQPA safety factor or uses a different margin of safety does not ultimately have a determinative impact on the Agency's conclusions regarding the safety of chlorpyrifos in the final rule; therefore, this objection is denied for lack of materiality. Nonetheless, EPA concludes that its consideration of the epidemiological studies was reasonable and consistent with EPA's policy for consideration of all available data. EPA notes there is no requirement that the underlying data must be made available before EPA can rely on these studies, and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children. Furthermore, given the uncertainties surrounding the potential for neurodevelopmental effects at the time of the final rule, EPA's retention of the default 10X FQPA safety factor was consistent with the statutory standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children.

Regarding the third category—objections relating to EPA's assessment of drinking water exposures—EPA is denying the objections that EPA did not have a rational basis for relying on the 2016 DWA, because, unlike the 2020

DWA, the 2016 DWA considered contributions from all registered uses of chlorpyrifos, and so represented the most recent and robust "best available science" for use by the Agency in its final rule. EPA is also denying the objections that it was unreasonable for EPA to assess exposures to chlorpyrifos-oxon in its drinking water assessment, because EPA has reliable data that chlorpyrifos-oxon will be present in at least some drinking water, and because EPA concluded that even assuming chlorpyrifos-oxon is not more toxic and should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe.

Regarding the fourth category—objections relating to procedural matters—EPA is denying the objections that EPA acted inconsistently with the principles of due process and transparency in failing to consider and respond to comments previously submitted on the 2015 proposed rule and in response to the 2020 PID. EPA notes that these objections do not identify a specific element of the final rule that is problematic, and so do not conform to the required form of an objection per 40 CFR 178.30(a)(1). EPA also notes that EPA is not obligated to respond to comments on a rule that was never finalized (*i.e.,* the 2015 proposed rule), or on separate albeit parallel regulatory activities (*i.e.,* the 2020 PID). EPA is also denying the American Soybean Association's objection that the final rule failed to provide adequate procedural due process due to technical delays in opening the Federal eRulemaking Portal, because EPA's regulations only require that objections be filed with the Hearing Clerk, with the Portal serving as an additional means of protecting any CBI, and because the delayed opening of the Portal is harmless error. Lastly, EPA is denying the objections that EPA failed to comply with Executive Order 12866, because this is not a judicially reviewable issue and resolution of these objections has no bearing on any substantive issues with the final rule that could be raised separately.

Regarding the fifth and final category—objections that, as a matter of law, do not provide a basis for leaving tolerances in place—EPA is denying these assorted objections because they provide no reliable information pertaining to the FFDCA safety standard that could support leaving chlorpyrifos tolerances in place.

VIII. Response to Requests for Stay

A. The Standard for Granting a Stay

FFDCA section 408 provides that a regulation issued under subsection 408(d)(4) shall take effect upon publication in the **Federal Register** unless the regulation specifies otherwise. (21 U.S.C. 346(g)(1)) The effective date of the final rule was October 29, 2021, and tolerances for residues of chlorpyrifos on all commodities expire on February 28, 2022. However, section 408 also grants the Administrator the discretion to stay the effectiveness of a regulation if objections are filed. (21 U.S.C. 346a(g)(1))

The statute is silent on the standard to apply in granting a stay. The FFDCA gives EPA unlimited discretion to determine when it might be appropriate to issue a stay, requiring only that objections be filed before EPA may exercise that authority. EPA believes the discretionary nature of this authority gives EPA flexibility in any given case to determine whether and how to stay a rule or order issued under FFDCA section 408(d). EPA has indicated that it will consider the criteria set out in FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35, in determining whether to grant a stay. (*See, e.g.,* Carbofuran; Final Tolerance Revocations, 74 FR 23045, May 15, 2009; *cf.* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 FR 3422, Jan. 19, 2011 (evaluating stay request based on an amalgam of the 21 CFR 10.35 factors and a judicial stay factors)) Under 21 CFR 10.35, a stay shall be granted if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. (21 CFR 10.35(e))

B. Requests for Stay and EPA Responses

1. Summary of Requests for Stay

EPA received written requests for EPA to either stay the effective date of the final rule or allow for a longer phase-out period from the following objectors: Amalgamated Sugar Company, American Crystal Sugar Company, the American Soybean Association, the Sugarbeet Associations, the California Citrus Quality Council, the Cherry Marketing Institute, CLA/RISE, Gharda, the Minor Crop Farmer Alliance, the Agricultural Retailers Association, *et al.,* the Republic of Colombia, and several independent sugarbeet growers. (These written requests are available in the final rule docket at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.)

The requests for stay of the final rule can be sorted into three groups based on the form of the requests and the duration of the stay requested. The first group consists of the requests submitted by the Sugarbeet Associations and Gharda, both of which apply the criteria set out in 21 CFR 10.35 to argue that EPA is required to stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. The Sugarbeet Associations and Gharda also request a stay "until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections." (Refs. 66 and 67) The second group consists solely of the Republic of Colombia. Colombia requests a period of at least 12 months before chlorpyrifos tolerances expire so that it can "make the necessary adjustments in the production of [its] crops to ensure compliance." (Ref. 58) While Colombia does not explicitly frame its request as a request for a stay of the final rule, and does not reference the criteria at 21 CFR 10.35, EPA's interpretation is that this is best understood and assessed by EPA as a request for stay. Finally, the third group consists of the remaining stay requests. These Objectors do not specifically address the regulatory criteria set forth at 21 CFR 10.35; they simply request that EPA stay the final rule until EPA can address the issues raised in their various objections.

2. Denial of Requests for Stay

As noted previously, only the Sugarbeet Associations and Gharda frame their requests for stay by reference to the regulatory criteria at 21 CFR 10.35, and until "a final resolution" can be obtained with respect to the issues raised in their objections. The other stay requests do not reference the regulatory criteria. The sole rationale provided by Colombia for its request for an additional 12-month period before tolerances expire is to enable unspecified parties to "make the necessary adjustments" to ensure compliance. Colombia does not include any information regarding any potential injury (irreparable or otherwise) that

might otherwise be suffered, showing that their case is not frivolous and is being made in good faith, demonstrating sound public policy supporting a 12-month delay, or arguing that their desired 12-month delay is not outweighed by public health or other interests. EPA declines to speculate as to the bases for Colombia's request and denies Colombia's stay request due to the lack of supporting information. The other stay requests simply ask EPA to stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. These Objectors appear to contemplate a scenario in which EPA delays addressing their objections until well after the February 28, 2022, expiration date for chlorpyrifos tolerances specified in the final rule. Because EPA has addressed these objections via this Order, by the plain meaning of these stay requests, there is no longer any need to stay the final rule. As a result, EPA denies those requests for stay submitted by Objectors other than the Sugarbeet Associations and Gharda.

With respect to the requests for stay submitted by the Sugarbeet Associations and Gharda, EPA examines these parties' arguments in light of the four factors set forth in at 21 CFR 10.35.

a. Will the Sugarbeet Associations and Gharda suffer irreparable injury without the stay?

i. Summary of arguments concerning injury. The Sugarbeet Associations and Gharda each argue that they will suffer irreparable injury in the form of economic losses and reputational impacts due to the final rule, and Gharda also argues that the deprivation of its chlorpyrifos registration under FIFRA is a due process violation that constitutes irreparable harm. (Refs. 66 and 67) With respect to economic losses, the Sugarbeet Associations argue that due to the lack of similarly effective alternatives to chlorpyrifos, reduced crop yields could cause the sugarbeet industry significant economic harm. (Ref. 66 at pgs. 2 through 4) Similarly, Gharda claims that it could face significant economic losses if, due to the final rule, it is unable to formulate, distribute, and sell the significant volume of raw materials and U.S.-labeled product it has in inventory. (Ref. 67 at pgs. 6 and 7) With respect to reputational impacts, the Sugarbeet Associations argue that the sugarbeet industry is likely to suffer reputational harm as a result of the final rule and the August 18, 2021, press release announcing the final rule, including the potential for ill will against the sugarbeet industry from customers and the public that could affect the industry's ability to sell its products. (Ref. 66 at pgs. 4 and 5) Similarly, Gharda argues that it has suffered and will continue to suffer reputational harm, and that the final rule has strained and will continue to strain Gharda's relationships with its customers, who might not use Gharda products moving forward. (Ref. 67 at pgs. 6 through 8)

As described in more detail in this unit, EPA disagrees that any injuries to the Sugarbeet Associations and/or Gharda are in fact irreparable.

ii. Response to the Sugarbeet Associations' and Gharda's economic injury arguments. EPA disagrees that the Sugarbeet Associations and Gharda have established that they—or, in the case of the Sugarbeet Associations, the farmer-owners and beet sugar manufacturers they represent—will be irreparably harmed without a stay. As Gharda correctly notes, to establish irreparable harm, "injury must be both certain and great; it must be actual and not theoretical and of such imminence that there is clear and present need for equitable relief." (*Olu-Cole* v. *E.L. Haynes Pub. Charter Sch.,* 930 F.3d 519, 529 (D.C. Cir. 2019) (internal quotation marks and citations omitted)) However, this already high "barrier to proving irreparable injury is higher still" for the economic losses asserted by the Sugarbeet Associations and Gharda, "for it is well settled that economic loss does not, in and of itself, constitute irreparable harm." (*Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544, 555 (D.C. Cir. 2015)) "Mere injuries, however substantial, in terms of money, time, and energy necessarily expended in the absence of a stay are not enough." (*Wisconsin Gas Co.* v. *FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985)) Instead, "recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence" of a company. (*Id.*)

The Sugarbeet Associations and Gharda include identical statements arguing that "[l]osses for which an aggrieved party has no recourse, such as those caused by a governmental entity immune from suit for monetary relief, are 'irreparable *per se.*'" (Ref. 66 at pg. 3 and Ref. 67 at pgs. 5 and 6, respectively (each citing *Feinerman* v. *Bernardi,* 558 F. Supp. 2d 36, 51 (D.D.C. 2008))) However, the Sugarbeet Associations and Gharda fail to note that subsequent caselaw expressly disagrees with that principle. In *ConverDyn* v. *Moniz,* the District Court for the District of Columbia acknowledges that while in *Feinerman* it "characterized economic damages that are unrecoverable due to sovereign immunity as 'irreparable *per se*' . . . that characterization goes too far and the inability to recover economic losses can more accurately be considered as a factor in determining whether the movant has shown irreparable harm." (68 F. Supp. 3d 34, 49 (D.D.C. 2014) (internal citations omitted)) The Court observed that "[o]therwise, a litigant seeking injunctive relief against the government would always satisfy the irreparable injury prong, nullifying that requirement in such cases." (*Id.; see also N. Air Cargo* v. *U.S. Postal Serv.,* 756 F. Supp. 2d 116, 125 (D.D.C. 2010) ("this Court is of the opinion that a party asserting such a loss is not relieved of its obligation to demonstrate that its harm will be great . . . [otherwise] prospective injunctive relief would often cease to be an extraordinary remedy in cases involving government defendants") (internal quotation marks and citations omitted))

EPA finds that neither the Sugarbeet Associations nor Gharda have demonstrated that they or their member entities will suffer irreparable economic harm in the absence of a stay of the final rule. The Sugarbeet Associations provide a handful of statistics regarding the estimated financial impacts that they allege will result from the revocation of chlorpyrifos tolerances, and argue that because EPA estimated in the 2020 PID that the benefits of chlorpyrifos for sugarbeets in North Dakota and Minnesota *could* be up to $500 per acre, and there are over 140,000 acres of sugarbeets at risk from sugarbeet root maggots, the sugarbeet industry "would face tens of millions of dollars in irreparable damages annually" absent a stay. (Ref. 66 at pg. 4) EPA notes, however, that the Sugarbeet Associations omit key details, and that their conclusion is highly speculative.

The Agency included sugarbeets in its detailed economic analysis of agricultural uses of chlorpyrifos, which was conducted in 2020 to support the preliminary interim registration review decision. The analysis utilized proprietary pesticide usage surveys as well as publicly available pest management recommendations from extension crop experts. (Ref. 56) This analysis indicated that for most sugarbeet pests targeted with chlorpyrifos, several effective alternatives are available. The Agency found that for regions in the upper Midwest where populations of sugarbeet root maggot are very high, yield losses of up to 45% could occur without chlorpyrifos. The impacts of such yield losses are estimated at $498 per acre in

North Dakota and Minnesota, where an average of 61,200 acres were estimated to be affected. While EPA acknowledges that growers in these areas will be impacted, these areas represent about 20% of the sugarbeet acreage in Minnesota and 10% of the acreage in North Dakota. For purposes of comparison, the total national harvested sugarbeet acreage is approximately 1.1 million acres. Furthermore, effective alternatives to chlorpyrifos are available in other areas of the country. Thus, while there are likely to be impacts to some growers, EPA does not agree that the loss of chlorpyrifos will cause an irreparable injury to the sugarbeet industry overall.

EPA also notes that the Sugarbeet Associations fail to provide any context for the economic injuries they claim that they and their members will incur as a result of the final rule. As discussed previously, EPA acknowledges that sugarbeet yields in certain production areas could be reduced, and that some sugarbeet growers and/or beet sugar manufacturers may lose some portion of their revenue due to the final rule. However, even assuming that the figures provided by the Sugarbeet Associations are accurate, it is not clear to EPA what the specific implications of these figures might be for the Sugarbeet Associations or the growers and/or manufacturers they represent, and nowhere in their stay request do the Sugarbeet Associations assert that the failure to stay the final rule will threaten their or their member entities' very existence.

Finally, EPA notes that for many crops—including sugarbeets, as the Sugarbeet Associations acknowledge in their request for stay—alternatives to pesticides are readily available. While these alternatives may be more expensive than chlorpyrifos, or perhaps less effective than chlorpyrifos, the availability of alternatives to chlorpyrifos indicates that it is unlikely that sugarbeets will be left completely unprotected. This in turn suggests that any injury is likely to be temporary and reparable.

EPA also disagrees with Gharda's arguments regarding irreparable economic injury. Although EPA acknowledges that the revocation of tolerances will necessarily impact any registrant of chlorpyrifos products, EPA is not convinced that the economic injuries alleged by Gharda are in fact irreparable. Gharda argues that it will suffer certain economic losses due to the inability to formulate, distribute, and sell chlorpyrifos products, including a loss of future sales of chlorpyrifos products, and that Gharda and its customers will face a loss of their investments in chlorpyrifos. EPA finds that Gharda's claims regarding the loss of future sales of chlorpyrifos products are too speculative to satisfy the requirement that injury "must be actual and not theoretical." (*Olu-Cole,* 930 F.3d at 529) Gharda does not provide any basis for its assumptions regarding future revenues from chlorpyrifos other than a declaration from its president that contains an identical assertion as in the stay request and offers no further evidence. To provide but a few examples, these assumptions regarding future revenues could be undercut by changes in customer preferences, supply chain complications, and/or price fluctuations. Crucially, and in any event, Gharda does not claim that a failure to stay the final rule will threaten either its or its customers' very existences.

EPA notes that the 2020 PID proposed a subset of chlorpyrifos uses that might result in exposures below the Agency's level of concern if significant changes to the labels were made, including use cancellations and geographic limitations, among others. EPA also notes that the final rule does not foreclose Gharda's ability to sell or distribute its products outside of the United States for food applications in other jurisdictions, provided any such treated products are not imported into the United States in a manner inconsistent with FDA's channels of trade guidance. These possibilities undermine Gharda's assertion that any and all economic harms it has suffered or might suffer are irreparable.

EPA also notes that any potential economic injury suffered by Gharda has been significantly exacerbated by Gharda's independent business decisions. Gharda notes that in 2021 it increased production to meet demand for chlorpyrifos after Corteva exited the market, and that it now stands to incur certain losses due to its inability to formulate, distribute, and sell chlorpyrifos products. However, Gharda should have recognized that there was some risk to expanding production in light of the Agency's proposed findings in the 2020 PID (which indicated that some changes to existing registered products would likely be required, including some potentially significant changes), and following the issuance of the Ninth Circuit's decision in April of 2021.

More generally, pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* EPA conducted a small business analysis to assess the economic impact of the final rule on small entities. (Ref. 68) That analysis was prepared consistent with other analyses that are prepared for rules subject to notice and comment pursuant to the RFA, which requires an agency to consider the economic impacts that rules subject to notice and comment rulemaking will have on small entities. Since the final rule was not subject to notice and comment, the analysis was not required, but it was prepared to present information on the potential impact to small farms and possible job losses for industry as a result of the revocation of chlorpyrifos tolerances. Based on the analysis in the 2021 SBA memo, EPA concluded that there was not likely to be a significant impact on a substantial number of small entities and that there are unlikely to be significant job losses as a result of the revocation of the rule. Of the approximately 2 million farms currently in the United States, only an estimated 43,430 farms are using chlorpyrifos each year. For about 25,100 affected farms, the impacts of tolerance revocation are less than 1% of gross revenue. Up to 10,500 small farms could see impacts of between 1 and 3% of gross revenue per acre for affected crops. This is less than 1% of all small crop farms. An estimated 1,900 farms would see per-acre impacts of greater than 3%, about 0.13% of small farms producing crops. (Ref. 68 at pg. 2)

iii. Response to the Sugarbeet Associations' and Gharda's reputational arguments. EPA also disagrees with the Sugarbeet Associations' and Gharda's arguments regarding irreparable reputational injury. With respect to Gharda's arguments, EPA notes as a preliminary matter that Gharda claims that it "has suffered" reputational harm as a result of the final rule, and that EPA's revocation of the chlorpyrifos tolerances "has . . . strain[ed]" Gharda's customer relationships. (Ref. 67 at pg. 7) Even if EPA were to concede that Gharda has incurred such reputational injuries, staying the final rule would not resolve injuries that have allegedly already occurred. As a result, EPA will not further evaluate any reputational injuries Gharda alleges that it has already incurred for purposes of this first factor.

EPA will take the Sugarbeet Associations' and Gharda's remaining reputational arguments in turn. First, Gharda argues that by revoking chlorpyrifos tolerances, "EPA has directly attacked the safety of chlorpyrifos . . . and the credibility of Gharda in selling and distributing chlorpyrifos products." (*Id.*) While EPA has determined that aggregate exposures to chlorpyrifos from currently registered uses are not safe, EPA categorically rejects Gharda's claim that EPA directly

attacked Gharda's credibility. EPA finds it noteworthy that Gharda is unable to cite to a single source for this claim, other than a declaration from its president that simply contains a verbatim assertion as in the stay request and offers no further evidence. EPA also notes that the final rule did not single out Gharda's registered chlorpyrifos products. The final rule itself did not address any specific chlorpyrifos registered products or registrants; rather, the final rule revoked chlorpyrifos tolerances due to safety concerns with the chemical, not concerns with any specific registered product or individual company. Therefore, EPA finds no basis whatsoever for Gharda's claim that EPA attacked its credibility and thereby injured Gharda's reputation.

Second, Gharda asserts that because the final rule disregarded written commitments by Gharda prior to the final rule to modify Gharda's label consistent with EPA's proposal in the 2020 PID, and because "Gharda assured its customers that it was working cooperatively with EPA to reach agreement that would allow for many continued agricultural uses," Gharda suffered reputational injury and a loss of customer goodwill. (*Id.* at pgs. 7 and 8) As already discussed in Unit VII.C.1.b.ii. of this Order, EPA entered into such discussions with Gharda in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. However, it simply was not practicable for EPA to complete any modifications or voluntary cancelations in time to inform the final rule and meet the Ninth Circuit's deadline. Furthermore, at no point during its discussions with Gharda did EPA make a binding commitment to modify chlorpyrifos tolerances instead of revoking them altogether. To the extent that Gharda informed its customers that EPA would modify chlorpyrifos tolerances instead of revoking them, that was an independent business decision made entirely by Gharda, and EPA cannot be held accountable for any consequences of that decision. Any reputational injuries suffered by Gharda as a result of assurances they provided their customers that EPA would modify chlorpyrifos tolerances are wholly attributable to Gharda.

Third, Gharda argues that in light of the scientific record for chlorpyrifos, neither Gharda nor its customers expected EPA to revoke all tolerances, and that EPA's decision to do so "has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill." (*Id.*) EPA's review of the scientific record is already extensively detailed in the final rule and elsewhere in this Order, and EPA has made clear that based on its review of that record, it is unable to conclude that chlorpyrifos tolerances are safe due to the extent of currently registered uses. EPA also notes that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that on October 28, 2015 ((80 FR 69080, November 6, 2015) (FRL–9954–65)), EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. EPA also reiterates that the 2020 PID made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled under that proposed scenario. Finally, EPA notes that the Ninth Circuit rejected EPA's previous attempt to leave tolerances in place based on an argument that the petitioners had failed to provide sufficient data to support revoking the tolerances and found that the burden was on EPA to demonstrate that the tolerances were safe in order to leave them in place. The Court ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and therefore, a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Also, as noted in the preceding paragraph, any injury arising from Gharda's speculative discussions with its customers is an injury of Gharda's own making and not EPA's rule.

Fourth, Gharda argues that the final rule could result in long-term harm to Gharda due to "the stigma attached to the unfounded public statements by EPA that its action was taken 'to ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of [chlorpyrifos],' and 'follow[s] the science and put[s] health and safety first.'" (*Id.* at pg. 8, citing Ref. 57) The Sugarbeet Associations make a similar argument, claiming that because the final rule revoked chlorpyrifos tolerances despite the proposal in the 2020 PID concerning the 11 uses of chlorpyrifos identified by EPA, the sugarbeet industry is likely to suffer reputational harm in the form of "ill-will . . . from customers and the public." It is not clear to EPA why that would be the case. The final rule makes no mention of Gharda or the Sugarbeet Associations at all and includes only a single reference to sugarbeets in its discussion of the 2020 DWA. (See Ref. 1 at pg. 48331) Nowhere in the final rule does EPA disparage sugarbeets, or single out chlorpyrifos applications on sugarbeets as presenting a unique risk to the public. Quite the opposite: EPA revoked *all* chlorpyrifos tolerances due to its inability to conclude that aggregate exposures from all chlorpyrifos uses would be safe. Additionally, while it is not established that Gharda's, the Sugarbeet Associations' or the sugarbeet industry's reputations will suffer as a result of the final rule, EPA's view is that a stay might in fact lead to the reputational harm the Sugarbeet Associations and Gharda are seeking to avoid. As described in the final rule and reiterated throughout this Order, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA, and as of February 28, 2022, those tolerances will no longer be in effect. Assuming the Sugarbeet Associations and their member entities and Gharda comply with the revocation and abide by the guidance issued by the FDA and USDA, EPA sees no reason why customers or the public should have any ill will toward these entities for simply complying with the FFDCA. On the other hand, if EPA were to stay the final rule after concluding that tolerances are unsafe, customers and the public might have concerns about the safety of chlorpyrifos residues on food products, and Gharda's and the Sugarbeet Associations' members' roles in making these products available to the public. Therefore, EPA disagrees with Gharda and the Sugarbeet Associations that they and/or the sugarbeet industry will suffer irreparable reputational injury due to the final rule.

iv. Response to Gharda's due process argument. Finally, EPA disagrees with Gharda that EPA has infringed its due process rights via the final rule. As a preliminary matter, EPA notes that Gharda's stay request omits a key element of the due process analysis. Gharda's request characterizes "the deprivation of a legally protectable property right (*i.e., pesti*cide registration)" as a due process violation. However, as Gharda itself makes clear in its Objections to the final rule, any such deprivation must also be "unreasonable, arbitrary or capricious." (Ref. 67 at pg. 37 (*citing Nebbia* v. *New York,* 291 U.S. 502, 525 (1934))) As EPA explains in more detail in Unit VII.C.5.g. of this

Order, Gharda has failed to provide information sufficient to establish that the final rule unfairly or arbitrarily revoked chlorpyrifos tolerances. EPA also notes that as a legal matter, the final rule does not in fact effectuate a cancellation of Gharda's registrations. Instead, the final rule simply revokes chlorpyrifos tolerances. As a result, it cannot be said that the final rule infringed Gharda's substantive due process rights and thereby caused Gharda irreparable harm.

b. Were the Sugarbeet Associations' and Gharda's cases for a stay frivolous, and not pursued in good faith?

EPA generally believes that the Sugarbeet Associations' and Gharda's requests for a stay were made in good faith and reflect their concern about the potential implications of the final rule for their and their represented entities' business interests and/or ability to produce food (as the case may be). Chlorpyrifos has been an available insecticide for decades, and EPA recognizes that many growers have come to rely on it as a tool for controlling insect pests. Nor is there any indication in their requests for stay that the Sugarbeet Associations or Gharda are making frivolous arguments; EPA's impression is that the Sugarbeet Associations' and Gharda's requests for stay appear to reflect their good-faith interpretation of 21 CFR 10.35. As discussed in Unit VIII.B.2.a.iii., EPA note that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that in 2015 EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. The 2020 PID also made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled. Finally, the Ninth Circuit ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and that a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, the Sugarbeet Associations and Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Notwithstanding this fair warning, however, EPA generally agrees with these Objectors that their cases for a stay are not frivolous and are being pursued in good faith.

c. Have the Sugarbeet Associations and Gharda demonstrated sound public policy grounds supporting a stay?

The Sugarbeet Associations and Gharda each argue that public policy grounds support their stay requests, though EPA notes that the Sugarbeet Associations combined this factor and the fourth factor into a single discussion. Both of these Objectors' arguments on this point incorporate several of the arguments raised in their objections, which were submitted under separate cover: That good public policy does not support regulatory decisions that are at odds with EPA's "best available science" and the 2020 PID; that EPA issued the final rule in a process that was fundamentally unfair and marked by bad faith; that EPA disregarded cancelation procedures, prior public comments, and interagency review processes, and abdicated its responsibility to oversee a lawful and orderly phase-out of chlorpyrifos products; and that the final rule will result in economic harms to U.S. growers and environmental harms from increased application of chlorpyrifos alternatives. Gharda also argues that the timeframe imposed by the final rule "will result [in] the needless waste of safe and wholesome food," (Ref. 67 at pg. 11) and the Sugarbeet Associations include a general assertion that chlorpyrifos "is used only when and only as much as necessary." (Ref. 66 at pg. 9)

EPA finds that the Sugarbeet Associations and Gharda have failed to demonstrate sound public policy grounds supporting a stay of the final rule. First, EPA notes that most of the arguments marshaled by the Sugarbeet Associations and Gharda on this point are simply restatements of their objections to the final rule, and that these Objectors frequently fail to explain how exactly any particular public policy is furthered by these objections. For example, the Sugarbeet Associations argue that EPA's alleged failure to consider relevant scientific information, as indicated by its decision to revoke chlorpyrifos despite the 2020 PID, is itself a reason that the public interest supports a stay. However, the Sugarbeet Associations do not elaborate on how or why that alleged failure relates to sound public policy or furthers the public interest or in this particular case, supports a conclusion that EPA erred in concluding that chlorpyrifos tolerances were unsafe. Similarly, Gharda argues that the final rule will cause significant hardship to U.S. growers who might need to rely on more expensive and/or less effective alternatives to chlorpyrifos but does not explain in its stay request why that is a matter of public interest, rather than an issue of concern particular to those growers.

Second, EPA notes by requesting a stay "until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections," while failing to define what exactly constitutes a "final resolution," the Sugarbeet Associations and Gharda are essentially asking for the final rule to be stayed indefinitely. Even if EPA interprets "final resolution" as being limited to the conclusion of judicial review of the final rule—which EPA notes is a much narrower interpretation than the plain language of these Objectors' request—it is extremely unlikely that this matter would be fully and finally resolved by the courts for at least two or three years. FFDCA section 408(h)(1) provides that any person who will be adversely affected by the final rule may obtain judicial review in the relevant U.S. Court of Appeals. Review in the Court of Appeals may, by itself, take several years; for example, over a year and a half elapsed between the LULAC Petitioners' and States' August 7, 2019, petition in the Ninth Circuit for review of the Denial Order and Final Order and the Ninth Circuit's decision on April 29, 2021. However, the process could take still longer, since FFDCA section 408(h)(4) provides that the judgment of the court affirming or setting aside the final rule is subject to review by the Supreme Court of the United States. Even if the Supreme Court denies certiorari, significant time will have elapsed before it could reasonably be said that there has been a "final resolution" in terms of judicial review of the final rule. Furthermore, EPA is confident in its legal and scientific analyses, and sees no compelling policy rationale for staying the final rule and leaving chlorpyrifos tolerances in place pending judicial review. Doing so would only perpetuate the public's exposure to the unsafe levels of chlorpyrifos that the Agency identified based on its review of the science and the aggregation of relevant exposures from all currently registered uses, all to mitigate the potential for impacts to Gharda and/or the sugarbeet industry. EPA's position is that there are no sound public policy grounds supporting such a course of action.

It is also clear to EPA that the Sugarbeet Associations' and Gharda's ultimate goal with respect to their stay requests is the rescission or revocation of the final rule. This is evident from the fact that the Sugarbeet Associations and Gharda incorporate many of the arguments made in their objections,

which request that the final rule be immediately or summarily reversed, and from Gharda's stay request, which discusses the economic losses Gharda will allegedly face if the final rule is not "reversed or rescinded." To the extent the Sugarbeet Associations and Gharda are seeking to utilize the stay process to rescind the final rule, EPA notes that there is no need for EPA to stay the final rule simply to give the Sugarbeet Associations and Gharda more time to file litigation seeking rescission. EPA has outlined the relevant judicial review process in the preceding paragraph, and notes that there is no barrier to the Sugarbeet Associations and Gharda deciding to pursue judicial review of the final rule through a challenge to this Order. Nor does EPA believe that any public policy interest is furthered by such a course of action.

In light of the foregoing, EPA has significant concerns that the Sugarbeet Associations and Gharda are seeking to use the stay process to compel the consideration of factors not permitted by the FFDCA, thereby keeping chlorpyrifos tolerances in place despite EPA's inability to make the safety finding required by the FFDCA and the Ninth Circuit. By arguing that public policy grounds favor an effectively indefinite stay of the final rule due to the potential for economic harm, the Sugarbeet Associations and Gharda are asking EPA to keep chlorpyrifos tolerances in place despite EPA's inability to make a statutorily required safety finding for these tolerances and despite the fact that the FFDCA safety standard does not permit consideration of economic costs or benefits. This is a significant request, and EPA expects any party making such a request to demonstrate in detail how it furthers the public interest. However, as noted in the preceding paragraph, the Sugarbeet Associations and Gharda fail to sufficiently explain how the stay request is in the public interest at all, much less how any such public interest warrants deviating from the plain language of the FFDCA. EPA's position is that there are in fact overwhelming public policy grounds supporting EPA's reliance on the plain language of the FFDCA, particularly given the public health concerns underlying that statute.

Specifically, there is a significant public policy argument in favor of the Agency fulfilling its statutory obligation to follow the law as it was enacted by Congress. As enacted by Congress, section 408 of the FFDCA is clear that in order to leave tolerances in place, EPA must determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos, including all anticipated dietary exposures and all other exposures for which there is reliable information. If the tolerances are not safe, EPA must modify or revoke them; any tolerances so modified, however, must also be safe. As discussed throughout this document, the FFDCA does not permit consideration of economic factors in the Agency's determination of safety. There is a compelling public policy argument that EPA must act in accordance with Congress' intent, as evidenced by the plain language of the statute. As a result, EPA's analysis in the final rule was necessarily limited to an assessment of aggregate exposures, including dietary, residential, and drinking water exposures, as instructed by the statute. Because EPA could not determine that such aggregate exposures were safe, EPA revoked tolerances for chlorpyrifos. Furthermore, EPA notes that to disregard the clear statutory language would also entail turning a blind eye to EPA's inability to find that chlorpyrifos tolerances are safe. That is, EPA taking action in direct contravention of the FFDCA is not only poor public policy from an administrative law standpoint, but also from a public health perspective. EPA considers the protection of public health to be a matter of overwhelming importance and is not inclined to so readily disregard its own inability to conclude that chlorpyrifos tolerances are safe.

Notwithstanding, EPA is not saying that it is precluded from ever delaying an effective date of a tolerance revocation rule. In a proposed order granting objections to revoke sulfuryl fluoride tolerances, EPA proposed to phase-out tolerances over varying periods of time due to lack of alternatives and the relatively low contribution of harm coming directly from the use of the pesticide itself as opposed to naturally occurring fluoride. (*See* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay (76 FR 3422, January 19, 2011 (FRL–8867–9))) But that is not the case here: For chlorpyrifos, the use of the pesticide itself is directly contributing to harmful aggregate exposures, there are some alternatives, and EPA has already delayed the expiration of the revoked tolerances. Therefore, EPA concludes that there are not compelling public policy grounds to further delay in light of the Agency's finding that the chlorpyrifos tolerances are not safe.

With respect to Gharda's argument that the final rule will "result [in] the needless waste of safe and wholesome food," EPA notes that Gharda is incorrect. FFDCA section 408(l)(5) provides for the continued distribution of food treated with chlorpyrifos as long as the conditions in that provision are met. Moreover, FDA has developed guidance describing how FDA intends to monitor any foods containing chlorpyrifos residues and detailing intentions concerning enforcement. (Ref. 65) As a general matter, implementation of the FDA guidance will not result in the "needless waste" of food since foods treated with chlorpyrifos prior to the expiration of the tolerances on February 28, 2022, will continue to move through the channels of trade for the next few years consistent with the terms of section 408(l)(5) and the guidance. Therefore, as implemented, EPA does not anticipate that the final rule will result in the disposal of massive amounts of foods treated with chlorpyrifos, or in any "needless waste."

Finally, while the Sugarbeet Associations include a general assertion that chlorpyrifos "is used only when and only as much as necessary," EPA again notes that the Sugarbeet Associations fail to demonstrate how that assertion supports a determination that sound public policy grounds support a stay of the final rule. EPA has provided significant detail in the final rule and in this Order describing the analysis supporting its revocation of revoking chlorpyrifos tolerances, which analysis included consideration of estimated exposures from all approved uses of chlorpyrifos.

d. Is the delay resulting from the stay outweighed by public health concerns or other public interests?

The Sugarbeet Associations and Gharda each argue that the delay resulting from a stay is not outweighed by public health concerns or other public interests, though as noted the Sugarbeet Associations combined this factor and the third factor into a single discussion. Gharda's arguments in support of this factor are brief and conclusory. Gharda argues that "[t]here are no public health or other public interests that will be adversely impacted by granting a stay," referencing back to its arguments that the final rule is at odds with the 2020 PID, that EPA incorrectly applied the 10X FQPA safety factor, and that the final rule will result in economic and environmental harms. (Ref. 67 at pg. 11) Similarly, the Sugarbeet Associations state that the "weighing of the public interest supports a stay" based on the potential economic harm to growers if no stay is granted, as well as "the corresponding lack of public health or public interest

counseling against a stay." (Ref. 66 at pg. 9)

EPA disagrees with the Sugarbeet Associations and Gharda and finds that the delay resulting from an effectively indefinite stay of the final rule is outweighed by public health concerns and other public interests. First, EPA strongly disagrees with the Sugarbeet Associations and Gharda that there are no public health concerns or other public interests counseling against a stay. Most obviously, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA. Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe. While FFDCA section 408(l)(5) and the FDA's Channels of Trade guidance will continue to allow some foods treated with chlorpyrifos to move through the channels of trade, the revocation and expiration of the tolerances will ensure that no chlorpyrifos is used on food after the expiration, thus, limiting the ultimate universe of foods that may contain chlorpyrifos residues to less than what would be available if EPA stayed the rule. Moreover, the final rule's revocation of chlorpyrifos tolerances, which precludes continued application to food crops, would also prevent additional contributions of chlorpyrifos from ending up in drinking water due to its use on food. EPA does not take lightly the FFDCA's clear mandate that tolerances may only be left in place if they are safe and views the safety of pesticide chemical residues on food as a significant public health concern and a matter of overwhelming public interest.

Nor have the Sugarbeet Associations or Gharda presented any persuasive evidence in support of this position. The Sugarbeet Associations simply state that there is a "lack of public health or public interest counseling against a stay," and provide no support whatsoever for this proposition. Gharda makes a similar assertion, and then includes a few sentences briefly referencing arguments made in its objections. However, Gharda does not identify how these points, which appear to be made almost in passing, support their argument that there is a complete absence of public health or other public interests that will be adversely impacted by granting a stay.

Second, EPA is unsettled by the open-ended nature of the Sugarbeet Associations' and Gharda's stay requests, which ask EPA to stay the final rule "until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections." EPA notes that neither Objector defines or otherwise limits what exactly might constitute such a "final resolution," particularly since their requests include, but are not limited to, potential judicial review. As a result, EPA views Objectors' request as at best an indefinite stay of the final rule, and at worst as an attempt to effectively rescind the final rule via the stay process—all in direct contravention of a statutory mandate that requires EPA to determine that tolerances are safe in order to leave them in place. While EPA does not necessarily require requests for stays to include a specific timeframe for the duration of the requested stay, EPA does not believe that the public interest is served by granting a stay with such ill-defined parameters. This is particularly true where, as is the case here, the subject matter bears directly on public health concerns. If EPA were to indulge Objectors' requests and stay the final rule on this basis, and after several years Objectors exhaust their judicial avenues for challenging the final rule, Objectors could nonetheless continue to assert that any or all of the specific issues raised in their objections have not been fully resolved and that the stay should continue. As a result, EPA would necessarily have to agree to a definable endpoint for the stay. EPA cannot agree to this indefinite postponement, particularly in light of its inability to conclude that chlorpyrifos tolerances are safe.

Finally, EPA recognizes that the Sugarbeet Associations' and Gharda's requests ask EPA to continue relying on the precise approach for which EPA was so recently and explicitly chastised by the Ninth Circuit. That is, EPA is asked to set aside the final rule in order to engage in "further factfinding after thirteen years of interminable delay," which the Ninth Circuit stated, "would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." (*LULAC*, 996 F.3d at pg. 702) In light of the Ninth Circuit's clear frustration with EPA for its long delay, EPA is unwilling to return to an approach that would result in further delay for more study of chlorpyrifos tolerances, all in pursuit of an amorphous "final resolution" of the Sugarbeet Associations' and Gharda's various concerns. As reiterated several times herein, EPA is unable to conclude that chlorpyrifos tolerances are safe. The statute does not permit EPA to leave tolerances in place when it cannot conclude that they are safe. As a result, EPA refuses to further delay revoking chlorpyrifos tolerances.

e. Denial of the Sugarbeet Associations' and Gharda's Stay Requests

As stated in the regulation, the Agency shall grant a stay if all four of the criteria in 21 CFR 10.35(e) are satisfied. As explained previously, EPA find that the Sugarbeet Associations and Gharda have failed to satisfy three of the four criteria in 21 CFR 10.35(e). Consequently, EPA denies the Sugarbeet Associations' and Gharda's requests for a stay of the final rule.

IX. Earthjustice Feedback and Comments

A. Overview

On October 28, 2021, prior to the close of the objections period, Earthjustice submitted a document titled *LULAC Petitioners' Feedback on the Environmental Protection Agency's Chlorpyrifos Tolerance Revocation Rule and Comments on Growers' Objections* on behalf of the following 12 public interest groups: League of United Latin American Citizens, NRDC, PANNA, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers. (Ref. 69) Earthjustice previously submitted objections to the 2017 Order Denying Petition on behalf of these same 12 public interest groups in June 2017. Earthjustice also represented these 12 public interest groups in their lawsuit challenging the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial before the Ninth Circuit Court of Appeals, in which they sought to have the chlorpyrifos tolerances revoked.

Notably, Earthjustice does not object to the final rule's revocation of tolerances for chlorpyrifos. On the contrary Earthjustice's submission says that "[t]he LULAC petitioners . . . celebrate EPA's action." (*Id.* at pg. 1) Rather, these comments are primarily focused on arguments that Earthjustice (on behalf of the advocacy groups) believes the Agency must consider and address in the event that chlorpyrifos tolerances would be retained or reinstated at a future time. For the most part, Earthjustice reiterates arguments that it has made previously in its objections to the 2017 Order Denying Petition, including that use of 10% cholinesterase inhibition as the regulatory endpoint, which EPA used in the final rule, is underprotective, even with the retention of the 10X FQPA

safety factor, and should not be used as precedent in future registration review actions for non-food uses of chlorpyrifos or for other organophosphate pesticides.

Earthjustice asserts that, as a scientific and legal matter, EPA is unable to make a finding of reasonable certainty of no harm using 10% cholinesterase inhibition as the regulatory endpoint. Earthjustice alleges that not only does the science support the conclusion that neurodevelopmental harms occur below levels of this regulatory endpoint, but the record and the Ninth Circuit's decision in *LULAC* foreclosed EPA from making such a finding. Earthjustice also takes issues with certain EPA statements in the final rule, which Earthjustice argues are intended to "disparage" the causal link between chlorpyrifos exposure and neurodevelopmental harm to children. Earthjustice believes that these statements are at odds with the record and unsupported. Finally, Earthjustice reiterates arguments made previously in response to EPA's 2017 Order Denying Petition that the final rule's retention of the 10X FQPA safety factor is not sufficient to ensure reasonable certainty of no harm to children.

B. Response to Earthjustice's Feedback and Comments

Because EPA is leaving the final rule in place as promulgated in August 2021 and not leaving any tolerances in place, EPA does not believe the Earthjustice comments necessitate a response at this time. While the comments might be relevant in the event that tolerances were retained or in any future action in which EPA considers petitions to establish chlorpyrifos tolerances, they are not relevant to a final rule that revokes tolerances. EPA does not need to address any of these comments as part of this Order, as they are not ripe for consideration at this time.

X. Conclusion

For all of the reasons specified in Unit VI., VII., and VIII. of this document, EPA denies, in full, the objections and requests for hearing on those objections and requests for stay, respectively.

XI. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying objections filed under the FFDCA section 408. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

XII. Congressional Review Act (CRA)

The CRA, 5 U.S.C. 801 *et seq.*, does not apply to this Order because this action is not a rule for purposes of 5 U.S.C. 804(3).

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

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In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 22-1422

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,

Petitioners,

v.

MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, et al.,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

REPLY IN SUPPORT OF PETITIONERS' RENEWED MOTION FOR A PARTIAL STAY PENDING REVIEW

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The same motion for partial stay has now been briefed twice. Given this second chance, EPA corrects some egregious errors it made in opposing the original motion. But even as EPA's story evolves, it continues to be divorced from reality and in conflict with the requirements of the FFDCA, FIFRA, and APA. EPA made the necessary safety determination for the 11 uses at issue here, considering only the science as required by law. EPA narrowed its focus from all registered uses to this subset because EPA recognized that they are "critical and high-benefit" to agriculture. 87 Fed. Reg. at 11,244. EPA relied upon its safety determination for the 11 uses at issue in its dealings with Gharda. EPA's own actions demonstrate that it had the evidence and the authority to modify tolerances and narrow permissible uses consistent with this safety determination. EPA's Final Rule, however, rejected the FFDCA's plain text, EPA practice, and EPA's own scientific conclusions. Revocation of chlorpyrifos tolerances for the uses EPA found safe, and which EPA acknowledges are "critical, high-

benefit" uses to agriculture, threatens Petitioners with irreparable harm. The Court should grant Petitioners' motion.[1]

ARGUMENT

I. Petitioners Are Likely to Succeed on the Merits.

A. The Court faces a legal question, not a scientific debate.

EPA's Denial demonstrated that EPA made the relevant safety finding for EPA's Designated Safe Uses. 87 Fed. Reg. at 11,241. EPA's response confirms it. Kiely Decl. ¶18 (EPA made a safety determination in the PID). EPA's sole reason for rejecting this safety determination is its newfound interpretation of the FFDCA as preventing it from narrowing permissible uses. This case therefore requires no resolution of scientific issues.[2] Rather, it presents a simple

[1] EPA suggests in its Opposition to Petitioners' Renewed Motion for Partial Stay, ECF No. 5135786 ("Opp.") at 15, that the Court lacks jurisdiction under 40 C.F.R. § 23.10. Any such claim is wrong and, in any event, now moot with today's filing of a third petition.

[2] The record contradicts EPA's argument, Opp. at 7, that the necessary safety determination is missing. *Supra*. It also contradicts EPA's new suggestion, Opp. at 16, that it cannot find chlorpyrifos safe based on alleged evidence of neurodevelopmental impacts. 87 Fed. Reg. at 11,232 ("EPA remains unable to make a causal linkage between chlorpyrifos exposure and the [neurodevelopmental] outcomes reported"). Proposed Amici's brief, re-arguing EPA's scientific findings, is similarly beside the point.

legal question: does the FFDCA prohibit EPA from narrowing pesticide uses to those it considers safe, or instead must EPA reject ***all*** uses if ***any*** use could be unsafe?

The FFDCA's plain text answers this question. EPA must employ a tolerance-by-tolerance approach for revocation: examining the data to determine whether "a tolerance" is safe. Petitioners' Renewed Motion for a Partial Stay, ECF No. 5132688 ("Mot.) at 20-22; 21 U.S.C. § 346a(b)(2)(C). To be clear, EPA must assess safety for the individual tolerance by considering "aggregate exposure" to the pesticide residue, including "all anticipated dietary exposures." 21 U.S.C. § 346a(b)(2)(A)(ii)). In other words, EPA must examine a tolerance's safety in the context of other relevant exposures. But Congress never required EPA to conduct this assessment only for the "universe of proposed and approved uses for the pesticide." Opp. at 17.

EPA's new interpretation that all tolerances must rise or fall together reads key text out of the statute. Congress authorized EPA to "modify" an existing tolerance, as well as to "leave in effect" or "revoke" a tolerance. 21 U.S.C. § 346a(b)(2)(A)(i). Congress intended modification to include narrowing permissible uses, as it expressly

prohibited "expanding the tolerance to cover additional foods" through modification. *Id.* § 346a(b)(1). By expressly prohibiting ***expansion*** of uses, while leaving open the ***reduction*** of uses, Congress clearly intended to allow EPA the option of narrowing uses through modification of tolerances—precisely what EPA did in the PID. This option of narrowing uses through modification is consistent with the forward-looking direction of Congress to evaluate safety based on "anticipated dietary exposures." 21 U.S.C. § 346a(b)(2)(A)(ii).

EPA's new interpretation would produce absurd results. EPA established over 75 different tolerances for chlorpyrifos. 40 C.F.R. § 180.342. Similarly, dozens of different tolerances exist for many other pesticides. *See, e.g.*, *id.* § 180.339 (MCPA); *id.* § 180.332 (Metribuzin). If all tolerances must rise or fall together, EPA would have to revoke all tolerances for any pesticide every time it concluded an individual tolerance was unsafe. That makes no sense. *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("absurd results are to be avoided").

B. EPA's litigation position conflicts with its established interpretation.

Prior to the Final Rule, EPA never construed FFDCA and FIFRA to prohibit narrowing of permissible uses in making a safety determination. As Petitioners have previously explained, Reply in Support of Petitioners' Motion for Partial Stay, ECF No. 5129157 ("Reply") at 9-10, EPA's established practice is to modify both tolerances and associated food use registrations to conform to its safety findings. Here, EPA declared it would "use its FFDCA rulemaking authority to make the needed changes to the tolerances." Long Decl. Ex. B at 62. EPA would not have contemplated making "needed changes" if the only decision allowed was a yes/no decision covering all tolerances.

After *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673 (9th Cir. 2021) ("*LULAC*"), EPA negotiated for months with Gharda on narrowing the permissible uses. Seethapathi Decl. ¶¶21-33. This negotiation process assumed a tolerance-by-tolerance assessment could be conducted, considering the aggregate exposures of the anticipated tolerances that would remain. If EPA thought a finding of safety for all currently registered uses was required, it would not have wasted time and resources on discussions with Gharda on EPA's Designated Safe

Uses. *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) ("existing practice" evidence of agency interpretation). EPA's post-hoc litigation position contradicts the FFDCA's text and EPA's established interpretation. It must be rejected. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012).

C. EPA's excuses for abandoning its established interpretation ring hollow.

In attempting to excuse its rewriting of the FFDCA and abandonment of past practice, EPA suggests it was forced to do so. This only demonstrates the weakness of EPA's arguments.

First, EPA claims that it required "voluntary cancellation requests by all registrants of the other uses" in order to render a safety finding on a subset of uses. Opp. at 20. Notably, that claim conflicts with what EPA previously said it needed: "a reasonable basis to believe" that other uses will cease. 87 Fed. Reg. at 11,246. EPA certainly had a reasonable basis to anticipate the narrowing of registered uses. EPA had a written commitment from Gharda, the most significant supplier of chlorpyrifos in the agricultural market, to conform its registration to

EPA's safety finding. Seethapathi Decl. ¶¶29-33.[3] EPA asserts a voluntary cancellation agreement was not finalized because Gharda sought "unreasonable cancellation terms," such as a phased out production and exhaustion of existing stocks. Opp. at 21. But ***EPA*** proposed these terms—and EPA's terms were more generous than those proposed in Gharda's July 2021 Email. Seethapathi Decl. Ex. 3 at F (June 24, 2021 EPA email to Gharda stating "[EPA is] considering the following dates for ***existing stocks***" and referencing a "12 to 18 month" production phaseout period and grower use "until exhausted") (emphasis added).[4] As discussions progressed, EPA informed Gharda that it would likely need a written voluntary cancellation agreement quickly to reference it in the Final Rule and would let Gharda know when to submit it. Seethapathi Decl. ¶33. EPA thanked Gharda for its

[3] EPA's new declaration acknowledges additional communications after the "Second Gharda Letter" (thus conceding its prior declaration was inaccurate) but continues to mischaracterize the discussions.

[4] EPA offers a very narrow definition of "existing stocks" that is contrary to its own use of the term in discussions with Gharda. Seethapathi Decl. Ex. 3 at Ex. F. EPA's existing stocks proposals to Gharda also undermine EPA's claim that tolerance actions are separate from actions under FIFRA.

"continued patience and engagement." *Id.* Ex. 3 at Ex. J. EPA then inexplicably terminated discussions. *Id.* ¶34.

Second, EPA implies that the Ninth Circuit required it to make a single up-or-down decision for all tolerances—claiming that the relief Petitioners seek is "in tension with" the *LULAC* order. Opp. at 8. Not true. The Ninth Circuit told EPA to modify or revoke the tolerances based on the evidence. *LULAC*, 996 F.3d at 703. EPA could have modified the tolerances within 60 days (having already made the necessary safety determinations in the PID) and then allowed for an orderly phaseout of existing stocks for other uses within a reasonable time thereafter. This was what Congress expected: for EPA "to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties." H.R. Rep. 104-669(II) at 51.[5] This was what the Ninth Circuit ordered.

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[5] EPA claims Petitioners seek "lengthy existing stocks periods" for the non-11 uses but Gharda was prepared to accept mere months. Seethapathi Decl. Ex. 3 at Ex. H. A short period to exhaust existing stores of a product registered for over fifty years is reasonable and consistent with FDA's recently announced phased approach to enforcement for chlorpyrifos. *See* Food & Drug Administration, *Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues* (Feb. 2022), https://www.fda.gov/regulatory-information/search-fda-

LULAC, 996 F.3d at 703–04. And this was what EPA did in its discussions with Gharda, before reversing course in the Final Rule. Seethapathi Decl. ¶¶21-33.

D. EPA cannot ignore the PID.

Because its legal arguments fail, EPA tries to sideline the PID by questioning its relevance. Those attempts also fail.

First, EPA claims its PID safety findings have nothing to do with the FFDCA. Opp. at 16. Petitioners have already explained why EPA is wrong. Reply at 14. FIFRA explicitly incorporates the FFDCA safety standard. 7 U.S.C. § 136(bb) ("unreasonable adverse effects" includes dietary risk inconsistent with FFDCA "reasonable certainty of no harm" standard).

Similarly, EPA attempts to disregard the PID as a mere proposal. Opp. at 19. What matters is not the label EPA puts on a decision, but how it treats that decision. *Cf. FWS v. Sierra Club*, ___ U.S. ___, 141 S. Ct. 777, 786 (2021) (decision is final where agency treats it as such).

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guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities. A stay is thus required to fix EPA's failure to address existing stocks as to the non-11 uses.

EPA made a safety determination in the PID. Kiely Decl. ¶18. EPA acknowledged that "a final decision for chlorpyrifos may be issued" based on the PID. Long Decl. Ex. B at 62. And EPA treated the PID as final—relying upon it when negotiating with Gharda on retention of EPA's Designated Safe Uses. Seethapathi Decl. ¶¶21-33. EPA could not have done so if it did not consider the uses safe and understand it had the authority to "modify" tolerances accordingly. 21 U.S.C. § 346a(b)(2)(A)(i). EPA's attempt to distance itself from the PID is simply a convenient litigating position.

II. Petitioners Demonstrate Irreparable Harm.

Rather than dispute whether Petitioners will suffer harm, EPA tries to downplay its severity. Opp. at 25-28. As demonstrated by Petitioners' 24 declarations, Petitioners established harms that are both irreparable and substantial. These harms are imminent, as EPA intends to initiate cancellation proceedings if it does not have voluntary cancellation requests in hand by March 30, 2022. Kiely Decl. ¶26.[6]

[6] Although EPA argues that its cancellation order will address existing stocks, without tolerances in place there can be no orderly phaseout. This is not the harmonization Congress intended. *See* H.R. Rep. 104-669(II); *see also* Mot. at 7-8, 21.

First, Petitioners' economic losses are unrecoverable, which "qualif[ies] as irreparable harm." *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996). Although EPA suggests that regulatory compliance costs are insufficient for a stay, "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring in part and in the judgment).

Second, Petitioners' irreparable harm is substantial. EPA found the 11 uses "critical" and of "high-benefit" to growers. 87 Fed. Reg. at 11,244. EPA itself predicts $53 million in losses for farmers—a substantial figure—from revocation of chlorpyrifos tolerances. Anderson Decl. ¶15. Although EPA downplays these losses by comparing them to overall business, an entire industry need not be decimated to support a stay. "[W]hen the threatened harm is more than *de minimis*, it is not so much the magnitude but the ***irreparability*** that counts." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 279 (5th Cir. 2012) (emphasis in original; quotations omitted).

Petitioners have also shown substantial harm to individual farmers, who will suffer tens to hundreds of thousands of dollars in

annual losses under the Final Rule. These growers rely upon chlorpyrifos to control pests for which no other pesticide is effective. Att. 2, Ex. B (Baldwin Decl.) at ¶10. Elimination of chlorpyrifos tolerances will result in significant crop losses. Att. 2, Ex. G (Hastings Decl.) at ¶¶9-23, 27. The affected growers cannot mitigate these losses by switching to another crop. Att. 2, Ex. E (Hultgren Decl.) at ¶9. Nor can these growers avoid these losses through crop insurance. Att. 2, Ex. D (Markwart Decl.) at ¶12. For the Grower Petitioners, eliminating the "critical and high-benefit" uses of chlorpyrifos, by definition, represents a substantial loss.[7]

Similarly, Gharda has shown substantial irreparable harm in lost sales and lost investment in significant inventory, which EPA does not contest. Instead, EPA says that because Gharda has not alleged it will go out of business, its harm cannot be irreparable. Again, that is not the law. *Supra* at 11. EPA also argues that Gharda's harm is self-inflicted because Gharda decided to produce chlorpyrifos in 2021 when

[7] EPA cannot rebut these facts with the Anderson Declaration. Anderson merely sponsors generic, industry-wide information, while admitting that EPA cannot evaluate impacts on the individual farm or business. Anderson Decl. ¶24 ("EPA is unable to estimate effects on individual entities, whether farms … or processors").

chlorpyrifos' regulatory status was uncertain. But EPA led Gharda to believe, until shortly before it issued the Final Rule, that EPA would allow chlorpyrifos for EPA's Designated Safe Uses. Seethapathi Decl. ¶¶21-33.

EPA's suggestion that Gharda could start over with a request to establish new registrations and tolerances is no solution. The process would take years and cost hundreds of thousands of dollars. Stephens Declaration, ECF No. 5132908 at ¶6. More importantly, it would do nothing for the Grower Petitioners and their members who need chlorpyrifos in the 2022 growing season, to avoid unrecoverable losses now and increased pest pressure in the future.

III. The Remaining Factors Support a Stay.

The public interest and balance of equities support Petitioners' narrowly-tailored stay request. EPA found no harm to human health from EPA's Designated Safe Uses, whereas denying Petitioners the opportunity to use and supply chlorpyrifos for these discrete uses would cause irreparable harm. Mot. at 31.

In these circumstances, Congress expected EPA to "modify" existing pesticide tolerances as necessary to comport with the agency's

conclusions concerning safety. It did not expect the absurd result EPA advocates here: the revocation of all tolerances if it suspects any of them may not be safe. The balance of the equities and the public interest support a stay. EPA provides nothing to show otherwise.

CONCLUSION

Petitioners are entitled to the relief sought in their motion.

March 14, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply In Support of Motion for Partial Stay complies with the type-volume limitation of Federal Rule of Appellate Procedure because it contains 2,586 words. This Motion complies with the typeface and the type style requirements of Federal Rule of Appellate Procedure 27 because this brief has been prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Dated: March 14, 2022

s/ Nash E. Long
Nash E. Long

CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system, which will send a notice of electronic filing to all parties on the electronic filing receipt. Parties may access this filing through the Court's system.

Dated: March 14, 2022

s/ Nash E. Long
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In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1503

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITIONERS' OPENING BRIEF

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SUMMARY OF THE CASE AND ORAL ARGUMENT REQUEST

This case concerns an arbitrary and capricious U.S. Environmental Protection Agency ("EPA" or "Agency") rule effectively banning the insecticide chlorpyrifos, a crop protection tool growers have relied on for decades. Petitioners challenge EPA's denial of objections to the rule and the rule itself as contrary to the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Agency's own scientific findings. *See* AR 1[1], Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"); Add. 1[2]; Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("Denial Order"); Add. 23.

Petitioners respectfully request oral argument in this case due to the novel and important issues raised, and in light of the ramifications of EPA's Final Rule and Denial Order on Petitioners and the agricultural community. Petitioners respectfully request 20 minutes to present their case.

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[1] "AR" refers to EPA's Certified Index to the Administrative Record. Case No. 22-1422, Doc ID: 5146142 (under seal).

[2] "Add." refers to the Addendum filed with this Brief.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure Petitioners submit the following corporate disclosure statement:

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International, Inc**. states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

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JURISDICTIONAL STATEMENT

I. THIS COURT HAS JURISDICTION OVER PETITIONERS' CLAIMS

This Court has jurisdiction to review Petitioners' challenge to the EPA's Denial Order and to the Final Rule under FFDCA § 408(h)(1). 21 U.S.C. § 346a(h)(1) ("any person . . . adversely affected by" an order on objections to a final rule revoking tolerances "may obtain judicial review . . . in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business"). This action properly lies in this circuit because most of the Petitioners reside within the Eighth Circuit. Eleven of the nineteen Grower Petitioners[3] are all based in States located within the Eighth Circuit. *See id.* An additional five Petitioners[4] have members located within the Eighth Circuit. The aggregate value of the eleven crops adversely affected by

[3] These eleven Petitioners are Red River Valley Sugarbeet Growers Association, Minn-Dak Farmers Cooperative, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, and North Dakota Soybean Growers Association.

[4] These five Petitioners are U.S. Beet Sugar Association, American Sugarbeet Growers Association, American Farm Bureau Federation, National Association of Wheat Growers, and National Cotton Council.

the revocation of chlorpyrifos tolerances to the U.S. economy is more than $59 billion annually.[5] A large share of those crops are grown within the Eighth Circuit.

II. PETITIONERS HAVE STANDING TO BRING THIS CASE

Petitioners have standing to seek review of EPA's Final Rule and Denial Order. To satisfy Article III's standing requirements, a petition must show: (1) a "concrete and particularized" and "actual or imminent" "injury in fact"; (2) that is "fairly traceable" to the conduct complained of; and (3) that will be "redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citations omitted). An association has standing to sue on its members' behalf "when its members would otherwise have standing, . . . the interests at stake are germane to the organization's purpose," and the claim and requested relief do not require the individual members' participation in the lawsuit. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

[5] USDA, National Agricultural Statistics Service, www.nass.usda.gov.

"[W]here one plaintiff establishes standing to sue, the standing of other plaintiffs is immaterial to jurisdiction." *Jones v. Gale*, 470 F.3d 1261, 1265 (8th Cir. 2006); *Nat'l Wildlife Fed'n v. Agric. Stabilization & Conservation Serv.*, 955 F.2d 1199, 1203 (8th Cir. 1992) (internal quotation marks omitted). "[A] regulated party generally has standing to challenge an agency action regulating its behavior." *Ameren Servs. Co. v. FERC*, 893 F.3d 786, 792 (D.C. Cir. 2018).

The Grower Petitioners, on their own behalf or on behalf of their members, demonstrate a "concrete and particularized" and "actual or imminent" injury in fact because EPA's unlawful revocation action has deprived them of a pest control tool that is critical for their crops, including sugarbeets, cherries, and soybeans. *See, e.g.*, Pet. App. 1374[6] ¶ 8; Pet. App. 1384–85 ¶ 10; Pet. App. 1394 ¶ 9; Pet. App. 1405 ¶ 9; Pet. App. 1418–19 ¶¶ 13–14; Pet. App. 1427–28 ¶ 12; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1455–56 ¶ 9; Pet. App. 1463–64, 1466–74 ¶¶ 4, 9–22; Pet. App. 1479–81 ¶¶ 10–15; Pet. App. 1486–93 ¶¶ 6–19; Pet. App. 1499–501 ¶¶ 11–14; Pet. App. 1508–09 ¶¶ 12–16; Pet. App. 1516–18 ¶¶ 12–18; Pet. App. 1525–26 ¶¶ 11–14; Pet. App. 1535 ¶¶ 12–14;

[6] "Pet. App." refers to the Petitioners' Appendix.

Pet. App. 1543–44 ¶¶ 11–15; Pet. App. 1560–63 ¶¶ 4–16; Pet. App. 1568–69 ¶ 8; Pet. App. 1579–80 ¶¶ 10–14; Pet. App. 1586–87 ¶¶ 12–14; *see also Lujan*, 504 U.S. at 560; *Ameren Servs.*, 893 F.3d at 791.

As a result of EPA's revocation of tolerances, any commodity treated with chlorpyrifos as of the rule's February 28, 2022, effective date is deemed "adulterated," 21 U.S.C. §§ 342(a), 346a(a)(1), and subject to seizure, *id.* § 334(a)(1), and any grower who applies chlorpyrifos to commodities in interstate commerce is subject to criminal sanctions, *see id.* §§ 331, 333. The inability to lawfully apply chlorpyrifos will likely cause the growers represented by Grower Petitioners financial harm from reduced crop yields due to an increase in pest pressure, *see, e.g.*, Pet. App. 1378 ¶ 21; Pet. App. 1396 ¶ 14; Pet. App. 1405, 1407 ¶¶ 10, 16; Pet. App. 1419 ¶ 14; Pet. Ap. 1431–32 ¶ 22; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1386–87 ¶¶ 10–15; Pet. App. 1458 ¶ 14; Pet. App. 1471–72 ¶ 18, as well reputational harm, *see, e.g.*, Pet. App. 1397–98, 1399 ¶¶ 21, 25; Pet. App. 1472–73 ¶ 20; Pet. App. 1492 ¶ 17. This harm would be remedied for the 2023 growing season and beyond by a favorable decision from this Court.

Petitioner Gharda also has standing as the chlorpyrifos registrant and primary supplier of chlorpyrifos for agricultural use in the United States. *See Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 870 (8th Cir. 2013) (injury based on members' interest in Clean Water Act permits); *Coteau Props. Co. v. Dep't of Interior*, 53 F.3d 1466, 1472 (8th Cir. 1995) (applicant for surface mining permit had standing). Gharda similarly has a "concrete and particularized" interest in the tolerances and the harm to that interest is "actual or imminent," *Lujan*, 504 U.S. at 560, because EPA's Final Rule has denied Gharda the necessary authorizations for Gharda to manufacture and sell chlorpyrifos for use on food, 7 U.S.C. § 136(bb). These concrete injuries are directly caused by EPA's revocation of tolerances and would be remedied by a decision from this Court vacating the Final Rule and Denial Order with respect to those uses. *See Lujan*, 504 U.S. at 560–61.

STATEMENT OF ISSUES

Whether EPA's Final Rule and Denial Order revoking all food tolerances for chlorpyrifos are arbitrary and capricious, an abuse of discretion, and otherwise contrary to law in light of:

1. EPA's disregard of its own scientific evidence supporting the retention of eleven uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in specifically designated regions the Agency unequivocally found safe (the "Safe Uses").

2. The plain text and intent of the FFDCA, which require a forward-looking, individual review of tolerances, based on the latest scientific developments.

3. EPA's failure to coordinate its actions under the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as the statutes require and consistent with prior Agency practice.

4. EPA's failure to offer a reasoned explanation justifying its departure from its own scientific findings.

Apposite statutory provisions and cases for issue 1: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State*

Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *Chlorine Chemistry Council v. E.P.A.*, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000).

Apposite statutory provisions and cases for issue 2: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 3: 21 U.S.C. § 346a(l)(1); 7 U.S.C. § 136(bb); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 4: *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

STATEMENT OF THE CASE

III. EPA'S REGULATION OF FOOD USE PESTICIDES UNDER TWO INTERRELATED STATUTES: THE FFDCA AND FIFRA

Pesticides are among the most heavily regulated substances in the United States. EPA regulates pesticides used on food under a comprehensive, science-based regime arising primarily under two separate but interrelated federal statutes: the FFDCA, 21 U.S.C. § 346a, and FIFRA, 7 U.S.C. §§ 136–136y. Congress made clear that it intends for EPA to coordinate its actions under the two laws. H.R. Rep. No. 104-669(II), 104th Cong. at 51 (1996) ("The Committee expects EPA to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties.").

A. The FFDCA

The FFDCA requires EPA to set food safety "tolerances," which are maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a. EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* § 346a(b)(2)(A)(i). Food containing pesticide residues that exceed an established tolerance level is deemed "adulterated" under the FFDCA and may not be moved in interstate commerce. *Id.* §§ 331, 342. In considering whether to establish, modify, or revoke a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." *Id.* § 346a(b)(2)(D)(i).

In 1996, Congress amended the FFDCA with the passage of the Food Quality Protection Act ("FQPA") which, among other things, established a new safety standard for pesticide tolerances covering pesticide residues in or on raw agricultural commodities. A tolerance is deemed "safe" under the FFDCA if "there is a reasonable certainty that

no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). This includes exposure from food, drinking water, and in residential settings, but does not include occupational exposure. In assessing reasonable certainty of no harm, EPA is to apply an additional tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" but EPA has discretion to apply a different margin of safety if there is "reliable data" to support that determination.[7] *Id.* § 346a(b)(2)(C)(ii).

While application of "reasonable certainty of no harm" to tolerances for raw agricultural commodities was new to EPA when the

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[7] The FFDCA does not define "reliability" or "reliable data." In a February 2002 guidance document, EPA counseled that "the data and information" relied upon to inform a safety factor determination "must be *sufficiently sound* such that [EPA's Office of Pesticide Programs] could routinely rely on such information in taking regulatory action." AR 9, *EPA, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance* (Feb. 28, 2002) at A-6; Pet. App. 536 (emphasis added). Data that are not replicable are not reliable. AR 24, *EPA, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (Dec. 28, 2016) at 30; Pet. App. 1055 ("[R]eliability general[ly] refers to the ability to reproduce results. . . .").

FQPA was passed, EPA and the Food and Drug Administration ("FDA") had used the same standard for decades when establishing tolerances for processed foods under FFDCA § 409. And the FDA used the same standard in approving food additives under FFDCA § 409.[8]

B. FIFRA

EPA also regulates pesticides under FIFRA. Under FIFRA, all pesticides must be registered by EPA before they can be marketed, distributed, or sold in the United States. 7 U.S.C. § 136a(a). FIFRA registrations operate as "product-specific license[s]" and confer on registrants legally protectable property rights. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 36 (D.D.C. 2011); Add. 79–80, *Ctr. for Biological Diversity v. E.P.A.*, No. 11-cv-00293-JCS, 2013 WL 1729573, at *6–7 (N.D. Cal. Apr. 22, 2013) ("[O]wners of the pesticide

[8] In the 1958 amendments to the FFDCA, Congress made clear that a safety determination under the "reasonable certainty of no harm" standard does not require absolute proof of safety: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rep. No. 85-2422, 85th Cong., reprinted in 1958 U.S.C.C.A.N. 5300, 5305; *see also* H.R. Rep. No. 83-2284, 83rd Cong (1958).

registrations . . . have property and financial interests in the registrations.").

As originally enacted, "FIFRA was primarily a licensing and labeling statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). Through a series of amendments to the law in the 1970s, Congress transformed FIFRA into a "comprehensive regulatory statute" under which EPA exercises broad authority. H.R. Rep. No. 92-511, 92d Cong., at 1 (1971).

To approve a pesticide registration, EPA must determine, based on a review of extensive scientific data, that use of the product in accordance with its label will not pose "unreasonable adverse effects" on humans or the environment. 7 U.S.C. § 136a(c)(5)(D). The product label establishes the scope of the FIFRA registration, and is submitted to and approved by EPA as a core element of every registration. *See, e.g., id.* § 136a(c)(1)(C). Every registered product is required to display an EPA-approved label that identifies the approved crop uses, applications, and directions for use. Use of a pesticide in a manner inconsistent with that label is unlawful. *Id.* § 136j(a)(2)(G).

FIFRA also requires EPA to conduct comprehensive reevaluations of all registered pesticides every fifteen years, a process known as registration review. This process ensures that all pesticides and their approved uses continue to satisfy FIFRA's safety standard as scientific capabilities improve and agricultural practices change over time. *Id.* § 136a(g)(1)(A)(iii)–(iv); 40 C.F.R. § 155.40(a). During registration review, EPA reviews available data and information and conducts a number of risk assessments. EPA makes these assessments available for public comment, conducts further scientific analyses, and revises its assessments, as necessary.

C. Congress's Intended and Purposeful Harmonization of the FFDCA and FIFRA

FIFRA and FFDCA cross-reference one another and are intended to be carried out in harmony. For pesticides used on food, FIFRA's "unreasonable adverse effects" registration standard expressly incorporates FFDCA's "reasonable certainty of no harm" safety standard. 7 U.S.C. § 136(bb). Thus, when EPA registers a pesticide for use on food, it must determine that doing so will not cause higher amounts of pesticide residue on food commodities than the approved tolerances allow. Moreover, through the FQPA, Congress amended

FIFRA to adopt the fifteen-year registration review process: part of the purpose of this update to the law was to ensure that existing tolerances are consistent with current science. *See* 142 Cong. Rec. H8127-02, 104th Cong. (1996), at H8147 (contemplating that tolerance assessments would "take advantage of the latest scientific advances"); *see also* Add. 99, EPA Testimony on Pesticide Regulations Before the H.R. Subcomm. on Health & Env't and Comm. on Com., 1995 WL 347288 (June 7, 1995) (fifteen-year registration review process will "ensure that tolerances keep pace with advances in scientific knowledge").

Additionally, the FFDCA mandates that when revoking a tolerance EPA "shall coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(l)(1). For example, EPA may modify or cancel the pesticide's registration and enter an "existing stocks" order to "permit the continued sale and use of existing stocks" of a pesticide whose registration is being cancelled. 7 U.S.C. § 136d(a), (b).

IV. CHLORPYRIFOS AND ITS IMPORTANCE TO U.S. AGRICULTURE

A. Chlorpyrifos Has Benefited U.S. Farmers and Contributed to a Safe and Affordable Food Supply for Decades

Chlorpyrifos is an organophosphate insecticide that has been approved for use in the United States since 1965. Chlorpyrifos is a vitally important agricultural tool that protects valuable U.S. food crops from destruction due to insect pests. *See* AR 62 (EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos, EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits")); Pet. App. 299. Growers rely on chlorpyrifos due to its broad-spectrum efficacy against multiple pests, low cost, and minimal impact on beneficial insects. It is the leading active ingredient to control a wide variety of difficult-to-control insect pests and is often relied on as the first line of defense against new or unknown insect pests. For some growers represented by Grower Petitioners, chlorpyrifos is the only effective crop protection tool available. *See* Pet. App. 1373–74 ¶ 7; Pet. App. 1385–86 ¶ 10; Pet. App. 1393–94 ¶ 8; Pet. App. 1405 ¶ 9; Pet. App. 1417 ¶ 8; Pet. App. 1427–28 ¶ 12; Pet. App. 1440–41 ¶ 11; Pet. App. 1455–56 ¶ 9; Pet. App. 1466–67

¶ 10; Pet. App. 1568–69 ¶ 8; Pet. App. 1586 ¶ 10; *see also* AR 62 at 2; Pet. App. 301.

The eleven crops adversely affected by the revocation of chlorpyrifos tolerances contribute more than $59 billion to the U.S. economy annually. Access to chlorpyrifos as a crop protection tool protects growers' crops and income and benefits consumers who enjoy affordable, healthy, and high quality produce throughout the year.

B. EPA's Revocation Decision Threatens the Viability of Essential U.S. Food Crops

EPA's revocation decision will have a significant, negative impact on the agricultural economy. Without chlorpyrifos, some crops will be left without viable alternatives, putting those crops and their growers' livelihoods at risk. Lack of access to chlorpyrifos will significantly diminish the production capabilities of many growers, causing crippling economic losses. *See* Pet. App. 1500–01 ¶ 13; Pet. App. 1489–90 ¶ 13; Pet. App. 1386, 1387 ¶¶ 11, 14; Pet. App. 1455–56 ¶ 9; Pet. App. 1444–46 ¶¶ 20–21; Pet. App. 1431–32 ¶ 22; Pet. App. 1471–72 ¶ 18. In particular, loss of chlorpyrifos threatens the continued viability of sugarbeet production in the United States. *See* Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc ID 5132688 (Mar. 3, 2022) at 4–5.

These economic impacts will ultimately be felt by U.S. consumers, who are already experiencing staggering inflation and supply chain disruptions.

V. EPA'S SHIFTING REGULATORY OVERSIGHT OF CHLORPYRIFOS LEADING UP TO THE 2020 PID

A. EPA Reaffirms Chlorpyrifos's Safety In a 2006 Reregistration Action

EPA has long evaluated the safety of chlorpyrifos based on its potential to inhibit acetylcholinesterase ("AChE"), an enzyme necessary for proper nervous system function in target pests and other organisms, as well as in humans. AChE inhibition can be measured at very low levels in the blood, enabling EPA to determine safe levels of exposure to humans, in accordance with its safety standard under FIFRA and the FFDCA. EPA has concluded that exposure to chlorpyrifos below levels that cause 10% red blood cell AChE ("RBC AChE") inhibition does not adversely affect human health. This conclusion is supported by decades of scientific review and an extensive and complete database of toxicology studies. AR 1 at 48,323; Add. 9.

Since it was first registered in 1965, EPA has reviewed chlorpyrifos several times to ensure that it continues to meet FIFRA and FFDCA safety standards. In 2006, EPA completed "reregistration"

of chlorpyrifos, a review of older pesticides required by FIFRA, which included a reassessment of existing tolerances. In a final decision, EPA reauthorized all existing agricultural uses and determined that all chlorpyrifos food tolerances are "safe," meaning there is "a reasonable certainty that no harm will result from aggregate exposure" to chlorpyrifos. AR 33, EPA, Reregistration Eligibility Decision for Chlorpyrifos (2006); Pet. App. 546–48; 21 U.S.C. § 346a(b)(2)(A)(ii). That decision remained undisturbed until the Final Rule.

B. A 2007 Administrative Petition Spurs Inconsistent Regulatory Action

In 2007, a group of nongovernmental organizations that oppose pesticide use petitioned EPA to revoke all chlorpyrifos tolerances. The petition was based principally on an epidemiology study claiming associations between trace levels of chlorpyrifos (below those that cause 10% RBC AChE) in umbilical cord blood and neurodevelopmental effects in children later in life.

In response to the administrative petition, EPA accelerated registration review of chlorpyrifos. As part of that process, EPA conducted multiple risk assessments and sought public comment on those assessments. EPA also convened several sessions of its FIFRA

Scientific Advisory Panel ("SAP"), an independent advisory committee of scientific experts, *see* 7 U.S.C. § 136w(d)(1), to evaluate several scientific issues relating to chlorpyrifos, including the epidemiology study. The SAP looked closely at the epidemiology data and concluded that they contained numerous deficiencies and were insufficient to support a new regulatory standard.[9]

From 2007 to 2015, EPA gave every indication that it intended to deny the administrative petition. In March 2015, in litigation challenging EPA's response to the administrative petition, EPA informed the Ninth Circuit that it planned to deny the petition, having determined based on its 2014 Revised Human Health Risk Assessment that the petition's claims did not provide a basis to revoke tolerances. *See* Status Rep. at 2, *In Re Pesticide Action Network North America*, No.

[9] *See, e.g.*, AR 27 at 19; Pet. App. 914 (2012 SAP concurring with EPA that the epidemiology data "are not adequate enough to obtain a point of departure (POD) for the purposes of quantitative risk assessment."); AR 41 at 46; Pet. App. 853 (2008 SAP stating that "the Panel agreed with the Agency that there were limitations in the . . . epidemiological studies that precluded them from being used to directly derive the [point of departure] or the uncertainty factor"). "Point of departure" refers to the maximum level of pesticide exposure for which there are no observable adverse effects. It is the "starting point" for EPA's risk calculations. *See* AR 1 at 48,322; Add. 8.

14-72794 (9th Cir. Mar. 31, 2015), ECF No. 14. EPA also informed the court that the scientific evidence was "insufficient" to depart from the 10% RBC AChE inhibition regulatory standard upon which its 2006 safety determination was based. *Id.*, Attach. 1 at 3.

Later in 2015, EPA changed course, not due to any newfound concern related to the administrative petition, but instead based on drinking water issues the Agency was in the process of studying. In response to a court deadline, EPA issued a Proposed Rule to revoke tolerances, published on November 6, 2015. Pet. App. 994, Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080 (Nov. 6, 2015) (the "Proposed Rule").[10] EPA made clear that the Proposed Rule was based on a preliminary drinking water assessment it was working to refine, not food or other exposures, which EPA said in the Proposed Rule "*are safe*." *Id.* at 996, 1021 (emphasis added). EPA reiterated that "AChE inhibition remains the most robust quantitative dose response

[10] Some regulatory materials referenced in Petitioners' Statement of the Case are not included in EPA's AR. While these materials do not bear directly on the issues before the Court, they are cited here as background and context for Petitioners' arguments. If the Court would like copies of any of these documents, Petitioners will be pleased to provide them.

data for chlorpyrifos and thus continues to be the critical effect for the quantitative risk assessment." *Id.* at 1002. EPA acknowledged that its drinking water assessment was ongoing and stated that it "may update this action with new or modified analyses as EPA completes additional work." *Id.* at 999.

In April 2016, EPA took a radical regulatory detour, convening an SAP to review an unprecedented proposal that would base a new regulatory standard for chlorpyrifos directly on cord blood concentrations reported in the epidemiology study. EPA, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies (Mar. 11, 2016). The SAP rejected EPA's proposal: "[T]he majority of the Panel considers the Agency's use of the results from a single longitudinal study to make a decision with immense ramifications based on the use of cord blood measures of chlorpyrifos as a [point of departure] for risk assessment as premature and possibly inappropriate." AR 28 at 25, EPA, Scientific Advisory Panel for Chlorpyrifos; Analysis of Biomonitoring Data (Apr. 19–21, 2016).

Ignoring the SAP's admonition, in November 2016 EPA proposed and sought comment on yet another new regulatory standard, also

based solely on the same epidemiology study previously rejected.[11] *See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049 (Nov. 17, 2016). The proposal was severely criticized in public comments, including by the Obama Administration U.S. Department of Agriculture. *See* Pet. App. 1078, USDA Comments on the Risk Assessment Underlying the Reopened Proposed Rule "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment" (EPA-HQ-OPP-2015-0653-0648), Jan. 17, 2017 (expressing "grave concerns that ambiguous response data from a single, inconclusive study are being combined with a mere *guess* as to dose levels . . . to underpin a regulatory decision about a pesticide chemical that is vital to U.S. agriculture, and whose removal from market would have a major economic impact on growers and consumers").

[11] Rather than accept the weaknesses the SAP identified with the cord blood data, EPA's new 2016 proposal doubled down and used a dose reconstruction approach to develop a new point of departure. Under this approach, EPA interviewed New York City pesticide applicators in 2016 to estimate the amounts of chlorpyrifos the study subjects might have been exposed to 15–20 years earlier.

In April 2017, EPA retreated from pursuing novel regulatory approaches based on unreliable, previously rejected epidemiology data. EPA denied the administrative petition, finding the epidemiology data urged in support of the petition were not sufficiently valid, complete, or reliable. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Pet. to Revoke Tolerances, 82 Fed. Reg. 16,581 (Apr. 5, 2017). The NGO petitioners filed objections and simultaneously challenged EPA's petition denial order in the Ninth Circuit. *League of United Latin American Citizens v. Wheeler*, Case No. 17-71636 (9th Cir.) ("*LULAC I*"). An *en banc* panel of the Ninth Circuit found that it had no jurisdiction to review EPA's petition denial but ordered EPA to act on the objections by July 18, 2019. *LULAC I*, 922 F.3d 443 (9th Cir. 2019). EPA then denied the objections to its petition denial order, again finding concerns about neurotoxicity of chlorpyrifos at levels below 10% RBC AChE inhibition unsupported by valid, complete, and reliable data. *See* Chlorpyrifos; Final Order Denying Objs. to Mar. 2017 Pet. Denial Ord., 84 Fed. Reg. 35,555, 35,563 (July 24, 2019). The NGO petitioners challenged the objection denial order in the Ninth Circuit. *LULAC v. Wheeler*, Case No. 19-71979 (9th Cir.) ("*LULAC II*").

VI. EPA FINDS ELEVEN CROP USES SAFE AND BEGINS NEGOTIATIONS WITH THE REGISTRANT TO MODIFY LABEL USES ACCORDINGLY

A. EPA's 2020 Proposed Interim Decision ("PID") Finds Eleven Critical Crop Uses Safe

On December 7, 2020, as part of its ongoing registration review of chlorpyrifos,[12] EPA published its PID. Pesticide Registration Review; PID for Chlorpyrifos; Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020); AR 40, PID for Chlorpyrifos; Pet. App. 366. The PID is supported by a number of underlying risk and benefits assessments, including: EPA's September 21, 2020, Third Revised Human Health Risk Assessment (the "2020 RHHRA"), AR 2; Pet. App. 157, which in turn relied on EPA's September 15, 2020, Updated Chlorpyrifos Refined Drinking Water Assessment (the "2020 DWA"), AR 38; Pet. App. 1. EPA's PID and the risk assessments on which it relies reflect a fulsome, measured, and well-reasoned evaluation by EPA's expert scientists of potential human health and drinking water risks of chlorpyrifos. In these assessments, EPA reaffirmed its reliance on its long-standing 10%

[12] Registration review for chlorpyrifos is scheduled to be completed by October 2022.

RBC AChE endpoint as the appropriate standard for assessing human health risks. AR 2 at 5; Pet. App. 161.

The PID was also based on EPA's 2020 DWA, which updated and refined the Agency's 2016 drinking water assessment (the "2016 DWA"). The 2020 DWA is one of the most sophisticated drinking water analyses EPA has conducted and relied on EPA's most highly refined methods for assessing drinking water risks. *See* Pet. App. 1774–75 ¶¶ 9–11. EPA subjected the 2020 DWA to peer review by nine EPA expert scientists, an unprecedented level of peer review for an assessment of its kind. *Id.* ¶ 12. In the 2020 DWA, EPA considered eleven crop uses identified as high-benefit, critical uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) (the Safe Uses). AR 38 at 9, 17, 19–21; Pet. App. 10, 18, 20–22. The 2020 DWA conducted an analysis of these crops in select regions of the country where estimated drinking water concentrations are below the drinking water level of concern. AR 38 at 27–28; Pet. App. 28–29.

In the 2020 RHHRA and PID, EPA assessed potential risk to human health from aggregate exposure to chlorpyrifos residues. EPA determined that there were *no* potential risks of concern from exposure

to chlorpyrifos in food or residential uses alone. AR 2 at 12; Pet. App. 168; AR 40 at 14, 18; Pet. App. 379, 383. With respect to drinking water, EPA determined that risks exceeded safe levels taking into account all registered uses. But, relying on its 2020 DWA, EPA found that risks were *below* the drinking water level of concern benchmark when anticipating use only on the Safe Uses. AR 40 at 18; Pet. App. 383.

In its 2020 RHHRA and PID, EPA presented two approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to the Safe Uses, or (ii) application of a 1X FQPA safety factor, which would allow for the retention of *all* currently registered uses. Regarding the first approach, EPA was unequivocal that it had found the Safe Uses safe: "[the Safe Uses] are the high-benefit agricultural uses that ***the agency has determined*** *will not pose potential risks of concerns with an FQPA safety factor of 10X*." AR 40 at 40 (emphasis added); Pet. App. 405. EPA acknowledged that it was "currently in discussions with the registrants regarding the proposed/considered mitigation measures." AR 40 at 40; Pet. App. 405. EPA stated that it would "consider registrant and stakeholder input on

the subset of crops and regions from the public comment period and may conduct further analysis to determine *if any other limited uses may be retained*." AR 40 at 40; Pet. App. 405 (emphasis added). In other words, the Safe Uses were the minimum subset of uses that EPA said it would retain, which EPA would consider expanding through review of public comment and further analysis.

B. EPA Negotiates with Petitioner Gharda a Voluntary Narrowing of Chlorpyrifos Uses Consistent With Its Safety Finding

In early April 2021, EPA approached Gharda about a possible agreement to voluntarily cancel some uses of chlorpyrifos. Pet. App. 1611–12 ¶ 21. In these initial discussions, EPA urged Gharda to accept a voluntary phase-out of all uses other than the Safe Uses. *Id*.

On April 29, 2021, the Ninth Circuit issued a decision in *LULAC II*. The Ninth Circuit held that EPA's denial of objections to its 2017 denial of the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition. *LULAC II*, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit gave weight to EPA's proposals in 2015 and 2016 in which EPA suggested that existing tolerances were

not sufficiently health protective, *see id.* at 677—proposals that were based on drinking water analyses the Agency later refined and on epidemiology data it ultimately deemed insufficient. Crediting these proposed findings by the Agency, the Ninth Circuit ordered EPA "*either* to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "*or* to revoke all chlorpyrifos tolerances." *Id.* at 678 (emphasis added).

In making this ruling, the court acknowledged that EPA's scientific analyses were ongoing and expressly recognized the importance of the PID. The court observed that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." *Id.* at 703. The court also acknowledged the need to harmonize EPA's proposed tolerance action with action under FIFRA, ordering EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." *Id.* at 678.

After the Ninth Circuit decision in *LULAC II*, EPA continued discussions with Gharda about a voluntary narrowing of chlorpyrifos uses. Pet. App. 1613–14 ¶ 23. The PID continued to provide the backdrop for these discussions, as they culminated in Gharda's *written commitment* to EPA to voluntarily cancel all uses of chlorpyrifos except the Safe Uses. *Id.* 1614–15 ¶ 24. As part of these discussions, Gharda and EPA actively discussed and exchanged written proposals for the orderly phase-out of existing stocks of all *other* uses. *Id.* 1613–22 ¶¶ 23–33. As the parties neared an agreement, EPA informed Gharda that it would likely need a written voluntary cancellation letter to reference quickly in the Final Rule and thanked Gharda for its "continued patience and engagement." *Id.* 1621–23 ¶¶ 33–35. Gharda was standing by awaiting guidance from EPA on when to submit the voluntary cancellation letter when EPA abruptly terminated the discussions, without explanation. *Id.* 1622–25 ¶¶ 34–40.

VII. EPA DOES A REGULATORY TURNABOUT AND INEXPLICABLY ISSUES A FINAL RULE REVOKING CHLORPYRIFOS TOLERANCES FOR *ALL* CROP USES

To the shock of growers and registrants, EPA then did a regulatory 180-degree turn and, in August 2021, announced the Final

Rule revoking *all* chlorpyrifos tolerances. AR 1 at 48,315; Add. 1. EPA stated that, "taking into consideration the *currently registered uses* for chlorpyrifos," it is unable to make ***any*** safety finding under the FFDCA. AR 1 at 48,315, 48,317; Add. 1, 3 (emphasis added).

In reaching this conclusion, EPA did not rely on any new data or scientific analyses, nor did it attempt to walk back in any way its scientific conclusions in the PID. In fact, the scientific analysis in the Final Rule is largely consistent with that outlined in the PID. For example, EPA's Final Rule reaffirmed its long-standing 10% RBC AChE standard as the appropriate regulatory endpoint for assessing human health risks. AR 1 at 48,325; Add. 11 ("EPA has determined that the most appropriate toxicological endpoint for deriving points of departure for assessing risks of chlorpyrifos is 10% RBC AChE inhibition."). And as in the PID, EPA stated that it "remains unable to make a causal linkage between chlorpyrifos exposure and the [neurodevelopmental] outcomes reported" in epidemiology data. AR 1 at 48,324; Add. 10.

As to the aggregate exposure assessment, EPA confirmed in the Final Rule, as it had found in the PID, that "exposures from food and non-occupational exposures individually or together do not exceed

EPA's levels of concern." AR 1 at 48,333; Add. 19. EPA agreed that it is only drinking water exposures, when combined with food and non-occupational (residential) exposures, that create risks of concern. AR 1 at 48,333; Add. 19. As to drinking water, the Final Rule acknowledged EPA's findings in the PID that drinking water exposures do not exceed levels of concern when assuming use on only the Safe Uses. AR 1 at48,333; Add. 19.

Nevertheless, and despite admitting that it had found eleven uses safe, EPA claimed that because it is required to assess aggregate exposure taking into account all "currently registered uses," and based on the 2016 DWA, it could not find that aggregate exposures to chlorpyrifos are safe. AR 1 at 48,333; Add. 19. The Agency stated, without explanation or any reference to Gharda's commitment to drop all but the Safe Uses, that it lacked "effective mitigation upon which to base a reduced aggregate exposure calculation." AR 1 at 48,333; Add. 19. The Final Rule stated that the tolerances would expire six months later, on February 28, 2022.[13] AR 1 at 48,334; Add. 20.

[13] EPA's press release announcing the Final Rule made statements that are not supported by the Final Rule or its scientific findings, including that tolerance revocation would ensure

Petitioners timely submitted objections to the Final Rule, pursuant to Section 408(g) of the FFDCA. 21 U.S.C. § 346a(g)(2)(A). In light of the irreparable harm revocation of tolerances would cause, several Petitioners also sought an administrative stay of the Final Rule pending EPA's review of the objections. *See, e.g.*, AR 44–47, 49, 51, 54–56, 58–59, 67, 69, 71–72, 75–78, 80–84; Pet. App. 1085–284.

VIII. EPA'S INACTION ON PETITIONERS' OBJECTIONS AND STAY REQUESTS LEADS TO LITIGATION

EPA refused to act on the objections and stay requests for months, despite Petitioners' claims of irreparable harm and the approaching effective date of the Final Rule. Accordingly, on February 9, 2022, Petitioners petitioned this Court for review of the Final Rule and EPA's constructive denial of the objections and stay requests. *Red River Valley Sugarbeet Growers Ass'n v. Regan* (No. 22-1294), Doc. ID 5126162 (the "First Petition"). Petitioners also filed a motion for partial stay of the Final Rule on February 10, 2022, Doc. ID 5126280. On

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"farmworkers . . . are protected from the potentially dangerous consequences of this pesticide" and that EPA was "follow[ing] the science." AR 63, Press Release, EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health (Aug. 18, 2021) https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.

February 18, 2022, EPA filed a motion to dismiss the First Petition, contending that this Court had no jurisdiction because EPA had not yet made a "final" decision on the objections and stay requests. *See* Pet. App. 1285–306; Resp't Opp. to Pet'rs' Mot. to Stay Pending Review, Doc. ID 5129078 at 7, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 18, 2022).

The following business day, EPA released its 193-page Denial Order, denying all of Petitioners' objections and requests for an administrative stay. *See* Resp'ts Rule 28(j) Notice of Issuance of Final Order, Doc. ID 5130160 at 1, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 24, 2022). The Denial Order was published in the Federal Register on February 28, 2022, the same day the Final Rule took effect. Add. 23. EPA's Denial Order, like the Final Rule, did not retreat from any scientific findings in the PID. *Id.* at 42 ("EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [*i.e.*, the Safe Uses]."). EPA's Denial Order instead repeated the rationale for revocation outlined in the Final Rule: that EPA is required to assess

aggregate exposure under the FFDCA based on "currently registered uses," which it acknowledged as a "legal matter." *Id.*

On the same day the Final Rule was published, Petitioners filed a second Petition for Review in this Court, incorporating all issues raised in the First Petition as well as a challenge to EPA's Denial Order. Pet. App. 1355–67 (the "Second Petition"). Petitioners also renewed their motion to stay the Final Rule ("Renewed Motion to Stay"). Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc. ID 5132688. In the midst of the briefing, EPA asserted a novel, unprecedented argument that the Court lacked jurisdiction to hear the Second Petition because it was filed fewer than fourteen days after publication of the Denial Order in the Federal Register. Pet. App. 1343. For avoidance of doubt, on March 14, 2022, Petitioners filed a third petition for review, Pet. App. 1816–913, incorporating the Second Petition and its attachments in their entirety, as well as the Renewed Motion to Stay.

On March 15, 2022, the Court entered an order stating that it is exercising jurisdiction in this matter and denying Petitioners' Motion for a Partial Stay Pending Review. Thereafter, the parties submitted

and the Court granted a stipulation consolidating the Second and Third Petitions and setting a briefing schedule. Pet. App. 1914–15.

SUMMARY OF THE ARGUMENT

This action challenges EPA's arbitrary and capricious decision to revoke all tolerances for chlorpyrifos, effectively banning an agricultural tool farmers in the Midwest and around the country depend on to protect their crops and investment from destructive insect pests. Without adequate protection, an infestation of insect pests can cripple crop production and threaten farmers' livelihoods. This reality is especially stark for some of the growers represented by Petitioners here, for whose crops there exist no effective alternatives. *Supra* § IV.

The Final Rule was an abrupt and unexpected change in position not only because chlorpyrifos has been safely used for over fifty years but because just months earlier, EPA completed a rigorous scientific human health assessment that unequivocally found that use of chlorpyrifos on eleven high-benefit crops in select regions is safe. This assessment was based on a highly sophisticated Agency drinking water assessment that had undergone unprecedented peer review. After completing this assessment, EPA then spent months negotiating with

Petitioner Gharda to modify the approved uses on the label consistent with its safety finding. And Gharda committed to do just that.

Then, EPA abruptly ceased those discussions and pulled the rug out from under the regulated community by revoking *all* tolerances. EPA did so at a time when growers and consumers already face severe supply chain shortages and record-high inflation.

In revoking all tolerances, EPA did not back away from the scientific findings supporting its safety finding as to the eleven uses. Rather, in a flawed and unheard-of interpretation of the law, EPA claimed that it is required to assess safety by considering exposure from all currently approved uses, and that it is powerless to order changes to the product labels consistent with the science.

EPA's refusal to act on its own scientific evidence is arbitrary and capricious, an abuse of discretion, and contrary to law. EPA has a statutory mandate to review tolerance safety based on current science. This is reflected in the FFDCA's forward-looking text, which compels EPA to review tolerances on an individual basis, considering "anticipated" exposures based on the "reliable information" at its disposal. It is confirmed in the legislative history in which Congress

explicitly directed EPA to periodically review tolerance safety "based on the latest advancements in the science." EPA's position that it is confined to review only currently approved uses reads EPA's authority to "modify" tolerances out of the statute, and disregards EPA's obligation to coordinate its tolerance actions with registration actions under FIFRA. It is also at odds with the Agency's consistent historical practice of using tolerance modification and corresponding FIFRA action as a risk mitigation tool.

None of the reasons EPA offers to justify its revocation decision are defensible. EPA claims that a court order mandated this result, but that court in fact recognized EPA's ongoing scientific assessment and directed EPA to "act based on the evidence." While it ordered EPA to revoke or modify tolerances in sixty days, it gave EPA flexibility to modify related FIFRA registrations in a "timely fashion." EPA's attempt to diminish its scientific findings as "proposals" also fails. Scientific evidence confirmed by numerous expert Agency scientists is not entitled to less weight because it is summarized in a document labeled a proposal. The record also reflects that EPA believed its

scientific findings were final and actionable, and that EPA relied on them to negotiate corresponding label changes with the registrant.

The Agency's revocation decision was not driven by science or any reasonable reading of the statute. It therefore appears to be a pretext for an unexplained policy change. The law is clear that EPA must provide a reasoned, science-based explanation for its change in position, especially given the harms its revocation decision have caused and will continue to cause the growers, registrants, and consumers. For reasons outlined more fully below, this Court should vacate EPA's arbitrary and capricious Final Rule and Denial Order.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews EPA's Final Rule and Denial Order for compliance with the FFDCA under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Under the APA, the court shall hold unlawful and set aside an agency action found to be "in excess of statutory jurisdiction, authority, or limitation. . ." or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A), (C).

An agency decision is arbitrary and capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *accord Nebraska v. E.P.A.*, 812 F.3d 662, 666 (8th Cir. 2016). When an agency changes course, it must "supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42. A reviewing court "'may not supply a reasoned basis for the agency's action that the agency itself has not given.'" *Id.* at 43 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

II. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT DISREGARDS THE AGENCY'S OWN SCIENTIFIC EVIDENCE

EPA's scientific review of chlorpyrifos over the past fifteen years has examined a number of different issues, and not always in a consistent manner. But the current scientific record before the Agency is not the subject of dispute.

EPA previously (in 2015 and 2016) explored proposals to address claims of neurodevelopmental effects below the current regulatory

standard. EPA has since consistently concluded (under prior and current leadership) that the data urged in support of those claims are insufficient. EPA has accordingly maintained its longstanding 10% RBC AChE regulatory standard, and it has chosen to address potential neurodevelopmental risks by application of an FQPA Safety Factor of 10X. EPA's Final Rule and Denial Order unequivocally reaffirmed those scientific conclusions. AR 1 at 48,317; Add. 3, 23.

EPA does not dispute that the sole dietary exposure source of concern—and therefore the focal point of the Agency's latest human health risk assessment of chlorpyrifos—is drinking water, and only in certain parts of the country. While EPA years ago issued a Proposed Rule to revoke all tolerances for chlorpyrifos based on drinking water concerns, it did so in response to a court mandamus deadline and in reliance on its incomplete drinking water assessment. Pet. App. 995, 999. EPA has since updated, refined, and completed that assessment—a process that culminated in the 2020 DWA.

The 2020 DWA is EPA's most cutting edge, sophisticated drinking water assessment yet, that reflects the most advanced, updated tools and methodologies for assessing drinking water exposures and risks.

AR 38 at 9–11; Pet. App. 10–11, 1774 ¶ 9. It has undergone an unprecedented level of peer review by nine expert Agency scientists. Pet. App. 1774 ¶ 9. In the 2020 DWA, EPA analyzed risks from exposures from eleven high-benefit agricultural uses in select regions where estimated drinking water concentrations of chlorpyrifos are below EPA's benchmark level of concern (the Safe Uses). EPA's PID relied on the 2020 DWA and unequivocally found those uses *safe*:

> To mitigate potential dietary exposure to chlorpyrifos, the agency is proposing to limit application to select uses in certain regions where the [estimated drinking water concentrations] are lower than the [drinking water benchmarks of concern]. . . . [T]he agency has determined that [those uses] ***will not pose potential risks of concerns*** with an FQPA safety factor of 10X . . .

AR 40 at 40; Pet. App. 405 (emphasis added). The PID and the 2020 DWA on which it relied reflect a careful, conservative, and well-reasoned scientific assessment.

EPA nevertheless cast these assessments aside in the Final Rule and Denial Order and refused to apply their findings. EPA's refusal to act on its scientific evidence is arbitrary and capricious. *See, e.g.*, *Chlorine Chemistry Council*, 206 F.3d at 1290–91 (D.C. Cir. 2000) (vacating EPA rule that "openly overrode" its own science); *Dow*

AgroSciences LLC v. Nat'l Marine Fisheries Serv., 707 F.3d 462, 472–73 (4th Cir. 2013) (finding arbitrary and capricious agency reliance on older data that was not "representative of current and future pesticide uses and conditions" and failure to adequately explain its decision "despite the existence of new data and the potential drawbacks of using the older data") (internal quotations omitted); *Sierra Club v. E.P.A.*, 671 F.3d 955, 966–68 (9th Cir. 2012) (EPA action was arbitrary and capricious for not utilizing a more recent model); *Am. Wildlands v. Norton*, 193, F. Supp. 2d 244, 257 (D.D.C. 2002) (finding agency action arbitrary and capricious where agency "ignored scientific data and existing models"); *cf. Sugule v. Frazier,* 639 F.3d 406, 412 (8th Cir. 2011) (rejecting agency action where weight of evidence went against agency decision).

EPA's refusal to follow its scientific evidence was not due to any error in the science—the Final Rule and Denial Order do not attempt to walk back the PID or 2020 DWA's scientific findings. *See* Add. 42 (EPA admitting that it "does not dispute its own scientific conclusions and findings in the 2020 PID" regarding the Safe Uses, and ultimately the issue is "whether EPA properly interpreted its obligation under the

FFDCA in assessing aggregate exposure to chlorpyrifos," which is "a question of law and not one of fact"). Rather, EPA's sole basis for revoking all tolerances and effectively banning an agricultural tool growers have depended on for decades is that EPA could not conclude that tolerances are safe taking into account all "currently registered uses" of chlorpyrifos. *Id.* at 47–48. None of the arguments EPA has put forward in support of this newly fashioned rationale hold water.

As outlined below, EPA has abused its discretion, and its Final Rule and Denial Order are arbitrary and capricious and otherwise contrary to law, because they disregard the text and intent of the FFDCA and FIFRA, are contrary to the record, and are contrary to the Agency's own past practice.

III. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS AND CONTRARY TO LAW BECAUSE IT IGNORES THE TEXT AND INTENT OF THE FFDCA AND FIFRA

A. The FFDCA Compels a Forward-looking, Individual Tolerance Approach That Is Driven by Science

EPA's rationale that it must assess safety by considering only currently registered uses is contrary to the FFDCA's plain language and Congress's expressed intent that tolerance actions be driven by science.

EPA's construction defies Congress's forward-looking mandate that EPA find "there is a reasonable certainty that no harm *will result* from aggregate exposure" to the pesticide residue from "all *anticipated* dietary exposures and all other exposures for which there is *reliable information*." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). If Congress intended for EPA to assess safety of existing exposures only, based on tolerances previously approved, it would have referred to existing exposures rather than using the word "anticipated." *United States ex rel. Harlan v. Bacon*, 21 F.3d 209, 210 (8th Cir. 1994) ("When construing a statute, we are obliged to look first to the plain meaning of the words employed by the legislature," and the court "must give effect to the unambiguously expressed intent of Congress") (internal quotations omitted).

EPA's position is also at odds with FFDCA's mandate that the Agency reassess tolerance safety by employing a tolerance-by-tolerance approach. In drafting the FFDCA, Congress specified that EPA "may establish or leave in effect *a tolerance* . . . if the Administrator determines that *the tolerance* is safe . . . [and] shall modify or revoke *a tolerance* if the Administrator determines *it* is not safe." 21 U.S.C. §

346a(b)(2)(A)(i) (emphasis added); *accord id.* § 346a(b)(2)(C). Congress reiterated in setting forth the standard for the safety determination that it is to be made "with respect to *a tolerance* for a pesticide chemical residue. . . ." *Id.* § 346a(b)(2)(A)(ii) (emphasis added). The FFDCA's use of "*a* tolerance" rather than "*the* tolerances" shows Congress intended for EPA to make safety determinations for each tolerance on an individual basis—not based on "the universe of currently registered chlorpyrifos uses" as EPA urges. Add. 45; *see Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 742 (2017) (courts must give meaning to the particular words Congress chose in drafting a statute, including its choice between the singular and plural form).

An approach focused on currently registered uses is also inconsistent with Congress's directive that tolerance assessments be driven by advancements in science. Indeed, the legislative history underlying the FQPA makes Congress's intent abundantly clear: the "reasonable certainty of no harm" standard was intended to promote "the efficient, science-based administration of FIFRA and the [FFDCA]" by ensuring that tolerance assessments are based on "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8147. EPA is to

assess safety based on the latest, reliable scientific evidence at its disposal and then leave in effect, modify, or revoke in accordance with that evidence.

Congress's decision to provide for modifying a tolerance if it is found not safe further supports an individual tolerance, science-based approach. The FFDCA encourages EPA to "modify *or* revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). The statute clarifies that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," and therefore to "modify" can only mean to *narrow* permissible uses. *Id.* § 346a(b)(1) (emphasis added). Thus, EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe.

EPA's position that all of the tolerances must rise or fall together and that it is required to assess currently registered uses effectively reads modification out of the statute. If accepted, it would lead to the absurd result that EPA would never be able to narrow uses based on new or updated scientific data. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("interpretations of a statute which would

produce absurd results are to be avoided"). By EPA's logic, any time it found currently registered uses cumulatively unsafe, it would have to revoke *all* tolerances. But that is not what the law says: EPA plainly has authority to modify tolerances by narrowing the uses.

EPA's own practice also undermines its contention that it must consider only registered uses, and not anticipated uses as the statute says, in making its safety determination. For example, EPA increased the tolerance for residues of benzobicyclon in or on rice grain without changing the tolerances for other uses. Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60,368 (Nov. 2, 2021). There, EPA explained that it could make a "determination on aggregate exposure for benzobicyclon, including exposure resulting from the tolerance established by this action," *id.* at 60,369, and considered "cumulative exposures . . . (based on proposed and registered pesticidal uses at the time the assessment was conducted)," *id.* at 60,370.

Relatedly, EPA has also previously amended individual tolerances, showing that tolerances do not have to rise or fall together. For instance, on May 18, 2022, EPA established in a final rule a new tolerance for the insecticide flonicamid in or on small fruit vine, and

amended the existing tolerance for flonicamid in or on alfalfa (hay) by increasing it from 1.0 ppm to 7.0 ppm. Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30,425 (May 19, 2022). According to EPA, the establishment of these new tolerances for flonicamid were based upon EPA's authority under section 408 of the FFDCA and the Agency's review of "available scientific data and other relevant information." *Id.* at 30,426. EPA also established tolerances of tebuconazole "in or on multiple commodities" while modifying other tebuconazole tolerances. Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60,932 (Nov. 12, 2019).

In short, EPA's position that it could not consider its scientific evidence because it is required to assess currently registered uses finds no support in the FFDCA's text or underlying legislative history. It is also contrary to the Agency's prior practice.

B. EPA Failed to Coordinate Its Action Under the FFDCA with FIFRA, as the Statutes Require

EPA's Final Rule and Denial Order are also contrary to law because EPA failed to harmonize its safety determinations under the FFDCA with FIFRA, as the statutes require. *Supra* § III.

FIFRA's registration standard expressly incorporates the FFDCA "reasonable certainty of no harm" standard. 7 U.S.C. § 136(bb). The

approved food uses identified on a pesticide label must conform to EPA's safety determinations under the FFDCA. The FFDCA, for its part, mandates that once EPA has made a safety determination with respect to individual tolerances, it is required to modify or cancel the FIFRA registrations accordingly. 21 U.S.C. § 346a(l)(1) ("[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]."). This is also consistent with the forward-looking approach specified in the FFDCA: the "anticipated exposures" considered as part of EPA's safety determination, *id.* § 346a(b)(2)(A)(ii), are the future uses that will be in effect based on EPA's coordinated action under FIFRA, *id.* § 346a(l)(1).

Congress's directive that EPA coordinate its actions under the two laws to reflect the latest science could not have been more clear. And yet, EPA has taken the never-before-asserted position that its actions under the two statutes are "separate," *see* Add. 45, and that, short of action by the registrant, it is powerless to modify the FIFRA registrations to conform to its safety findings, *see id.* at 47. EPA's rationale is untenable and cannot be squared with the law or the Agency's prior conduct.

1. *EPA's Denial Order Is Internally Inconsistent Regarding FIFRA*

EPA's Denial Order is riddled with statements that cannot be reconciled with one another or with the statutory directives. EPA claims that it has discretion to determine the proper order of its actions under FFDCA and FIFRA, and challenges the notion that the Agency cannot lawfully revoke tolerances unless it "has first cancelled—or simultaneously cancels—associated pesticide registrations under FIFRA." *Id.*

EPA's argument actually supports Petitioners' reasoning. EPA's revocation decision must be reviewed based on the adequacy of its rationale—and EPA's sole explanation for not following the science is that it could *not* legally retain a subset of uses found safe without conforming FIFRA registrations in place. EPA cannot have it both ways—it cannot claim that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses. EPA cannot claim that the FIFRA and FFDCA actions are separate, and then state that it "could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations [in the

2020 DWA and PID], *unless all other uses were canceled*." *Id.* at 57 (emphasis added).

2. *EPA's Claim That Harmonization Was "Not Practicable" Fails*

EPA next claims that it did attempt to harmonize its tolerance actions under the FFDCA with cancellation actions under FIFRA but that coordination ultimately was "not practicable." *Id.* at 48–50 (citing 21 U.S.C. § 346a(l)(1)). First, EPA claims that the Ninth Circuit did not give it sufficient time to coordinate its FIFRA and FFDCA actions. *Id.* This argument is unavailing. While the Ninth Circuit gave EPA sixty days to either modify or revoke tolerances, it imposed no time limit on EPA's corresponding action under FIFRA—ordering only that EPA modify or cancel related FIFRA registrations "in a timely fashion." *LULAC II*, 996 F.3d at 678. The Ninth Circuit thus expressly recognized EPA's authority to modify tolerances and then update the FIFRA registrations accordingly. The Ninth Circuit further acknowledged that FIFRA actions would take more time and follow EPA's tolerance action.

Second, EPA claims that it did not have a "reasonable basis" to believe registrations would be amended consistent with its safety

finding because it did not have voluntary cancellation requests. Add. 47. This argument ignores law and reality. Congress conferred on EPA broad authority to regulate the safe use of pesticides on food under two comprehensive federal statutes, and directed that the Agency administer those statutes in an "efficient, science-based" manner that reflects "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8145-46. This includes the authority to initiate cancellation actions to conform FIFRA registrations to the Agency's safety determinations, with or without the registrant's cooperation. 7 U.S.C. § 136d(b), (f); *see also* 40 C.F.R. § 155.58(d) (EPA "may take appropriate action under FIFRA" if a registrant fails to comply with a registration review decision). EPA's assertion that it is incapable of acting on its scientific evidence without some affirmative action by a regulated party strains credulity. EPA is not only empowered to conform its FIFRA registrations to its scientific findings but compelled to do so by law.

Indeed, EPA admits registrant negotiations are largely irrelevant to the validity of its actions under the FFDCA: "Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the

tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question." Add. 49. This is precisely Petitioners' point: EPA made a scientific finding that the Safe Uses are safe. AR 40 at 40; Pet. App. 405. EPA did not back away from that safety finding either in its Final Rule or Denial Order. EPA was thus required to follow that scientific determination and modify the tolerances and registrations accordingly.[14]

In any event, EPA downplays that it *had* a voluntary cancellation commitment from Petitioner Gharda, the primary supplier of chlorpyrifos for agricultural use in the United States. Pet. App. 1611–21 ¶¶ 21–32. EPA and Gharda had spent months negotiating voluntary cancellation terms, and Gharda had submitted to EPA a written commitment to conform its registration to EPA's safety finding. *Id.*

[14] EPA states in the Denial Order that cancellation proceedings under FIFRA require a number of time-consuming procedural steps. EPA cannot claim that it did not have time to complete these steps because the Ninth Circuit required only that it take action under FIFRA "in a timely fashion." 996 F.3d at 678. More importantly, aggregate exposures would not have exceeded those analyzed and found safe in the PID during the pendency of any cancellation proceeding because the tolerance revocation and modification consistent with the PID would have ensured as much. 21 U.S.C. § 346a(a)(1).

1626–27 ¶ 43. Gharda was standing by awaiting word from EPA on when to submit a formal voluntary cancellation request reflecting the agreed terms when EPA abruptly ceased discussions. *Id.* 1622–23 ¶¶ 34–35. Weeks later, EPA took a 180-degree turn and revoked all tolerances. *Id.* 1623 ¶ 37.

3. *EPA Has Consistently Coordinated Its Tolerance Actions With FIFRA In the Past*

Where, as here, EPA has conducted a tolerance assessment based on thorough and detailed scientific analyses and found, based on that scientific evidence, that a subset of uses are safe, it must leave in effect the uses found safe, and modify or revoke tolerances to narrow the scope of permissible uses as the science dictates. It is then empowered to modify or cancel the FIFRA registrations in accordance with that science. This is how EPA has consistently applied the law in the past. *See Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) ("existing practice" evidence of agency interpretation).

EPA routinely mitigates risks identified in its tolerance assessments by taking corresponding action to modify or cancel FIFRA registrations. For example, EPA modified some, but not all, tolerances for dicloran and later modified the FIFRA registrations for dicloran.

See Acephate, Cacodylic, Dicamba, Dicloran, et al.; Tolerance Actions, 75 Fed. Reg. 60,232 (Sept. 29, 2010); Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71,022 (Nov. 16, 2011); Dicloran and Formetanate; Tolerance Actions, 77 Fed. Reg. 40,812 (July 11, 2012); Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4,651 (Feb. 1, 2018). EPA's action with respect to chlorpyrifos is not consistent with this prior practice. Such "inconsistent treatment" by the Agency "is the hallmark of arbitrary agency action." *Clean Wisconsin v. E.P.A.*, 964 F.3d 1145, 1163 (D.C. Cir. 2020).

IV. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT OFFERS NO REASONED EXPLANATION LET ALONE ONE THAT ADEQUATELY ADDRESSES THE RELEVANT FACTORS AND EVIDENCE

It is a foundational principle of administrative law that agencies must provide a reasoned explanation for departing from prior conclusions. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Northport Health Services of Arkansas, LLC v. HHS*, 14 F.4th 856, 873 (8th Cir. 2021). "Reasoned decision-making requires that when departing from precedents or practices, an agency must 'offer a reason to distinguish them or explain its apparent rejection of their

approach.'" *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020) (quoting Sw. *Airlines Co. v. FERC*, 926 F.3d 851, 856 (D.C. Cir. 2019); *see also Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978) (greater scrutiny applies to agency actions departing from prior norms and "it is at least incumbent upon the agency carefully to spell out the bases of its decision when departing from prior norms"). An agency may not "gloss[] over or swerve[] from prior precedents without discussion." *Sw. Airlines Co.*, 926 F.3d at 856 (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970).

EPA admits that its revocation decision disregards the Agency's safety finding in the PID. EPA's primary reason for revoking all tolerances is that EPA claims it was required to consider all currently registered uses because EPA had no reason to believe that the registrations would be amended. As outlined above, that reasoning is plainly contrary to the statute and the Agency's prior course of dealing. *Supra* §§ III.A–B. EPA's additional arguments for departing from the scientific evidence are not defensible.

A. EPA Cannot Escape from the Scientific Evidence by Disguising It as A "Proposal"

EPA does not attempt to argue that the scientific findings as to the Safe Uses are wrong. Instead, EPA tries to assert that the PID was simply a "proposal," and thus, EPA was not required to consider it. Add. 45–48. EPA is wrong.

The Ninth Circuit in *LULAC II* expressly recognized that EPA issued the PID proposing to modify tolerances while that proceeding was pending, such that the PID was not part of the record before the Ninth Circuit when it issued its decision. The Ninth Circuit nevertheless acknowledged the PID in ordering EPA to act, stating that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." 996 F.3d at 703. The Court made clear that "*EPA must act based upon the evidence*." *Id.* (emphasis added). The PID was *evidence* before the Agency that EPA was required to act on or, at a minimum, offer a reasoned explanation before departing from it.

EPA cannot disregard the scientific evidence before it simply because it may later be revised. In *Chlorine Chemistry Council*, 206

F.3d at 1291, the D.C. Circuit vacated an EPA rule that blatantly disregarded the Agency's own scientific evidence. In doing so, the court rejected EPA's characterization of its scientific findings as not representing the Agency's "ultimate conclusions" as "semantic summersaults." *Id.* The court observed that "[a]ll scientific conclusions are subject to some doubt," and "however desirable it may be for EPA to consult [a Scientific Advisory Board] and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime." *Id.* at 1290–91.

Moreover, EPA's claim that it was permitted to simply ignore the scientific findings in the PID because it was merely a "proposal" is at odds with the record. The PID may have been labeled a "proposed" interim decision, but that is because EPA still needed to complete two additional assessments: (1) the Endangered Species Act analysis and (2) the endocrine screening for the chlorpyrifos registration review. *See* EPA Registration Review Process, https://www.epa.gov/pesticide-reevaluation/registration-review-process (last visited May 16, 2022) (explaining that during Registration Review "EPA may issue a proposed interim decision *when the Agency needs to conduct additional*

assessments such as an endangered species assessment or endocrine screening") (emphasis added). Neither of those issues is relevant to the safety determination for purposes of establishing or leaving in effect tolerances under the FFDCA. 21 U.S.C. § 346a(b)(2).[15]

As to the safety findings in the PID, EPA made clear that further analyses and review of public comment on its tolerance assessments would only *expand* the scope of permissible uses, not contract them. AR 40 at 40; Pet. App. 405 ("[T]he agency will consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if *any other limited uses may be retained*.") (emphasis added). EPA went on to state in the PID that it could issue a final decision for chlorpyrifos without issuing an interim decision. AR 40 at 62; Pet. App. 427; *see also* https://www.epa.gov/pesticide-reevaluation/registration-review-process (explaining that interim decisions may be issued to, among

[15] That EPA's scientific findings are reflected in Agency proposals does not diminish their weight. The Ninth Circuit credited scientific findings in EPA proposals in ordering EPA to "act based on the evidence" and issue a final order revoking or modifying tolerances. *See LULAC II*, 996 F.3d at 703. It recognized that EPA could act on the PID. *Id.*

other things, explain changes to or respond to comments on a proposed interim decision). EPA thus unquestionably believed that its scientific findings concerning tolerances were final and actionable. Indeed, there is no logical reason EPA would have devoted enormous resources to developing a sophisticated drinking water assessment based on a limited subset of uses, and then a proposed interim decision based on that assessment, if it did not believe that decision could support corresponding regulatory action.

EPA's actions treating the PID as final are not an anomaly. EPA regularly takes action to amend uses in response to a proposed interim registration review decision. For instance, a registrant agreed to make certain changes to uses for the fungicide famoxadone based on EPA's proposed interim registration review decision for that product. Corteva Agriscience, Response Comments to: Famoxadone: Proposed Interim Registration Review Decision (Dec. 17, 2021), https://downloads.regulations.gov/EPA-HQ-OPP-2015-0094-0067/attachment_1.pdf (last visited May 15, 2022).

B. EPA Treated Its Scientific Findings In the PID As Final

Even more, EPA has treated the scientific findings in the PID as its final decision on the safety of chlorpyrifos under the FFDCA. *Cf. FWS v. Sierra Club*, ___ U.S. ___, 141 S. Ct. 777, 786 (2021) (decision is final where agency treats it as such). EPA relied on the PID when attempting to reach an agreement with Gharda on a voluntary narrowing of uses consistent with the PID.

For months, EPA and Gharda actively exchanged proposals for the retention of uses, for which the PID was the backdrop. At all times, Gharda understood that the Safe Uses would be retained. Pet. App. 1611–18 ¶¶ 21–29. For example, during these discussions EPA rejected a proposal by Gharda to retain chlorpyrifos for use on cotton in Texas, saying that "[t]he PID indicated that if cotton were maintained, it could be used in AL, FL, GA, NC, SC, and VA," but "Texas would not be an option." *Id.* 1746; *see Am. Maritime Ass'n v. Blumenthal*, 458 F. Supp. 849, 858 (D.D.C. 1977) (agency action is final where it "represents the final, crystallized agency position on the matter"). EPA never backed away from the scientific findings in the PID or hinted that they were not final and subject to change. Ultimately, Gharda put forward a

written commitment to modify its label consistent with the safety finding in the PID. Pet. App. 1743–44, 1756–58.

EPA could not have entertained these proposals, and all of these months of negotiations would have been pointless, unless EPA believed that its PID could support a coordinated modification of registered uses under FIFRA. Thus, in treating and relying on the PID as a final Agency action, and in causing regulated parties to rely on the PID accordingly, EPA has cemented the finality of the PID with respect to the Safe Uses. *See Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)) ("When an agency changes course, . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'"). EPA has given no reasoned explanation for ignoring this final safety determination and so its decision is arbitrary and capricious. *Supra* § IV.

CONCLUSION

For all of the foregoing reasons, Petitioners respectfully request that EPA vacate the Denial Order and Final Rule.

May 24, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief compiles with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,170 words. I further certify that Petitioners' Brief complies with the typeface and type style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), as it was prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Pursuant to Eighth Circuit Rule 28A(h)(2), I certify that the electronic version of this Brief has been scanned for viruses and is virus-free.

/s/ Nash E. Long
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 24, 2022, a true and accurate copy of the foregoing Petitioners' Opening Brief was electronically filed with the United States Court of Appeals for the Eight Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, Petitioners will serve each party separately represented with a paper copy of the Brief.

I further certify that ten (10) paper copies of the foregoing Brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Rule 28A(d).

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IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422 and 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION et al.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

BRIEF OF *AMICUS CURIAE* CROPLIFE AMERICA IN SUPPORT OF PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *Amicus Curiae* CropLife America states that it is a non-profit corporation, that it has no parent corporation, and that no publicly held corporation owns 10% or more of its stock.

Dated: May 25, 2022 /s/ *Kara M. Kapke*

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INTEREST OF *AMICUS CURIAE*[1]

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management. CropLife America's member companies produce, sell, and distribute crop protection products, including herbicides, insecticides, and fungicides, which farmers use to provide consumers with abundant food and fiber.

CropLife America is committed to the safe and responsible use of the industry's products, and its members are deeply invested in the discovery and development of new crop protection products and product uses. CropLife America's member companies spend, on average, $286 million and 11.3 years on research, development, and registration of

[1] Pursuant to Fed. R. App. P. 29(a), *amicus curiae* states that all parties have consented to the filing of this brief, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission.

each crop protection product that reaches the marketplace.[2] These registration costs have increased in recent years, largely due to increased environmental safety and toxicology data required by regulators.

CropLife America represents its members' interests by, among other things, monitoring federal agency actions and related litigation of concern to the crop-protection and pest-control industry, and by participating in such actions as appropriate.

CropLife America files this brief in support of Petitioners to urge the Court to grant the Petition and vacate the Final Rule revoking all tolerances for the pesticide chlorpyrifos that the U.S. Environmental Protection Agency ("EPA" or the "Agency") issued under Section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a. Our member companies have a keen interest in how EPA regulates

[2] *See* Phillips McDougall, "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014," A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association 3-4 (March 2016), https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf.

pesticides under both FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*.

The Final Rule has the potential to affect countless other crop protection and pest management products regulated by EPA, as the Agency's novel—and erroneous—interpretation of its own powers creates a significant negative effect in how regulated entities will respond to EPA action. CropLife America's member companies act in reliance on the scientific findings issued by EPA, but here the Agency chose to disregard *its own* science in favor of a never-before-used interpretation of its own powers to conclude, erroneously, that it lacked the ability to modify tolerances under the FFDCA.

Because the implications of that decision are so far reaching and its conclusion so gravely wrong, this Court should grant the Petition to vacate the Final Rule.

SUMMARY OF ARGUMENT

In December 2020, EPA determined that 11 specific chlorpyrifos uses were safe. It reaffirmed that safety finding in the October 2021 Final Rule that is the subject of the Petition. Nevertheless, in that Final Rule, the Agency revoked *all* chlorpyrifos tolerances, erroneously

concluding that it lacked the authority to modify tolerances to permit the use of those 11 specific safe uses because to do so would pick "winners and losers" among potential uses. But EPA had already picked those winners in its December 2020 registration decision. Instead of using its statutory power to modify tolerances to allow for those "winners"—to allow those uses it had already deemed safe—the Agency in the Final Rule arbitrarily concluded that it must revoke *all* chlorpyrifos uses, thus making *every single* chlorpyrifos use a "loser" in a misguided attempt to avoid picking "winners and losers" at all. The Agency's refusal to pick "winners and losers" is arbitrary and capricious, illogical, contrary to the statute, and inconsistent with EPA's prior practices.

The regulated industry appropriately relies on EPA's scientific findings, particularly when the Agency itself *reaffirms* those scientific findings. EPA's new policy—untethered to any statutory mandate—that it cannot pick "winners and losers" among pesticide uses has the potential to dramatically upend how pesticides are regulated, leading to confusion, uncertainty, and endless litigation. Given the grave import of this new policy, amicus urges this Court to vacate EPA's Final Rule.

BACKGROUND[3]

Although the regulatory and litigation history of chlorpyrifos is long and complicated, at issue here are three regulatory actions:

- EPA's December 2020 Proposed Interim Decision finding 11 specified uses of chlorpyrifos to be safe (the "PID");[4]
- EPA's August 2021 Final Rule revoking all uses of chlorpyrifos (the "Final Rule");[5] and
- EPA's February 2022 Final Order denying objections to the Final Rule (the "Final Order").[6]

The Agency issued the PID as part of its then-ongoing registration review of chlorpyrifos under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* The Agency issued the Final Rule and Final Order as part of its role in establishing "tolerances," or maximum levels of pesticide residues allowed in or on

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[3] Petitioners' Brief accurately sets forth in detail the background relevant to this appeal as a whole, but *Amicus* provides this focused background for purposes of its specific arguments.

[4] *See* Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020). The actual PID is available as Administrative Record 40, in Petitioners' Appendix at 366, and by downloading it from Regulations.gov at: https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971.

[5] 86 Fed. Reg. 48,315 (Aug. 30, 2021).

[6] 87 Fed. Reg. 11,222 (Feb. 28, 2022).

food, under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a. The two statutes are to be read in harmony, such that EPA will not register a pesticide under FIFRA unless doing so will not cause higher amounts of pesticide residue than the approved tolerances under the FFDCA. 7 U.S.C. § 136(bb).

The Agency has explained the concept of tolerances under the FFDCA, as amended by the Food Quality Protection Act, using the analogy of a "risk cup." According to EPA, "each use of the pesticide contributes a specific amount of . . . risk to the cup."[7] And, "as long as the cup is not full, meaning that the combined total of all estimated sources of exposure to the pesticide has not reached [the level of concern], EPA can consider registering additional uses and setting new tolerances. If it is shown that the risk cup is full, no *new* uses could be approved until the risk level is lowered."[8] The Agency will lower the risk level in one of two ways: it might rely on new data that more accurately represents the risk, or it might "implement[] risk mitigation

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[7] ENV'T PROT. AGENCY, PRN 97-1, AGENCY ACTIONS UNDER THE REQUIREMENTS OF THE FOOD QUALITY PROTECTION ACT (1997), *available at* https://www.epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act.

[8] *Id.* (emphasis added).

measures," such as cancellation of uses, application restrictions, or user safety measures. *Id.*

ARGUMENT

I. EPA reaffirmed the science behind retention of some tolerances but then erroneously concluded it lacked authority to modify tolerances to permit those tolerances it had already deemed safe.

At the outset, it is important to note what the Petition does *not* do: It does not challenge EPA's scientific findings and conclusions. To the contrary, the Petition seeks to have the Agency follow its own scientific decisions made in the December 2020 registration review.

In the PID, EPA's expert scientists conducted an extensive assessment of potential risk to human health from aggregate exposure to chlorpyrifos. There, the Agency outlined risks using both a proposed "1x" safety factor and the currently applicable "10x" safety factor. The PID acknowledged that all registered uses of chlorpyrifos would be considered safe and allowable under the FFDCA standard if EPA decided that evolving scientific understanding warranted application of the lower safety factor of "1x." Nonetheless, the Agency also proposed mitigation measures in the event it retained the "10x" safety factor. *See* PID at 10, 17–18, 41; *see also* 21 U.S.C. § 346a(b)(2)(C)(ii) (requiring

application of a tenfold margin of safety unless reliable data suggests a different margin will be safe for infants and children). The Petition here does not challenge retention of the "10x" safety factor.

Regarding tolerances, the PID noted that "[n]o potential risks of concern were identified from exposure to chlorpyrifos in food only." PID at 14. Rather, the only concern was based on drinking water, when drinking water concentrations exceeded a comparison level. Even with the "10x" safety factor applied, a subset of 11 identified uses[9] would not exceed that comparison level, even under the conservative FIFRA/FFDCA regulatory risk assessment methods at issue. PID at 15–17. In other words, EPA determined those 11 uses were "safe" for purposes of FFDCA tolerances. PID at 16–17.

EPA reaffirmed its safety finding regarding those 11 uses in its Final Rule and Final Order. For example, the Agency stated: "EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document." Final

[9] EPA's designated safe uses include alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat.

Order at 11,241; *see id.* at 11,246 (noting that "there is at least one subset of chlorpyrifos uses that could be safe"). Indeed, the Agency noted that the Final Rule "was based on available information that EPA had already reviewed and incorporated into risk assessments and/or regulatory documents[,]" such that "EPA did not conduct additional analyses or engage in any additional fact-finding or scientific review." *Id.* at 11,236; *cf.* 87 Fed. Reg. 25,256, 25,259 (April 28, 2022) (in a voluntary cancellation notice for multiple pesticide products, including several containing the active ingredient chlorpyrifos, the Agency reaffirmed that it "has identified no significant potential risk concerns associated with these pesticide products").

Despite reaffirming the science that supported retention of the 11 uses the Agency previously deemed to be safe, EPA revoked *all* chlorpyrifos tolerances, including those 11. Final Rule at 48,333. The Agency posited that it was required to assess exposure from all "currently registered uses," *id.*, and thus it lacked the ability to modify tolerances in a way that would assess exposure from a subset of registered uses and allow only those uses. Instead of allowing the tolerance process under FFDCA to work side-by-side with the

registration process under FIFRA—as it always had—EPA reversed course in the Final Rule by mandating that reduction of registered uses must formally occur through the registration process *before* tolerance modifications. EPA claimed that it could not "assum[e] that uses would be limited in accordance with the 2020 PID mitigation proposal, [and t]hus, as a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time." Final Order at 11,241. The Agency further claimed that the FFDCA "does not allow EPA to leave tolerances in place if they would be safe at some unspecified time in the future based on certain mitigation that may not be implemented," ignoring that the FFDCA expressly permits EPA to modify tolerances to reduce uses and implement the very mitigation measures it claimed may not be implemented. *See id.* at 11,246.

One of the Agency's proffered, though internally inconsistent, rationales for requiring an "all or nothing" approach to tolerances was that because there could be *other* safe uses besides the 11 safe uses, it could not pick "'winners and losers' among the tolerances." *Id.*; *see also id.* ("[T]here are potentially multiple variations of the potential subset of tolerances that might meet the safety standard and that EPA did not

analyze."); *id.* at 11,245 ("[I]t is possible that a different set of crops and a different range of geographic areas could also result in safe aggregate exposures."). But what the Final Rule and Final Order ignore is that EPA had *already* picked winners and losers in the PID.

II. EPA's refusal to modify tolerances in spite of affirming that some uses are safe is arbitrary and capricious.

For all the reasons in Petitioners' brief, EPA's new "all or nothing" approach to risk tolerances is contrary to statutory directives, inconsistent with EPA's own past practices, and simply illogical. Through the interplay of FIFRA and the FFDCA, Congress sought to ensure the safety of pesticide use by requiring an appropriate and rigorous scientific analysis that would determine whether specified uses of a chemical meet the required safety standards to maintain the associated tolerance. Nowhere in either statute is there support for revoking a tolerance associated with a food use *that EPA itself determined was safe* simply because of an administrative sequencing problem that the Agency itself controls.

Consistent with how the FFDCA and FIFRA are to be read in *harmony*, the Agency has historically used a tolerance-by-tolerance approach based on the risk cup concept, *not* an "all or nothing"

approach. For example, EPA decreased the tolerance for residue of ethalfluralin only on potatoes, while leaving current tolerance levels for other commodities. 85 Fed. Reg. 45,336 (July 28, 2020). EPA recently established a tolerance for residue of flonicamid on certain fruit vines while amending the existing tolerance for residence of flonicamid on alfalfa. 87 Fed. Reg. 30,425 (May 19, 2022). EPA established tolerances for residues of fludioxonil in or on cabbage plants at 15 ppm, while separately modifying the watercress tolerance from 7 ppm to 10 ppm. 85 Fed. Reg. 51,354 (Aug. 20, 2020).

The plain language of the FFDCA directs the Agency to "modify *or* revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2) (emphasis added). The statute further provides that "'modify' shall not mean expanding the tolerance to cover additional foods," *id.*, such that modification will only *narrow* the permissible uses. EPA's new interpretation of the FFDCA's risk cup impermissibly rewrites the statute by functionally removing the option to modify. Under EPA's new approach, the Agency would never modify or revoke a single tolerance once it determined the tolerance is not safe, because it would only revoke all tolerances if the risk cup overflowed. But an

agency must give full meaning to the statute as written; it cannot write out an option under the statute. *See, e.g.*, *Chubb Custom Ins. Co. v. Space Systems/Loral, Inc.*, 710 F.3d 946, 966 (9th Cir. 2013) ("It is a well-established rule of statutory construction that courts should not interpret statutes in a way that renders a provision superfluous."); *Massachusetts v. U.S. Dep't of Transp.*, 93 F.3d 890, 893 (D.C. Cir. 1996) ("[A]n agency cannot exploit some minor unclarity to put forth a reading that diverges from any realistic meaning of the statute lest the agency's action be held unreasonable.").

Further, as Petitioners note, the Agency is required to coordinate tolerance actions under FFDCA with pesticide registrations under FIFRA. *See* 21 U.S.C. § 346a(l)(1). And, as EPA itself notes, there is no "particular order" or sequencing required as between FIFRA cancellations and FFDCA tolerance actions. *See* Final Order at 11,247. Rather, the Agency has stated that "the requirement to 'coordinate' is a direction to ensure that the substance of actions taken under FIFRA and the FFDCA are consistent." *Id.* Yet here, EPA's tolerance action is directly contrary to its PID, because the PID (as reaffirmed in both the

Final Rule and Final Order) expressly found 11 uses to be safe and EPA nevertheless revoked the tolerances for those 11 uses.

In support of its argument, EPA pointed to a Final Rule revoking all tolerances for carbofuran. Final Order at 11,247. In that instance, however, the Agency expressly noted that it could not maintain *any* uses of carbofuran under the registration process or the tolerance approval process. *See* 74 Fed. Reg. 23,046, 23,069 (May 15, 2009) ("EPA has determined with respect to carbofuran both that the tolerances established for that chemical fail to meet the safety standard set forth in section 408 of the FFDCA and must therefore be revoked under that statute, and that the pesticide registrations fail to meet the relevant standard under FIFRA, and must therefore be canceled under that statute."). In contrast, here, the Agency made an express finding that 11 specified uses are safe for purposes of both FFDCA tolerances and FIFRA registration. *See* PID at 17. EPA stated in its Final Order that there was no support for the idea that "the Agency lacks the legal authority to revoke pesticide tolerances under the FFDCA that do not meet the safety standard of that statute unless the Agency has first canceled—or simultaneously cancels—associated pesticide registrations

under FIFRA." Final Order at 11,247. But that misses the point entirely. The Agency cannot revoke *all* pesticide tolerances arbitrarily when it has expressly determined, and reaffirmed, that a subset of those pesticide tolerances are in fact safe. Indeed, EPA's point in the Final Order on the sequencing of cancellations and revocations, in fact, *confirms* that the Agency can act to modify or revoke tolerances even if a voluntary cancellation of uses through the registration process has not yet occurred.

Though EPA's new "all or nothing" approach might be easier for the Agency, its departure from careful consideration of individual tolerances (including the 11 uses determined safe here) under FFDCA pulls out the rug from registrants and growers alike, with no change in EPA's rules or guidance to registrants on registration requirements. When an agency has failed to provide sufficient justification for changing course, its action is arbitrary and capricious and therefore cannot carry the force of law. *E.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (emphasizing that an "unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change" (cleaned up)); *see also, e.g.*,

Physicians for Soc. Resp. v. Wheeler, 956 F.3d 634, 639 (D.C. Cir. 2020) (reversal in policy was arbitrary and capricious because EPA failed to provide a reasoned explanation for the change); *Sierra Club N. Star Chapter v. LaHood*, 693 F. Supp. 2d 958, 963 (D. Minn. 2010) ("The National Park Service's failure to acknowledge its previous contrary position, let alone explain why, in its opinion, a change is justified, is the hallmark of an arbitrary and capricious decision.").

III. Without a safety justification for revoking all tolerances, EPA's actions threaten to upend pesticide regulation.

Based on the Agency's well-established approach, industry has adapted its registration approaches for pesticides generally, and the process has informed the decisions of registrants to determine which uses they will register, seek to modify, or cancel, in order to maintain an acceptable risk level within the proverbial risk cup. EPA now claims it can no longer determine tolerances on an individual-use basis because it lacks authority to "pick 'winners and losers' among the tolerances." Final Order at 11,246. But, the Agency has long determined, through an individualized tolerance-by-tolerance approach, which tolerances fit within a risk cup and which do not. Each of those decisions, arguably,

has "winners and losers" among uses and potentially registrants. Even here, in its PID, EPA *already determined* "winners and losers" among chlorpyrifos uses, in its discretion and pursuant to an appropriate analysis under the FFDCA, in identifying the 11 safe uses in the PID. Rather than carry that fulsome analysis through in a final order that recognizes those tolerances as acceptable as it had in the PID, EPA adopted its novel all-or-nothing approach.

What the Agency is really doing is determining, without any new rule or revised guidance, that when a risk cup is full enough to require a hard look at acceptable versus unacceptable tolerances, then the risk cup simply shatters and EPA no longer has authority—or has made a conscious decision not to exercise its authority—to assess particular tolerances. Though in theory this "all or nothing" approach does allow the Agency to avoid picking "winners and losers" among tolerances, it effectively makes losers of all tolerances, regardless of the Agency's historically measured approach to assessing risk. The logical endpoint of EPA's decision then is *not* to apply FFDCA's aggregate risk approach when it really matters (that is, when not all proposed uses fit within the

risk cup), but to instead shatter the cup and abdicate its duty to determine whether each tolerance is safe.

The case of chlorpyrifos is somewhat *sui generis* given the Ninth Circuit's mandate in *LULAC II*.[10] However, *Amicus* is concerned that EPA will continue to take the position that it may (or must) revoke *all* tolerances of a pesticide, even when the Agency positively affirms the safety of particular uses and never suggests that it will take an "all or nothing" approach in its interim decisions or other public statements. If so, *Amicus* and its members face significant uncertainty in how to interact with EPA, potentially leading to unnecessary and repetitive litigation instead of productive negotiations with the Agency.

Pesticide registrants and growers rely on the typical course of dealing with EPA. It is not typical for the Agency to declare a subset of uses safe and then—without any scientific justification—forbid those uses under the guise of tolerance revocation and a refusal to pick

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[10] *See LULAC v. Wheeler*, 996 F.3d 673, 678 (9th Cir. 2021) ("*LULAC II*") (ordering EPA to, within 60 days of the Court's mandate, *either* to modify tolerances and concomitantly publish a finding that the modified tolerances are safe *or* to revoke all tolerances); *see also* Final Order at 11,247 (noting the Ninth Circuit's "very short and specific deadline for addressing pesticide tolerances").

"winners and losers." EPA itself recognizes that it must work with registrants, growers and other pesticide users to pick those "winners and losers" in the registration process. *See* Final Order at 11,246 ("EPA's general policy is to defer to the pesticide registrant and the public to determine which of the various subsets of tolerances are of sufficient importance to warrant retentions since not all parties might agree on the particular combination that should be retained."). But with the Agency's new policy of revoking all tolerances whenever the risk cup overflows—even though modification of tolerances would achieve a safe risk cup—registrants and other stakeholders have no basis to rely on EPA's ability to negotiate and work with them to determine what specific subsets of uses warrant retention. It is not practical or advisable—for EPA, the courts, registrants, growers or the public—to determine the subset of uses that warrant retention through litigation instead of good-faith negotiations.

EPA's position in this matter has the potential to upend how pesticides are regulated without any consideration of safety. It is one thing to revoke tolerances in the name of safety; it is quite another to revoke tolerances that EPA has expressly deemed safe solely because of

the Agency's refusal to reaffirm choices it has already made. There was simply no basis for EPA to find it lacked the authority to maintain tolerances for the 11 designated safe uses as "winners" while revoking the remainder of tolerances as "losers." Continuation of this arbitrary policy makes "losers" out of everyone, as the 11 uses were already deemed safe.

CONCLUSION

Amicus Curiae CropLife America urges this Court to vacate the Final Rule.

Dated: May 25, 2022

Respectfully submitted,

/s/ *Kara M. Kapke*

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CERTIFICATE OF COMPLIANCE

I hereby certify that, pursuant to Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), the foregoing *amicus* brief is proportionately spaced using Word 14-point Century Schoolbook typeface and contains 3,870 words.

Pursuant to Eighth Circuit Rule 28A(h)(2), I further certify that the electronic version of this brief has been scanned for viruses and is virus-free.

/s/ *Kara M. Kapke*

CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2022, I electronically filed the foregoing Brief of *Amicus Curiae* CropLife America with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Within five (5) days of receipt of notice that the foregoing document has been filed and accepted, CropLife America will serve each party separately represented with a copy of the foregoing brief. I further certify that ten (10) paper copies of the foregoing brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Eighth Circuit Rule 28A(d).

/s/ *Kara M. Kapke*

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May 26, 2022

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RE: 22-1422 RRVSG Assoc., et al v. Michael Regan, et al
22-1530 RRVSG Assoc., et al v. Michael Regan, et al

Dear Counsel:

The amicus curiae brief of CropLife America in support of petitioner has been filed. If you have not already done so, please complete and file an Appearance form. You can access the Appearance Form at www.ca8.uscourts.gov/all-forms.

Please note that Federal Rule of Appellate Procedure 29(g) provides that an amicus may only present oral argument by leave of court. If you wish to present oral argument, you need to submit a motion. Please note that if permission to present oral argument is granted, the court's usual practice is that the time granted to the amicus will be deducted from the time allotted to the party the amicus supports. You may wish to discuss this with the other attorneys before you submit your motion.

Michael E. Gans
Clerk of Court

CMD

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District Court/Agency Case Number(s): EPA-HQ-OPP-2021-0523
EPA-HQ-OPP-2021-0523

Consolidated Case Nos. 22-1422, 22-1530

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, *et al.*,

Petitioners,

v.

MICHAEL REGAN, *et al.*,

Respondents.

On Petition for Review from the
United States Environmental Protection Agency

AMICUS CURIAE BRIEF OF THE STATE OF NORTH DAKOTA IN SUPPORT OF PETITIONERS

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GLOSSARY OF TERMS

Denial Order	Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022)
EPA	United States Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Final Rule	"Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021)
PID	Proposed Interim Decision for Chlorpyrifos (December 3, 2020)

THE IDENTIFY AND INTEREST OF *AMICUS CURIAE* THE STATE OF NORTH DAKOTA

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the State of North Dakota ("North Dakota" or "State") submits this brief *amicus curiae* in support of Petitioners Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, National Cotton Council of America, and Gharda Chemicals International, Inc. (hereinafter "Petitioners").

North Dakota writes in support of Petitioners' challenge to EPA's final rule entitled "Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule") (AR 1; Pet. Add. 1) and Petitioners' challenge of EPA's denial of their objections to objections to the Final

Rule in EPA's final decision entitled Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("Denial Order") (Pet. Add. 23).

Agricultural Production is Immensely Important to North Dakota:

Since its statehood in 1889 to the present, agriculture has played a central economic and social role in North Dakota. Agriculture comprises over 25% of the state's total economy and generates some eight billion dollars in cash receipts each year. In North Dakota, the average farm or ranch operation comprises approximately 1500 acres. North Dakota has roughly 26,000 farms and ranches comprising nearly 39.3 million acres. Nearly ninety percent of the total land area in North Dakota is devoted to farming and ranching. These many millions of acres of farmlands and ranchlands provide food and habitat for well over 75% of the wildlife in North Dakota.

North Dakota agriculture remains the leading industry in North Dakota. North Dakota agriculture contributes considerably over 30 billion dollars in economic activity annually to the state. Agriculture broadly supports nearly twenty-five percent of the state's workforce,

which is higher than the national average of nineteen percent. North Dakota is the nation's 9th largest agricultural exporting state, shipping $4.5 billion in agricultural commodities and products abroad in 2017. *See* U.S. Dept. of Agriculture ("USDA"), North Dakota Trade Facts; available at https://ustr.gov/map/state-benefits/nd. Amber waves of grain – hard red spring wheat, durum, and barley – have long been the mainstay of the North Dakota's economy.

In 2020, North Dakota led the nation in the production of 11 different commodities (dry edible beans, pinto beans, canola, flaxseed, honey, rye, all sunflower, non-oil sunflower, oil sunflower, all wheat (durum wheat, and spring wheat)). North Dakota Agricultural Statistics 2021, at 7, Compiled by USDA, National Agricultural Statistics Service, North Plains Region (available at https://www.nass.usda.gov/Statistics_by_State/North_Dakota/Publications/Annual_Statistical_Bulletin/index.php). North Dakota also ranked second in the production of black beans, navy beans, pink beans, small red beans, lentils, and dry edible peas, and third in the production of sugarbeets, cranberry beans, and barley. *Id.* at 10. North Dakota is also

a hotbed for emerging crops like industrial hemp, hops, fava beans, and carinata.

North Dakota has a Codified Interest in Promoting Safe and Sustainable Agricultural Production:

North Dakota's legislature has codified the State's interest in supporting and promoting a safe, sustainable, and productive agricultural sector. North Dakota's Agriculture Commissioner "shall call a meeting of representatives from each [agricultural] commodity group to engage in collaborative efforts to promote and market agricultural commodities." N.D. Cent. Code § 4.1-01-12(2). North Dakota's Agriculture Commissioner is also directed to "implement a program to promote agricultural commodities sustainably grown in North Dakota." N.D. Cent. Code § 4.1-01-10(1). In this context, sustainably grown means research-based practices resulting in "[d]ecreased reliance on tillage and other soil-depleting practices," "[i]ncreased efficiencies in the use of other necessary and measurable agricultural inputs," "[i]ncreased yield efficiencies," and "[g]reater economic benefit to producers." *Id.* at (6)(a)-(f).

North Dakota also fosters the sustainable development of its agricultural commodities through the responsible use of pesticides.

North Dakota's Pesticide Control Board oversees the "safe handling, transportation, storage, display, distribution, and disposal of pesticides and pesticides" in compliance with federal law. N.D. Cent. Code § 4.1-33-03(5)(b). To effectuate its mandate, North Dakota's Pesticide Control Board has adopted substantial regulations governing the safe and effective distribution, handling, disposal, and use of pesticides. *See* North Dakota Admin. Code, Articles 60-01 through 60-03. This mandate will now include managing the disposal of significant amounts of chlorpyrifos "stranded" as a result of EPA's arbitrary and capricious revocation of chlorpyrifos tolerances.

North Dakota's Interest in the Continued Use of Chlorpyrifos:

North Dakota's agricultural sector, in partnership with the State's regulators, has long utilized chlorpyrifos in a safe and effective manner. The majority of the crops grown in North Dakota rely significantly on the safe use of chlorpyrifos. The main uses of chlorpyrifos in North Dakota are for crop production of sunflowers, sugar beets, and soybeans. Chlorpyrifos is also used, albeit to a lesser degree, for crop production of wheat, corn, alfalfa, dry beans, chickpeas, and lentils.

Due to North Dakota's significant reliance on the safe and effective use of chlorpyrifos, North Dakota has followed and participated in EPA's rulemakings governing chlorpyrifos. For example, North Dakota participated in EPA's efforts to review the current science and update its tolerance determinations for chlorpyrifos, including EPA's Chlorpyrifos Proposed Interim Registration Review Decision (Dec. 2020) ("PID") (AR 40; Pet. App. 366), that in late 2020 found the key uses of chlorpyrifos in North Dakota to be safe. *See* North Dakota Department of Agriculture Comments on Proposed Interim Decision for Chlorpyrifos (Document No. EPA-HQ-OPP-2008-0850-1068) (March 5, 2021).

Similarly, multiple North Dakota trade associations, with which the North Dakota Department of Agriculture works closely, commented on the PID and joined objections to the Final Rule. *See e.g.* Objections submitted by Agricultural Retailers Association et al. (Document No. EPA-HQ-OPP-2021-0523-0001) (Joined by the North Dakota Corn, Grain, and Soybean Growers Associations); Northern Pulse Growers Association Comments on the Proposed Interim Decision for Chlorpyrifos (Document No. EPA-HQ-OPP-2008-0850-1060) (March 2, 2021).

Thus, North Dakota has an intimate familiarity with chlorpyrifos, the science behind its use, and the real-world impact that EPA's recent revocation of chlorpyrifos tolerances will cause to North Dakota's and the nation's agricultural sector, as well as the United States' continued ability to feed the world in the face of growing food shortages.

EPA's Chlorpyrifos Ban Directly Affects North Dakota's Interest in Promoting Sustainable Agricultural Production:

North Dakota's codified interests in the promotion of agriculture are threatened by EPA's August 2021 decision in the Final Rule to ban all chlorpyrifos uses, which was a sudden and unexplained reversal of the December 2020 PID in which EPA had just unequivocally determined that chlorpyrifos had at least 11 safe uses. *See* PID, AR 40 at 40; Pet. App. 405 (discussing "the high-benefit agricultural uses that the agency has determined will not pose potential risks of concerns with an FQPA safety factor of 10X").

For example, EPA's arbitrary and capricious Final Rule threatens North Dakota's codified interest in "[d]ecreased reliance on tillage and other soil-depleting practices," because alternative pesticides and crop management controls lack the efficacy and affordability that chlorpyrifos readily provides. North Dakota farmers are already facing rapidly

escalating input costs and logistical bottlenecks due to well-publicized supply chain constraints, including those related to the Russian invasion of Ukraine. Without chlorpyrifos, many North Dakota farmers will face additional significant challenges in meeting buyer standards and implementing conservation techniques. For example, some farmers who practice conservation tilling methods will be compelled to till ahead of planting season for weed and pest control, because conservation tilling is ineffective without efficiently coupling it with pesticide use due to increased pest counts in untilled soil.

North Dakota thus has a substantial interest in the outcome of Petitioners' challenge to the Final Rule, and EPA's denial of Petitioners objections to the Final Rule in the Denial Order. Based on North Dakota's substantial agricultural interests at stake, North Dakota's long history of regulating North Dakota's agricultural sector for the safe and effective application of chlorpyrifos, and the State's many years of participating in EPA's rulemaking relating to chlorpyrifos, North Dakota has a strong well-established interest in this case and the resolution of the challenge to EPA's Final Rule.

SUMMARY OF ARGUMENT

The Court should grant Petitioners' requested relief and vacate the Final Rule as arbitrarily and capriciously promulgated. North Dakota has a serious clear-cut reliance interest in the continued safe use of chlorpyrifos, which EPA arbitrarily and capriciously cast aside when it completely changed course from decades of allowing the safe use of chlorpyrifos, including its unexplained about-face from the Agency's December 2020 PID finding that at least 11 uses of chlorpyrifos met the applicable safety factor. The Court should specifically vacate the Final Rule's revocation of all existing chlorpyrifos tolerances until such time as EPA can incorporate its unequivocal conclusions in the PID that existing tolerances for chlorpyrifos are safe in a new final agency rule.

Real and substantial harms will fall on North Dakota's, and the Nation's, agricultural sectors if the arbitrary and capricious Final Rule is affirmed. North Dakota's growers will be left stranded with insufficient and inferior alternatives to chlorpyrifos treatments for crops, and significant harm will befall North Dakota, its growers, the nation's, and indeed, the world's citizens who regularly depend on the safe crops grown in North Dakota and distributed around the Nation and world.

Further, significant stores of chlorpyrifos will be left unusable, creating a considerable disposal burden on North Dakota in contravention of EPA's obligations to coordinate its tolerance actions under the Federal Food, Drug, and Cosmetic Act ("FFDCA") with cancellation actions under FIFRA.

ARGUMENT

I. The Final Rule Is Arbitrary And Capricious Based On EPA's Complete Reversal Of The PID.

North Dakota joins Petitioners' Opening Brief in whole, and specifically in Petitioners' arguments that the Final Rule is arbitrary and capricious based on EPA's decision to revoke all tolerances – including 11 high-benefit crop uses that it previously determined in its PID to be safe (which encompass six approved used in North Dakota: alfalfa, soybean, sugarbeet, strawberry, and wheat (spring and winter)). Pet. Br. 42-60. The PID carefully considered these 11 crop uses in specific regions and then scientifically determined that those uses "will not pose potential risks of concern with an FQPA safety factor 10x." Pet. Br. at 25; AR at 40; Pet. App. 405.

Even after reaffirming the PID's safety findings in the Final Rule (*see* AR 2 at 5; Pet. App. 161), EPA nonetheless arbitrarily and without

adequate justification refused to apply those findings when EPA inexplicably revoked the tolerances for the 11 safe high-benefit crop uses. EPA clearly has the necessary data, the ability, and the authority to preserve the tolerances for these uses it has determined are safe. Not leaving the tolerances in effect for these 11 uses when EPA's own administrative record supports doing so is arbitrary and capricious.

North Dakota also joins Petitioners in their arguments that EPA's Final Rule and Denial Order is arbitrary and capricious due to their patent inconsistency with FIFRA's pesticide registration cancellation requirements. Pet. Br. 42-53. EPA's failure to properly coordinate the Final Rule and Denial Order with FIFRA's pesticide registration cancellations leaves North Dakota with large stocks of "stranded" chlorpyrifos that were compiled in anticipation of continued use, creating great disposal burdens for North Dakota under FIFRA.

EPA's arbitrary and capricious reversal from its science-based PID findings, and the prior 15 years established safe tolerances for chlorpyrifos, adversely impacts North Dakota's several significant material reliance interests. It is well established that an Agency must provide a legitimate and more detailed justification when "its new policy

rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

When serious reliance interests are at issue, "in order to offer a satisfactory explanation for its action, including a rational connection between the facts found and the choice made, the agency must give a reasoned explanation ... for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Mingo Logan Coal Company v. EPA*, 829 F.3d 710, 719 (2016) (internal quotations omitted) (citing to *Motor Vehicle Manufacturers Assoc. of the United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *F.C.C.*, 556 U.S. at 516).

Here, EPA arbitrarily and capriciously reversed course from its factual scientific findings contained in the PID, including that there were 11 safe crop uses for chlorpyrifos. And, to be sure, this reversal did not come in a vacuum. The procedural history for this case (*see* Pet. Br. at 7-31) outlines how the EPA finalized its safety finding in July of 2006, stating that chlorpyrifos tolerances "meet the safety standard under

Section 408(b)(2) of the FFDCA.[1] For over a decade and a half North Dakota, and its agricultural industry, reasonably relied on that well-established science-based finding.

In 2020 EPA's PID scientifically once again confirmed that chlorpyrifos tolerances remained safe for 11 specific crop uses. EPA gave no indication to North Dakota, and its growers, that there was any imminent risk that the plug would be pulled on all chlorpyrifos uses, especially in light of these well-founded 2006 and 2020 safety determinations. And, as Petitioners note, EPA was in months-long negotiations with Gharda to modify the approved uses on the label consistent with its safety finding in the 2020 PID (Pet. Br. 34-35), and North Dakota also received no indication from Gharda that chlorpyrifos use was at risk for the 11 crop uses identified in the PID.

Nor did the Ninth Circuit's *LULAC* decision cast doubt on EPA's safety findings for chlorpyrifos tolerances in the PID. *LULAC v. Wheeler*,

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[1] AR 33; Pet. App. 547; EPA, Office of Prevention, Pesticides and Toxic Substances, Memo to Jim Jones from Debra Edwards, Finalization of Interim Reregistration Eligibility Decisions and Interim Tolerance Reassessment and Risk Management Decisions for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides 2 (July 31, 2006).

996 F.3d 673 (9th Cir. 2021) ("*LULAC*"). Instead, in *LULAC* the Ninth Circuit simply ordered EPA to issue a final regulation "that either revokes all chlorpyrifos tolerances or *modifies* chlorpyrifos tolerances." *Id.* at 703 (emphasis added). And in issuing that order, the Ninth Circuit explicitly acknowledged that the PID (and its safety findings for chlorpyrifos) were not before the court, and noted that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." *Id.*

Therefore North Dakota, the North Dakota Department of Agriculture, and the State's growers reasonably relied upon the almost two decades of prior scientific review by EPA, culminating in the PID, which continually concluded that chlorpyrifos tolerances remained safe for use on crops. They did so in preparation for the 2022 growing season, without the ability to change crop rotation practices (such as no till approaches) or the knowledge it was necessary to do so in light of the fact that their most effective pesticide in chlorpyrifos would be banned overnight.

EPA's arbitrary and capricious reversal of the PID in the Final Rule impacted significant and legitimate long-standing reliance interests existing in the North Dakota and its agricultural sector (*See* Section II, *infra*), for which EPA fairly owed North Dakota a "reasoned explanation ... for disregarding facts and circumstances that underlay or were engendered by the prior" chlorpyrifos tolerance safety findings in the PID. *Mingo Logan Coal Company*, 829 F.3d at 719. EPA failed to provide such a heightened justification supporting its recent direct about-face change in its treatment of Chlorpyrifos.

II. If The Final Rule Is Allowed To Stay In Effect, There Will Be Severe Consequences For Agriculture In North Dakota And The United States.

If the Court allows the Final Rule to stand, there will be severe effects for North Dakota's (and the Nation's) agricultural industry, extending to the global food supply chain as well. These adverse effects are not just economic, but also threaten environmental harm that should be considered in reviewing EPA's abrupt reversal of prior positions in the Final Rule. These harms are compounded by EPA's sudden and inadequately explained reversal from the PID issued in December of 2020 in which EPA determined there were 11 safe crop uses for chlorpyrifos.

States and growers reasonably relied on the PID to plan for effective crop management – and States and growers have not had time to adjust to EPA's drastic reversal in prohibiting the 11 safe uses of chlorpyrifos. Even EPA acknowledged in its PID that states such as California, Hawaii, New York, Maryland, and Oregon took the measured approach of "state-level actions to phase out all or most uses of chlorpyrifos" rather than initiate immediate bans of the pesticide. PID, AR at 50; Pet. App. at 376. It is thus confounding that EPA would immediately ban all uses of chlorpyrifos in the Final Rule without, at a bare minimum, providing pesticide distributors, applicators and agriculture producers a reasonable and meaningful phase out period.

A. North Dakota's Agricultural Industry (And The Nation's) Will Be Injured.

By EPA's own estimates, the per acre benefits of chlorpyrifos could be as high as $500 in parts of North Dakota, leading to Agency-estimated high-end benefits over $30 million overall nationwide. PID, AR at 81; Pet. App. at 407. The benefit of chlorpyrifos in soybean crops alone was estimated up to $4 per acre, and with over 3 million acres treated annually, the total benefit could be about $12 million nationwide. *Id.* For wheat and alfalfa, benefits were estimated at $1 per acre, but the agency

noted those costs would likely increase given their large production acreage, and EPA thus "estimated high per-acre economic benefits to growers." *Id.* EPA also acknowledges the lack of alternatives leading to potential yield loss in sugarbeet crops in Minnesota and North Dakota.[2] Losing chlorpyrifos as a critical agricultural tool in North Dakota would thus be devastating to its agricultural sector.

According to the USDA, the counties in eastern North Dakota collectively plant between 200,000 – 230,000 acres of sugarbeets annually, producing between 5.5-6.5 million tons of sugarbeets. *See* Sugar and Sweetener Yearbook Tables, U.S. sugar crop production and sugar production deliveries, and stocks, May 19, 2022, ERS/USDA (available at https://www.ers.usda.gov/data-products/sugar-and-sweeteners-yearbook-tables.aspx). This represents generally about 18% of total U.S. sugarbeet acreage.

According to a North Dakota State University study on the economic contribution of the sugarbeet industry in North Dakota, in 2010 the total direct impacts in North Dakota from sugarbeets were estimated

[2] AR 62; Pet. App. 299 (EPA, Memorandum, Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101), EPA-HQ-OPP-2008-0850-0969, at 5 (Nov. 18, 2020)).

at $592.3 million dollars. Economic Contribution of the Sugarbeet Industry in Minnesota and North Dakota, at 10 (AAE Report No. 688, February 2012) (available at https://www.ndsu.edu/agecon/research/research_reports/). This represents $36.8 million in collected taxes in the State. *Id.* 17. Sugarbeet production in both North Dakota and Minnesota create 2,473 full-time equivalent jobs and indirectly support an additional 18,830 full-time equivalent jobs. *Id.*

According to Dr. Mark Boetel, Ph.D., Entomology at South Dakota State University, there will be aggregate unrecoverable losses of approximately $39,299,642 in North Dakota in 2022 to the sugarbeet crop alone if EPA's Final Order is allowed to stand and chlorpyrifos use remains prohibited. Attachment 1, hereto, at 15.[3] This estimate is based upon the 104,000 North Dakota acres expected to be affected by sugarbeet root maggot in 2022 and using the next best pesticide alternative (Mustang Maxx) in place of chlorpyrifos. In Dr. Boetel's

[3] The use of chlorpyrifos insecticide to control sugarbeet root maggot (SBRM) [Tetanops myopaeformis (Röder)] specifically in sugarbeet, at 1 Joe Hastings, General Agronomist, American Crystal Sugar Company (May 27, 2022).

research, there would be a reduction of 1,565 lbs. of sugar/acre produced, which would involve revenue losses of $201 per acre. *Id.* The 1,565 lbs. of sugar/acre lost applied to the 104,000 acres results in 162,760,000 lbs. of sugar lost in SBRM affected areas.

Taking the $201 per acre lost multiplied by 104,000 acres, equates to $20,904,000 in losses in North Dakota SBRM areas. *Id.* Adding the $20,904,000 of total lost revenue to $18,395,642 in additional total production costs brings the total in losses to $39,299,642 caused by not having chlorpyrifos as an option for sugarbeet root maggot control in sugarbeets. *Id.* This one-year projected loss for 2022 will be compounded in each subsequent crop year due to the resulting use of less effective alternative insecticides.

Thus, North Dakota's (and the Nation's) agricultural industry stands to experience a dramatic adverse reduction in its yield, tax collections, and potentially in sugarbeet crop planting if the Final Order is allowed to stand. Moreover, North Dakota's small rural communities rely substantially on the economic activity of sugarbeet production. Jobs at local agri-businesses, farm equipment dealerships, tire shops, small retailers, diners, donations to high school events, etc. all rely on

sugarbeet production in the Red River Valley. All will likewise be detrimentally impacted.

i. There Are Currently No Viable Alternatives To Chlorpyrifos.

Chlorpyrifos is an essential tool in the North Dakota tool box for control of all arthropod pests in field crops. Different types of pesticides have different "modes of action" by which they mitigate pests. Having more than one pesticide available for pest mitigation is important, since rotation among insecticide groups decreases the development of resistance to insecticides by insects, which can lead to adverse effects such as crop losses or the increased use of less effective insecticides.

Prohibiting chlorpyrifos, which has a unique mode of action in the IRAC1B group, will leave only one remaining pesticide mode of action to "control" most of North Dakota crop pests. Continual use of one pesticidal mode of action generally leads to increased pest resistance, with resulting crop losses and potentially increased pesticide applications. In short, EPA's arbitrary and capricious chlorpyrifos ban will be highly detrimental to North Dakota agriculture as well as to state's agriculture-based economy, as well as to national (and international) food security.

For example, the North Dakota sunflower industry heavily relies on chlorpyrifos applications. Sunflowers attract many insect pests that attack the plants, including cutworms, banded sunflower moths, seed weevils, stem weevils, sunflower beetles, sunflower moths, and Lygus bugs. Unfortunately, many alternative chemistries have limited efficacy on these pests. For example, chlorpyrifos is the only chemistry that is currently able to control seed weevils.

Soybean aphids are also a substantial problem in North Dakota. Chlorpyrifos is heavily used for aphid control on soybean crops (found to be safe by EPA in the 2020 PID) as North Dakota has many insecticide resistance problems to other chemistries – especially pyrethroids which are the other main chemical used for aphids. These pests can lower yields 60% if left unchecked.

For most other commodities in North Dakota, chlorpyrifos is most widely used as a safe seed treatment. After a seed is planted it is highly vulnerable to ground dwelling pests and chlorpyrifos is the product shown to have the most control at this very sensitive stage of plant development.

Similarly, North Dakota's sugarbeet industry is also heavily reliant upon chlorpyrifos (found to be safe by EPA in the 2020 PID) to control webworms, cutworms, flea beetles, and lygus bugs. All are prevalent pests in North Dakota. Chlorpyrifos is the only product that can control sugarbeet root maggots ("SRBM"). In 2020, there were 90,994 total acres grown in areas affected by SRBM in North Dakota. *See* Attachment 2, hereto.[4] In 2021 there were 97,324 total acres grown in areas affected by SRBM in North Dakota, nearly a seven percent increase. *See* Attachment 3, hereto.[5] Based on these figures, approximately 104,000 sugarbeet acres in North Dakota are projected to be affected by SRBM in 2022. *See* Attachment 1 at 1. Without chlorpyrifos, SRBM can decrease crop yields by as much as 45%, a substantial impact to North Dakota's (and the Nation's) sugarbeet production.

EPA's revocation of chlorpyrifos residue tolerances has put sugarbeet producers at great risk, because alternative insecticides for post-emergence SBRM control are not adequate. Attachment 1 at 1.

[4] Map of Sugarbeet Root Maggot Severity (2020), Developed by American Crystal Sugar Company.
[5] Map of Sugarbeet Root Maggot Severity (2021), Developed by American Crystal Sugar Company.

Chlorpyrifos has long been the standard and most effective product used for postemergence SBRM control, it was found to be safe by EPA in the 2020 PID, and it is the insecticide that all potential postemergence insecticides are evaluated against.

Mustang Maxx is considered to be the "next-best" alternative to chlorpyrifos for postemergence insecticide applications for SBRM control but falls well short in efficacy with consequent significantly reduced yields and revenues. *Id.* Mustang Maxx is a pyrethroid insecticide, for which performance declines at temperatures over 80°F, a telling weakness given that fly activity peaks on days that are 80°F and above and that temperatures of 80°F and above are common during May 20th – June 30th.

Dr. Mark Boetel conducted a two-year (2020-2021) field experiment that compared Mustang Maxx and chlorpyrifos (Yuma 4E) for postemergence SBRM control titled Dual Applications of Mustang Maxx for SBRM Control. Dr. Boetel found that when using Mustang Maxx in place of Chlorpyrifos there was a loss of: 16.93% in recoverable sugar/acre; 19.18% in yield (tons/acre); 14.41% in gross revenue/acre, and 70.53% in Net Operating Revenue. *Id.* at 2.

Further, crop rotation is not an effective substitute for chlorpyrifos (or other pesticides) for SRBM control. *Id.* at 5. That is because SRBM larvae overwinter in fields and emerge the next year. Similarly, mechanical control (such as rotary hoe or field harrow cross) and use of cover crops are not an effective SBRM management tool. *Id.*

ii. EPA's Arbitrary And Capricious Final Rule Threatens To Destabilize North Dakota's, The Nation's, And The World's Agricultural Production.

EPA's Final Order effectively banning the use of chlorpyrifos is layered on top of current severe inflationary pressures and the disruption of global grain and fertilizer markets caused by the Russian invasion of Ukraine. EPA's decision comes at a time when North Dakota's growers are experiencing record inflationary farm costs – fuel, seed, fertilizer, and pesticide prices are rising rapidly. North Dakota's growers' already highly narrow margins are being cut yet again. Removing chlorpyrifos as an effective pet control management tool will severely and negatively impact production. The loss of access to chlorpyrifos will also further increase costs at the same time yields are cut since producers will have to use more expensive and much less effective alternatives that they will consequently be compelled to apply more frequently.

Separately, because the United States has invested in a strong domestic sugar industry, consumers are currently shielded from the erratic price swings of the global market. If North Dakota's (and the Nation's) domestic industry continues to get hit by additional production burdens and increased costs, many U.S. consumers will likely turn to less expensive and lower quality, foreign sugar whose production is subject to less stringent standards than those in the United States.

EPA's decision also comes at an extremely poor time for agriculture and sugarbeets. North Dakota's sugarbeet industry is coming off some of its most challenging years. In 2019, one-third of sugarbeet crops were left in the ground do to extreme wet weather in the fall and an early freeze. In 2020, sugarbeet growers had a shortened crops due to a late spring. In 2021 sugarbeet growers faced a record drought.

Now in 2022, North Dakota is having one of the latest springs on record caused by persisting cool and wet weather. While weather is obviously out of the industry's control, pests were previously manageable through safe and effective use of chlorpyrifos. Yet now, even though EPA's own data in the PID well demonstrates that chlorpyrifos is an effective and safe product, its use has been prohibited with little to no

warning, and more notably, no adequate explanation for the reversal of the 2020 PID.

B. North Dakota Will Be Forced To Expend Significant Resources To Deal With The Disposal Of Unusable Chlorpyrifos.

EPA's Final Rule is also arbitrary and capricious because it failed to harmonize EPA's tolerance determinations under the FFDCA with the cancellation process under FIFRA. Pet. Br. 47-54. This fatal error also works great harm to North Dakota and its obligations under FIFRA for pesticide disposal.

North Dakota's growers reasonably expected EPA to continue course with the PID determinations and that chlorpyrifos would be available for use in the 2022 growing season. While North Dakota has been unable to complete a comprehensive statewide survey at this time, it estimates that its growers have many tons of "stranded" and unusable chlorpyrifos stocks remaining, directly due to EPA's sudden revocation of the tolerances.

Section 19 of FIFRA authorizes EPA to establish requirements for disposal of pesticides, but FIFRA disposal regulations are implemented rarely and only in the context of risk-based and time-limited

cancellations. *See* EPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities (available at https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities).

Here, however, EPA has not proactively made any such necessary disposal regulations, again showing the arbitrary and capricious haste and nature in which the Final Rule was promulgated. Consequently, North Dakota's Pesticide Control Board has now inherited disposal obligations for the vast quantities of accumulated but now defunct chlorpyrifos. And North Dakota, just like the growers and chlorpyrifos manufacturers, had no meaningful advance warning of EPA's about-face in which to then prepare for those disposal obligations. EPA's Final Rule, in addition to being arbitrarily and capriciously promulgated, does not demonstrate good regulatory governance and is unacceptable.

CONCLUSION

For the reasons explained above, and as set forth in Petitioners' Opening Brief, the Court should grant Petitioners' requested relief and vacate the Final Rule.

Dated: May 31, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(5)-(7) of the Federal Rules of Appellate Procedure, I hereby certify that the foregoing brief is proportionately spaced using Word 14-point Century Schoolbook typeface and contains 4,975 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count, and therefore is within the word limit set by the Court.

Pursuant to Eighth Circuit Rule 28A(h)(2), I further certify that the electronic version of this brief has been scanned for viruses and is virus-free.

Dated: May 31, 2022

/s/ *Paul M. Seby*
Paul M. Seby

CERTIFICATE OF SERVICE

I hereby certify that, on this 31st day of May 2022, a copy of the foregoing brief was electronically filed with the United States Court of Appeals for the Eight Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, North Dakota will serve each party separately represented with a paper copy of the Brief.

Pursuant to Eighth Circuit Rule Rule 28A(d), I further certify that ten (10) paper copies of the foregoing brief will be provided to the Court, within five (5) days after receipt of notice that the foregoing has been filed and accepted.

/s/ *Paul M. Seby*
Paul M. Seby

The use of chlorpyrifos insecticide to control sugarbeet root maggot (SBRM) [*Tetanops myopaeformis* (Röder)] specifically in sugarbeet.

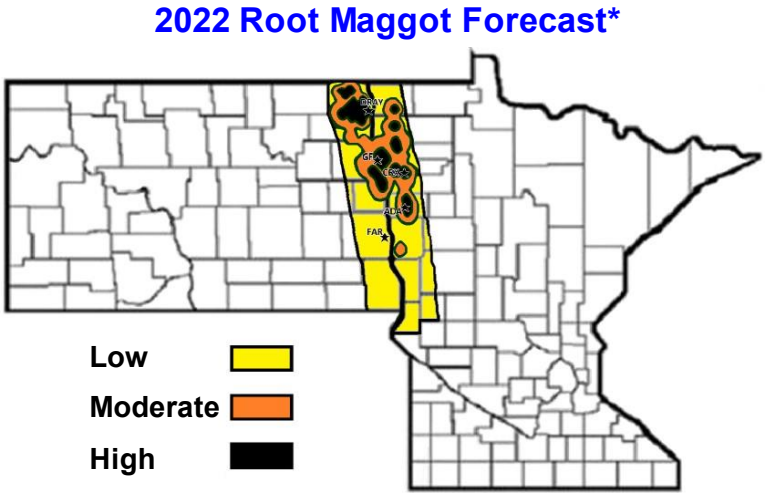
Document written and assembled by:
Joe Hastings, General Agronomist, American Crystal Sugar Company 5-27-22
Providing input and review: Dr. Mark Boetel, North Dakota State University Sugarbeet Entomologist

Total area in 2022 to be affected by sugarbeet root maggot (SBRM) in ND: 104,000 acres

Approximately 104,000 sugarbeet acres in North Dakota are projected to be affected by SBRM. This calculation is based on the acres identified in 2021 of SBRM observations from American Crystal Sugar Company (ACSC) Ag Staff and North Dakota State University Sugarbeet (NDSU) Entomologist Dr. Mark Boetel. From these observations a SBRM severity map was developed, and the 2021 acres planted to sugarbeets that were in these SBRM affected areas were totaled. The SBRM area and affected acres has been increasing at a rate of 7%/year in North Dakota. This 7% increase is built into the estimation of approximate acres to be treated for the 2022 projected acres.

The counties in which sugarbeet will be grown where SBRM pressure exists (2021 planted acreage): Grand Forks (33,125 acres), Pembina (59,712 acres), Traill (29,420 acres), and Walsh (44,708 acres).

Dr. Boetel (NDSU Sugarbeet Entomologist) Projected 2022 SBRM Severity Map



*Based on fly counts & *root maggot feeding injury* ratings

ALTERNATIVE METHODS OF CONTROL TO CHLORPYRIFOS

Alternative Insecticides for Control of Sugarbeet Root Maggot.
The statements on alternative insecticides and control practices were developed in collaboration with Dr. Boetel, NDSU Sugarbeet Entomologist as an additional qualified expert. All alternative insecticides to chlorpyrifos for post emergence SBRM control are not adequate.

Zeta-cypermethrin, Mustang Maxx (pyrethroid IRAC Group 3A). Mustang Maxx is considered to be the next-best alternative to chlorpyrifos for postemergence insecticide applications for SBRM control but falls short in efficacy reducing yield and revenue. Mustang Maxx can be applied at-plant and foliar at a rate of 4 fl oz/a (0.025 lb ai/acre). A maximum of 12 fl oz/acre (0.075 lb ai/acre) per season can be

applied. There is 50-day pre-harvest interval. Zeta-cypermethrin only provides suppression of SBRM larvae and not control. It is a pyrethroid insecticide, for which performance declines at temperatures over 80°F. It should be noted that fly activity peaks on days that are 80°F and above and that temperatures of 80°F and above are common during the period of May 20th – June 30th. Mustang Maxx is not as effective as chlorpyrifos for SBRM control. Dr. Boetel conducted a two-year (2020-2021) field experiment that compared Mustang Maxx and chlorpyrifos (Yuma 4E) for postemergence SBRM control titled Dual Applications of Mustang Maxx for SBRM Control.
See Table 1.

Table 1: Dr. Boetel study of Dual applications of Mustang Max in Comparison to Chlorpyrifos

2020-2021 Boetel study					*Cost of Production
Dual Applications of Mustang Maxx for SBRM Control					$1,110
At-Plant	POST	RSA	Tons/A	Gross Rev/A	Net $/A
Counter 8.9 lbs	Yuma 4E 2 pts. 2X	9,244	29.2	$1,395	$285
Counter 8.9 lbs	Mustang Maxx 4 oz. 2X	7,679	23.6	$1,194	$84
	Difference Chlor vs MM	1,565	5.6	201	$201
	% Difference	16.93%	19.18%	14.41%	70.53%
*Production Costs = $1,110					
Based on Minnesota & North Dakota Farm Business Management Education Report					
Red River Valley 2021. See Attachment: 2021 FBM RRV Report					
Weighted average of production costs scenarios pages 39-42					
Attachment: Grower Production Costs 2021 Update					

This most recent research study reflects the current state of elevated SBRM severity that is being experienced. Mustang Maxx did not perform as well as chlorpyrifos. When using Mustang Maxx in place of Chlorpyrifos (Yuma) there was a loss of: 16.93% in recoverable sugar/acre (RSA); 19.18% in yield (tons/acre); 14.41% in gross revenue/acre, and 70.53% in Net Operating Revenue. To note, specific yield, recoverable sugar/ace, and revenue data from separate research trials cannot be directly compared against other study's results as they are their own data set within the individual scientific study and the time period in which the evaluation occurred.

Esfenvalerate, Asana XL (pyrethroid IRAC Group 3A). Asana XL can be applied foliar at a rate of 9.6 fl oz/a (0.05 lb ai/acre). A maximum of 28.8 fl oz/acre (0.15 lb ai/acre) per season can be applied. There is 21-day pre-harvest interval. It is a pyrethroid insecticide, for which performance declines at temperatures over 80°F. It should be noted that fly activity peaks on days that are 80°F and above and that temperatures of 80°F and above are common during the period of May 20th – June 30th. Its performance for SBRM control is similar to that of Mustang Maxx only providing suppression of SBRM. Asana is not as effective as chlorpyrifos for SBRM control.

Terbufos, Counter 20G (organophosphate IRAC Group 1B). Counter 20G is a granular insecticide that can be applied at-plant banded at 3 – 6 oz./1,000 ft. of row. This equates to 4.5 – 8.9 lb/acre in 22-inch rows (0.9 – 1.8 lb ai/acre). Sugarbeets in the RRV are planted in 22-inch rows. Counter 20G can also be applied postemergence. Counter 20G can only be applied once per season and there is a 90-day preharvest interval. Counter 20G is the best at-plant insecticide for controlling SBRM larvae and is the standard in which all at-plant insecticides are evaluated against. Even with this level of control, it is not a standalone insecticide for SBRM control and postemergence insecticides applications are needed under moderate fly pressure for optimum control and protection to have the highest crop potential. Please note Dr. Boetel's study from 2020 – 2021 shown below.
See Table 2.

Table 2: Dr. Boetel study of Dual applications of Mustang Max in Comparison to Chlorpyrifos

2020-2021 Boetel study					Cost of Production
Dual Applications of Mustang Maxx for SBRM Control					$1,110
At-Plant	POST	RSA	Tons/A	Gross Rev/A	*Net $/A
Counter 8.9 lbs	Yuma 4E 2 pts. 2X	9,244	29.2	$1,395	$285
Counter 8.9lbs		6,797	21.4	$1,029	($81)
Untreated Check		6,085	19.4	$907	($203)
Diff. Chlorpyrifos + Counter vs. Counter		2,447	7.8	366	$366
	% Difference	26.47%	26.71%	26.24%	128.42%
*Production Costs = $1,110					
Based on Minnesota & North Dakota Farm Business Management Education Report					
Red River Valley 2021. See Attachment: 2021 FBM RRV Report					
Weighted average of production costs scenarios pages 39-42					
Attachment: Grower Production Costs 2021 Update					

Data from this study shows that an at-plant insecticide alone is not enough to achieve optimal SBRM control. When comparing only using Counter at-Plant to Counter at-plant with a postemergence Chlorpyrifos (Yuma) application there was a loss of 26.47% in recoverable sugar/acre (RSA), 26.71% in yield (tons/acre), 26.24% in gross revenue/acre, and 128% in Net Operating Revenue. To note, specific yield, recoverable sugar/ace, and revenue data from separate research trials cannot be directly compared against other study's results as they are their own data set within the individual scientific study and the time period in which the evaluation occurred.

Phorate, Thimet 20G (organophosphate IRAC Group 1B). Thimet 20G is a granular insecticide applied postemergence in 5 – 7-inch bands at 3.2 – 5.0 oz./1,000 ft. of row. This equates to 4.9 – 7.5 lb/acre in 22-inch rows (1.0 – 1.5 lb ai/acre). Sugarbeets in the RRV are planted in 22-inch rows. It can only be applied once and has a 30-day preharvest interval. Thimet applications require the modification/creation of existing equipment to attach delivery systems of the product which can create an additional hurdle for applications. Thimet needs to be applied in advance of sugarbeet root maggot fly pressure and requires moisture (precipitation) and incorporation into soil to become activated for fly control. Therefore, a post emergence liquid insecticide application is needed if these conditions do not occur which is out of the producer's control. Also, if fly pressure is at high levels a chlorpyrifos application is necessary for control even if Thimet had been applied.

Neonicotinoid Seed Treatments (IRAC Group 4A): NipsIt (clothianidin); Poncho Beta (clothianidin + beta-cyfluthrin); Cruiser (thiamethoxam). Neonicotinoid seed treatments are an at-plant insecticide option for SBRM larvae and do not offer complete control but only a small level of suppression. Neonicotinoid seed treatments do not control SBRM maggot as well as Counter 20G (terbufos) when it is applied at high rate of 8.9 lb/acre. Neonicotinoid seed treatments are not a stand-alone insecticide for SBRM root maggot control and require a supplemental postemergence insecticide under moderate pressure. Dr. Boetel conducted research from 2015 to 2021 which shows a neonicotinoid seed treatment (Poncho Beta) is not as effective as Counter 20G.
See Table 3 and attachment Boetel Additive Granular Insecticide.

Table 3: Dr. Boetel 2015-2021 Granular Insecticides for SBRM Control

Additive Granular Insecticides for SBRM Control		
At-Plant	**RSA**	**Tons/A**
Counter 8.9 lbs	7,771	27.1
Poncho Beta	7,533	26.3
Untreated Check	5,744	20.8

Data shows that Counter 20G at-plant is more effective than neonicotinoid seed treatments. To note, specific yield, recoverable sugar/ace, and revenue data from separate research trials cannot be directly compared against other study's results as they are their own data set within the individual scientific study and the time period in which the evaluation occurred.

Imidacloprid, Midac FC (neonicotinoid, IRAC Group 4A). Midac FC can be applied at-plant in-furrow at 13.6 fl oz/acre (0.18 lb ai/acre). It can only be applied once. Midac FC is a neonicotinoid and performs similarly to the neonicotinoid seed treatments and not as well as Counter 20G. Midac FC is not a stand-alone insecticide for SBRM root maggot control and requires a postemergence insecticide under moderate pressure.

Spirotetramat, Movento HL (tetronic and tetramic acid derivatives IRAC Group 23) Movento HL can be applied foliar at 2.25-4.5 fl oz./acre (0.07-0.14 lb ai/A). The maximum use per crop season is 9 fl oz./acre (0.28 lb ai/acre) with an application interval of 14-days and pre-harvest interval of 28-days. It is only labeled to suppress Sugarbeet Root Maggot and does not control it.

Naled, Dibrom 8 Emulsive (organophosphate IRAC Group 1B). Dibrom at 1 pt./acre can be applied foliar to sugarbeets. Not more than 5 pts/acre can be applied per season (4.7 lbs. a.i./acre). Do not apply within two days of harvest. The label requires a minimum of 7 days between applications and no more than 5 applications can be applied per season. Naled does provide some control of SBRM but is not as effective as a 2 pts./acre rate of chlorpyrifos. Naled has shorter residual activity than chlorpyrifos as well, which allows new flushes of flies to distribute into fields sooner.

Alpha-cypermethrin, Fastac CS, Fastac EC (pyrethroid IRAC Group 3A). Fastac CS at 3.8 fl oz./acre (0.025 lbs. a.i./acre) is applied in a 3 – 4-inch T-band at plant. Subsequent foliar applications can also be made. Maximum rate is 3.8 fl oz./acre with a maximum seasonal application of 11.4 fl oz./acre (0.075 lb a.i./acre). There is a 4-day application interval with a 50-day pre-harvest interval. Alpha-cypermethrin only provides suppression of SBRM larvae and not control. It is a pyrethroid insecticide, for which performance declines at temperatures over 80°F. It should be noted that fly activity peaks on days that are 80°F and above and that temperatures of 80°F and above are common during the period of May 20th – June 30th.

Integrated Pest Management and Cultural Control Practices:

Early planting & sugarbeet size. Early planting allows for possibly larger beet roots during peak SBRM feeding activity (mid-June to mid-July). Larger roots are more able to withstand feeding injury and can avoid potential yield impacts if adequate rainfall is received. Roots of smaller, late-planted beets are more vulnerable to feeding injury. Severe injury can kill seedlings and cause major stand reductions or result in smaller, sprangled, bulb-shaped roots at harvest. Early planting and sugarbeet stand establishment cannot be relied upon as a control measure as it is a product of the environment, field conditions, planting date, emergence, and growing degree days. Sugarbeet growers plant sugarbeets as early as they possibly can every year to optimize yields and try to minimize potential disease and insect pressure. If the environment and soil is too wet to plant, this delays planting later and results in smaller beets being present when fly activity and the resulting larval feeding occur.

SBRM Degree Day Model. A SBRM Degree Day Model has been developed to track root maggot development. It is extremely accurate and heavily relied upon by growers to determine when insecticide applications should be made for optimal SBRM control.

The formula for the daily sugarbeet root maggot degree days is:

Daily SBRM DD (Degree Days) = (((Daily Max Temp °F + Daily Min Temp °F) / 2) - 47.5 °F

The upper threshold on the maximum temperature is 99 °F. Calculations begin on April 1. Peak fly activity of sugarbeet root maggot occurs under warm (about 80 °F+), low-wind (less than 10 mph) conditions at about 651 DD. This typically occurs 2-3 days after reaching 600 DD.

The following table shows suggested timing to apply postemergence liquid or granular insecticides for three latitudinal zones within Red River Valley.

	Target DD for Insecticide Applications	
	Liquid Insecticides	Granular Insecticides
Northern RRV	590-620 DD	440-550 DD
Central RRV	585-615 DD	410-545 DD
Southern RRV	580-610 DD	400-540 DD

General recommendations

Granule Applications**:** apply at ***6-14 days*** before expected SBRM fly activity peak.
Liquid Applications**:** apply at ***2-3 days*** before expected SBRM fly activity peak.

Fly Stake Monitoring. Starting in late-May fly sticky stakes are deployed in fields that are grown in areas with a history of SBRM pressure. Each stake is coated with a sticky substance called "Tanglefoot®" to trap flies as they land on the stake. The number of flies captured reflects the level of fly activity for the area. Decisions whether a postemergence insecticide treatment is warranted are based on the fly count numbers. When a cumulative count of 70 flies have been captured, it justifies an insecticide application. Fly stakes are checked every Monday, Wednesday, and Friday until about the end of June. The population increases observed in recent years have led to increasing the sticky stake monitoring program to roughly 150 locations each growing season representing the areas affected by SBRM.

Crop rotation. Sugarbeets are part of a 3 – 4-year crop rotation in the RRV. Crop rotation is not an option for sugarbeet root maggot control because the adult fly stage of the pest is readily mobile and can easily move into and colonize neighboring sugarbeet fields. The larvae from the previous year overwinter in the sugarbeet field. The next spring, they pupate and then emerge as flies and travel to the current years sugarbeet field locations. They can be blown to new areas by high wind events.

Mechanical Control. Mechanical control is not a highly effective SBRM management tool. It is not a practice which is implemented in production. It is thought that using a rotary hoe or field harrow across beet rows in June following egg deposition may help marginally to reduce maggot numbers. These tillage practices can move eggs away from beet seedlings and onto the soil surface, which exposes them to predators and the elements. As a result of exposure to heat and dry air, the developing maggots sometimes die before or shortly after hatching. This cultural strategy works best if hot and dry weather coincides with egg deposition.

Cover Crops. Use of cover crops is not a highly effective SBRM management tool. It is mainly used to protect from wind erosion in fields. Sowing oat cover crops immediately before beet planting may reduce SBRM injury to sugarbeet roots. It is thought cover crops could provide a dense plant canopy and the shading helps keep soils moist. This condition is believed it would keep larvae feeding higher in the

soil profile (away from tap roots and nearer to insecticide-treated soil). Also, the dense network of oat roots may impair the ability of larvae to locate and feed on beet roots.

Host plant resistance. A couple of sugarbeet lines with varying tolerance to sugarbeet root maggot feeding injury were identified by Dr. Campbell at the Fargo USDA. Thus far, the genetic trait(s) that confer SBRM tolerance in these lines has not been successfully incorporated into elite germplasm. Thus, although this potential management tool is encouraging, it is not yet available commercial sugarbeet production

EFFICACY OF CHLORPRIFOS

To have optimum control of SBRM, growers in areas plagued with the pest need to couple their control measures with an at-plant and postemergence insecticide. The at-plant insecticide is applied so it is in place for early season protection against other pests and eventual control of SBRM larval feeding injury. The postemergence insecticide is used to reduce the number of SBRM flies and thereby the number of eggs that are laid that will turn into feeding larvae. This gives the at-plant insecticide a better chance to work effectively against the reduced larvae population.

Timing of the postemergence insecticide is critical so that control is optimized, and the insecticide is as effective as it can be. The SBRM Degree Day model and fly stake counts are used in order to get this timing right when fly populations warrant a treatment. Chlorpyrifos as a postemergence insecticide has been the most effective and most commonly used insecticide for this application for several years. When daily or cumulative captures of SBRM flies reach 70 flies/stake in an area, a chlorpyrifos application at 2pts/acre (32 oz/acre) is recommended. If a treatment is made, the location continues to be monitored and if SBRM fly populations resurge a second postemergence insecticide may be required.

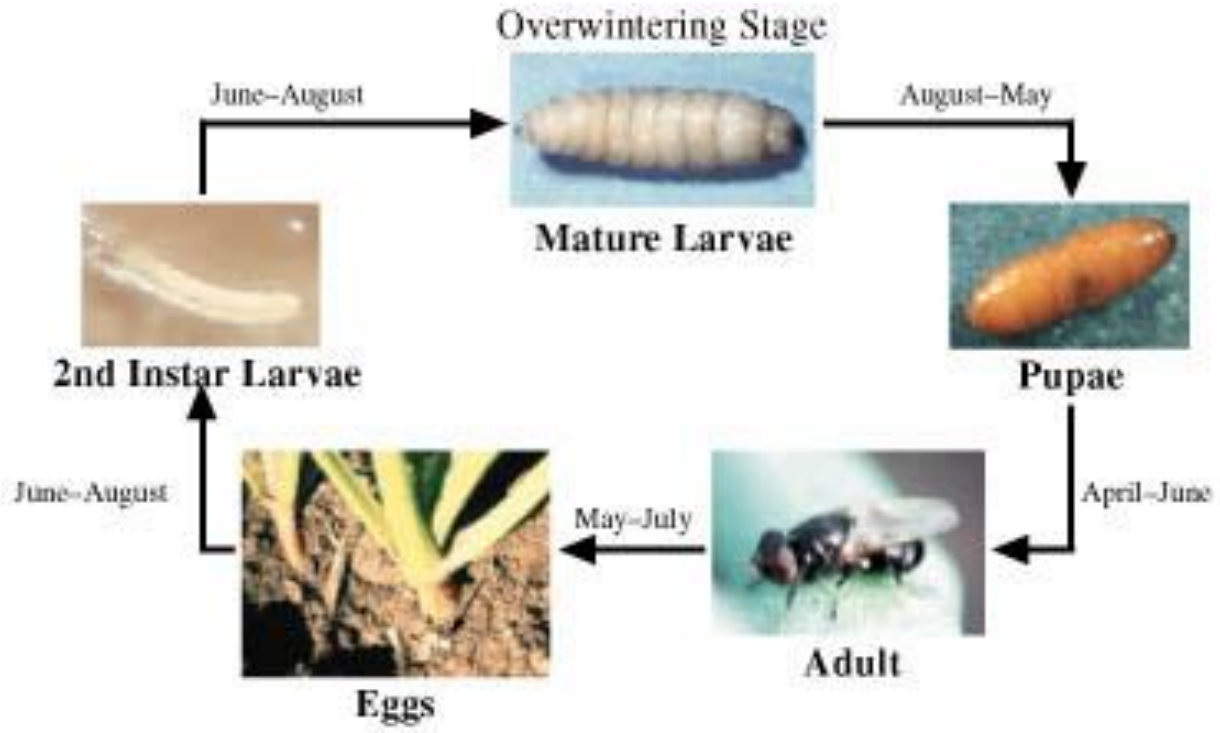
The EPA's revocation of chlorpyrifos residue tolerances has put great risk in the ability to control SBRM. Chlorpyrifos has been the standard product used for postemergence SBRM control and it is the insecticide standard that all potential postemergence insecticides are evaluated against**. Dr. Boetel, sugarbeet entomologist at NDSU, has continually evaluated possible alternative insecticides throughout the years that could provide similar efficacy; unfortunately, there are none that perform as well as chlorpyrifos**.

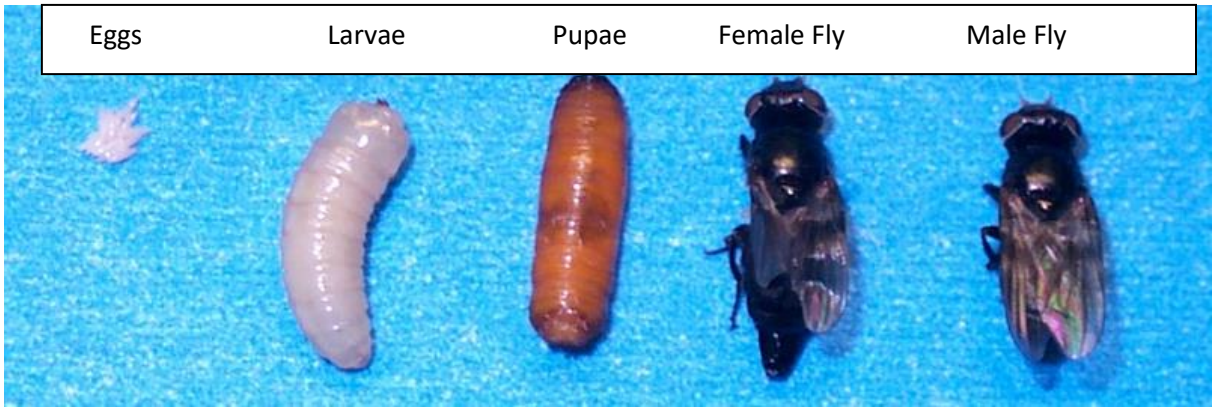
The researched documentation of this is in Dr. Boetel's 2020 and 2021 study evaluating Mustang Maxx against chlorpyrifos (Yuma 4E). This most recent research study reflects the current state of elevated SBRM severity that is being experienced. Referencing Table 1, Mustang Maxx has been identified as the next best postemergence insecticide, but Mustang Maxx clearly does not perform as well as chlorpyrifos. When using Mustang Maxx in place of Chlorpyrifos (Yuma) there was a loss of 70.53% in Net Operating Revenue.

When using (1) effective insecticides (2) at the right time and (3) place for the control of SBRM, resulting sugarbeet production can be on par with that of acres not impacted by SBRM. All three of these components are equally important to achieve this goal. The result of using a less effective postemergence insecticide, such as Mustang Maxx, would be increased losses in sugarbeet production and likely an increase in SBRM fly activity thus accelerating the expansion of their distribution throughout the RRV. This would lead to the pest affecting more acres and further increasing losses in yield and revenue for producers in the region. It not only impacts the current year, but with more surviving larvae the problem will likely continue to grow in severity and acreage affected the next growing season and in future years.

Sugarbeet root maggot life cycle

Sugarbeet root maggot (SBRM) can be devastating to the sugarbeet crop. It is capable of causing reductions in sugarbeet yield and quality, which leads to less recoverable sugar/acre being produced and therefore a loss in revenue. The damage to sugarbeet is caused from SBRM larvae feeding on the sugarbeet roots. To understand how to control SBRM, understanding of its life cycle is required. SBRM flies emerge from the previous year's beet fields in late-May through June. The SBRM flies migrate to the current year's beet fields then mate and lay their eggs next to sugarbeet seedlings. They lay their eggs directly next to the seedling sugarbeet root, so once the eggs hatch the larvae have easy access to feed on the sugarbeet roots. The larvae remain in these fields until the following spring, pupate then emerge from those fields as flies to start the cycle over again in another new sugarbeet field.





Sugarbeet Root Maggot Fly.

Eggs laid by SBRM flies next to sugarbeets.

Sugarbeet Root Maggot Feeding.

Sugarbeet Root Maggot feeding damage.

Pupating Sugarbeet Root Maggot.

Cycle starts over with the Sugarbeet Root Maggot Fly.

Current state of Sugarbeet Root Maggot:
Chlorpyrifos has been the most effective postemergence liquid insecticide available to use in sugarbeet root maggot control, and it has been vitally important as part of the overall SBRM control strategy. On February 28th, 2022, the EPA revoked all residue tolerances. The loss of chlorpyrifos for use in sugarbeets creates a critical void in which only substantially less effective postemergence insecticide options remain, thus creating the potential for accelerated severity and expanded geographic distribution of economically damaging SBRM populations. This will, in turn, likely increase the severity of economic loss in areas affected by the sugarbeet root maggot.

The American Crystal Sugar Company's (ACSC) growing area is in the Red River Valley (RRV) on the borders of North Dakota and Minnesota. American Crystal Sugar Company is a grower owned cooperative in which grower shareholders raise sugarbeets on roughly 413,000 acres each year. In 2021, 149,761 of those acres (36%) were grown in areas affected by sugarbeet root maggot pressure. Those acres are grown by 348 individual farms, or 54% of ACSC's total farms.

In 2021, 181,447 total sugarbeet acres were planted in North Dakota, where 198 North Dakota farmers grew 97,324 acres of sugarbeets in areas identified as being affected by SBRM. The 97,324 sugarbeet acres represents 54% of American Crystal Sugar Company's North Dakota Acres.

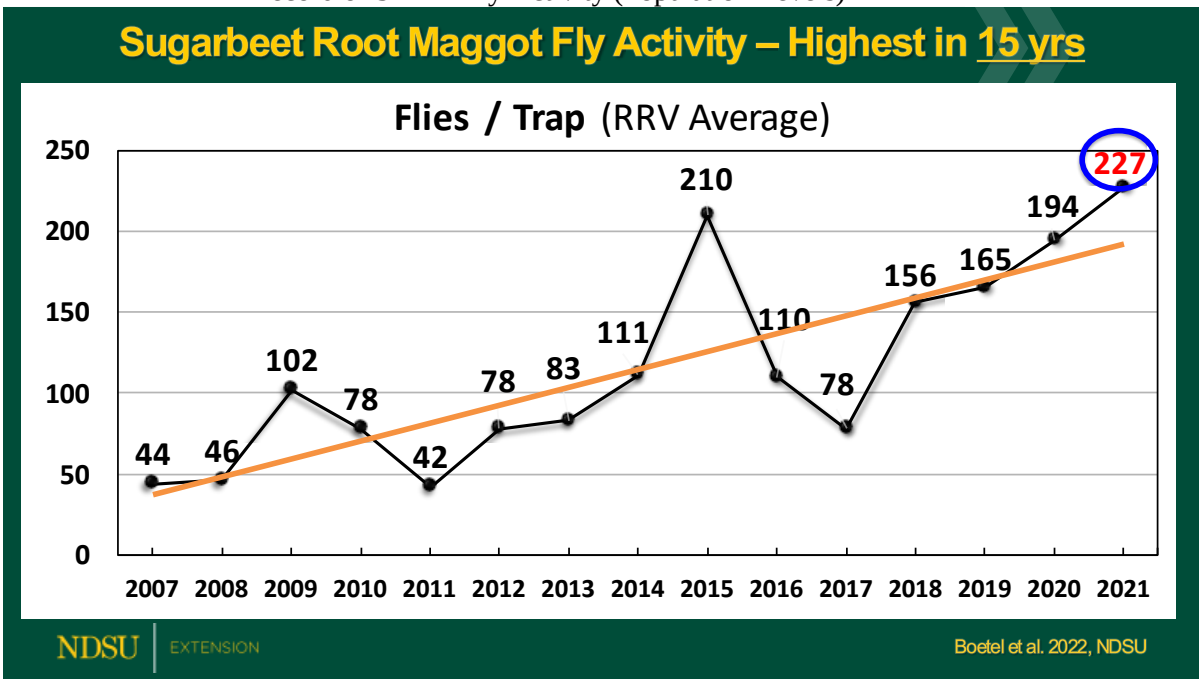
Over the past 5 years, the sugarbeet root maggot footprint has increased at an average rate of about 11,000 acres/year in the RRV.

Table 5: Sugarbeet Acres in SBRM affected areas by year.

	ND & MN Sugarbeet Acres Affected by SBRM based on Severity Maps					
	2016	2017	2018	2019	2020	2021
Acres	86,085	105,805	119,749	133,872	140,354	149,761

In addition to this, population levels have been increasing as well, with 2021 having the highest infestation levels in the last 15 years.

Dr. Boetel's Historical Record of SBRM Fly Activity (Population Levels)

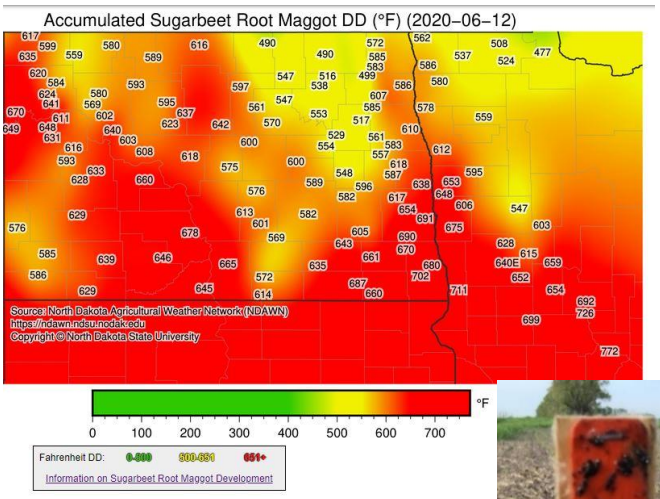


A two-pronged approach is needed to effectively protect the sugarbeet crop from SBRM damage. The first component of this strategy involves applying an effective At-Plant insecticide to protect the root from larval feeding injury; however, at-Plant insecticides are incapable of doing this all on their own due to the common occurrence of overwhelmingly high SBRM larval infestations. Therefore, an effective post emergence insecticide is essential to control the SBRM flies thereby reduce the fly population and minimize mating and egg deposition. This combination of at-plant and postemergence tactics provides the best potential for sufficient SBRM control. Chlorpyrifos has been the most effective insecticide for these postemergence insecticide applications for SBRM fly control.

American Crystal Sugar's Ag Staff is trained in SBRM identification and are Certified Crop Advisors (CCA's) and recommend the use of Chlorpyrifos as a precise, targeted application, only at the right time, right place, and in the right amount. To help us do this, we use tools to help us time insecticide applications in only the locations where the SBRM fly populations warrant their use.

Typically, SBRM fly activity occurs during the first 2-3 weeks in June. North Dakota State University has developed a SBRM Growing Degree Day model that helps predict the timing of SBRM Peak Fly Activity. The model also allows for proper timing of insecticide applications. An application based on the model's algorithm is publicly available on the North Dakota Agricultural Weather network (NDAWN) for producers, agriculturists, and other crop advisors to monitor Degree Day accumulations. It can be viewed at: https://ndawn.ndsu.nodak.edu/sugarbeet-growing-degree-days.html
Peak fly activity occurs around 650 Degree Days for SBRM.

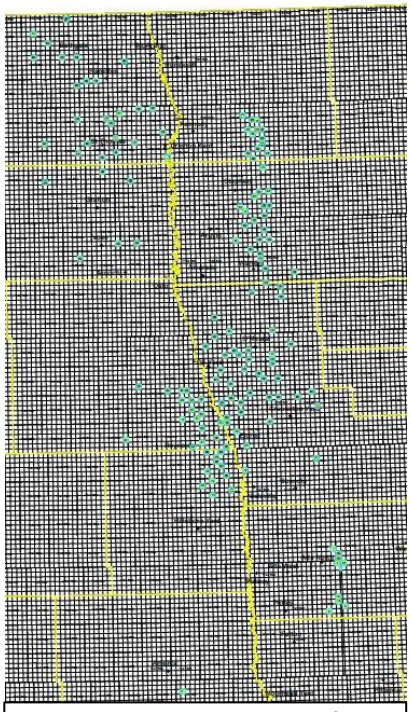
Below is a map from June 12th, 2020 showing SBRM GDD's at that time.



In order to only treat areas that have economically significant SBRM activity with Chlorpyrifos, our ACSC Ag Staff set up monitoring stakes throughout the pest's range. Staff from North Dakota State University does their own stake monitoring as well. In 2021 there were 150 total locations that were monitored every Monday, Wednesday and Friday during the SBRM fly season.

Fly stake counts are used to determine if fly activity is high enough, based on an economic threshold of the number of flies trapped, to justify a postemergence insecticide application. It is recommended to treat sugarbeet fields when fly capture counts reach a daily or cumulative total of 70 flies/stake.

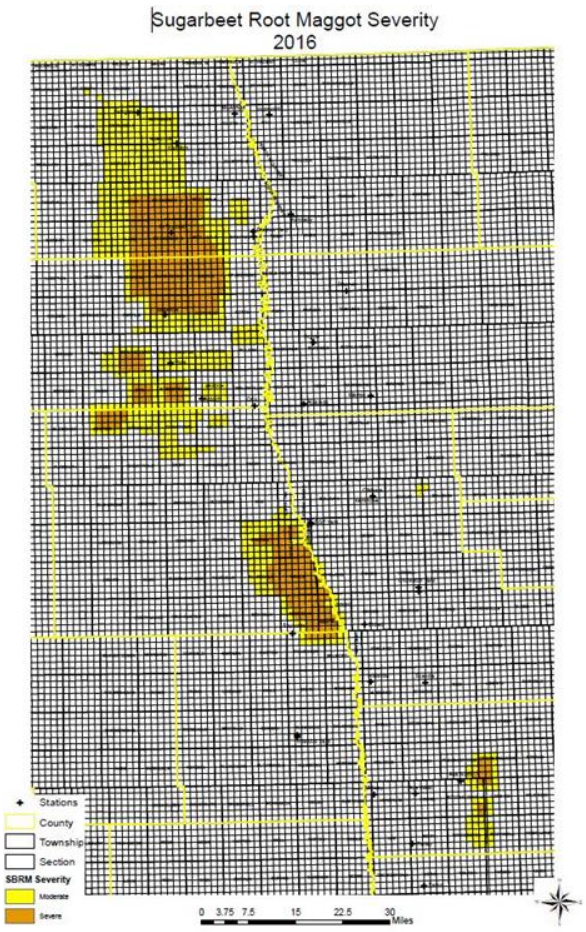
SBRM Monitoring Stake

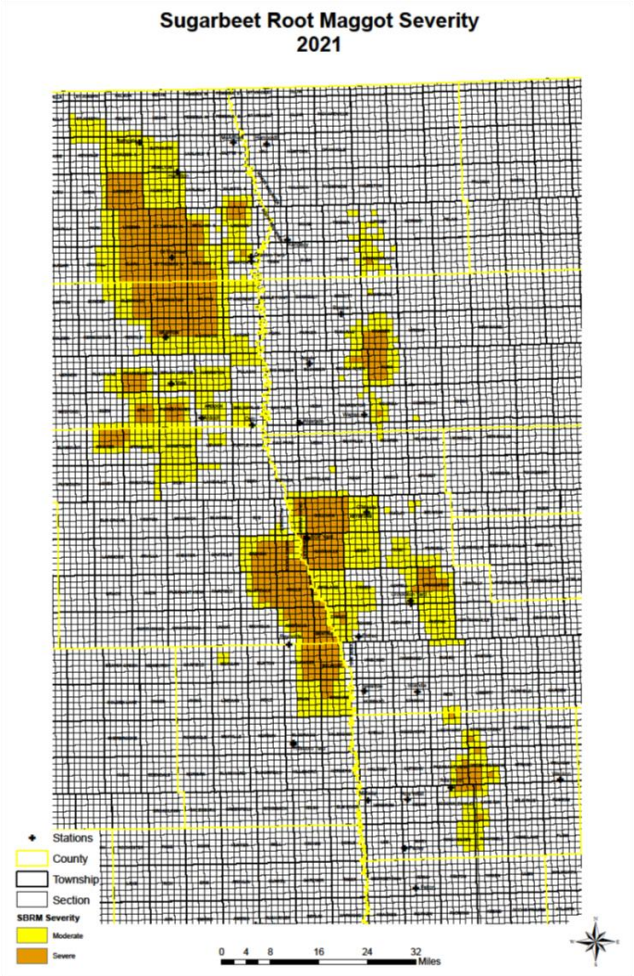


SBRM Monitoring Stake Locations

Through all of this monitoring, our Ag Staff has been able to develop maps of the areas affected with SBRM and their severity. This helps us to dial in where to monitor for the potential need of a postemergence treatment of chlorpyrifos for necessary SBRM control. We are seeing the areas affected by SBRM expanding in recent years as well as increases in the severity of the populations.

The maps below, and attached, illustrate the geographic expansion of the SBRM problem area from 2016 – 2021 as well as increases in population intensity (severe shown in orange). This demonstrates the critical situation growers are facing and underscores the importance of their having access to chlorpyrifos as a control option.





The use of pest management-related decision tools such as the Degree Day model, SBRM population monitoring, and the economic threshold, as well as a lot of time spent in the field, have made insecticide-based SBRM control a very targeted and precise crop management strategy in the RRV growing area.

All of this information is shared with our grower shareholders to educate them on the judicious and effective use of insecticides for SBRM control, and chlorpyrifos has been an integral component of this approach. This is accomplished through multiple educational avenues. Grower Seminars are delivered annually by university Extension specialists, and our own ACSC agricultural staff give presentations at our annual "Your Way To Grow" winter grower shareholder meetings. Additionally, ACSC publishes a periodic newsletter, "Ag Notes", that educates producers on best management practices on a variety of issues, including insect pest control.

One-on-one conversations between Agriculturists and growers occur throughout the year, and these conversations become more frequent as SBRM populations start to appear and decisions need to be made on whether there is a need to make a post emergence insecticide application as well as its proper timing and in the location where it is justified.

DISCUSSION OF ECONOMIC LOSS

The EPA's revocation of chlorpyrifos residue tolerances has put sugarbeet producers at great risk relating to their ability to control the SBRM. Chlorpyrifos has been the standard and most effective product used for postemergence SBRM control and it is the insecticide that all potential postemergence insecticides are evaluated against**. For much of the past two decades, Dr. Boetel, NDSU sugarbeet entomologist, has been pursuing possible alternative insecticides and other potential control tactics that could provide similar efficacy, unfortunately there are none that perform as well as chlorpyrifos.**

This was demonstrated in Dr. Boetel's most recent research study, Dual Applications of Mustang Maxx for SBRM Control 2020-2021, reflecting the current state of elevated SBRM severity that is being experienced. Mustang Maxx has been identified as the next best postemergence insecticide, but Mustang Maxx clearly does not perform as well as chlorpyrifos. Referencing Table 1, when using Mustang Maxx in place of Chlorpyrifos there was a loss of: 16.93% in recoverable sugar/acre (RSA); 19.18% in yield (tons/acre); 14.41% in gross revenue/acre, and **70.53% in Net Operating Revenue**.

In applying Dr. Boetel's recent research data from this 2020-2021 study, it is estimated that there will be aggregate unrecoverable losses of approximately $39,299,642 in North Dakota in 2022 for ACSC's grower members if those growers are not permitted to use chlorpyrifos. This estimate is based upon the 104,000 North Dakota acres expected to be affected by sugarbeet root maggot in 2022 and using the next best alternative (Mustang Maxx) in place of chlorpyrifos. In Dr. Boetel's research, there would be a reduction of 1,565 lbs. of sugar/acre produced, which would involve revenue losses of $201/acre. The 1,565 lbs. of sugar/acre lost applied to the 104,000 acres results in 162,760,000 lbs. of sugar lost in SBRM affected areas. Taking the $201/acre lost multiplied by 104,000 acres equates to $20,904,000 in losses in North Dakota SBRM areas.

To make up for the lost sugar production associated with those affected acres, would equate to an additional 16,573 acres of sugarbeets be produced. This is based on ACSC's 5-year average of recoverable sugar produced/acre (9,821 lbs. of sugar/acre). Dividing the 162,760,000 of lost sugar by 9,821 lbs. of sugar/acre results in 16,573 acres. The cost of sugarbeet production/acre is estimated at $1,110/acre from the 2021 Crop Enterprise Analysis done by Minnesota and North Dakota Farm Business Management Education program. One can assume that with recent inflation that this has increased for the 2022 crop year production costs. Applying $1,110/acre in production costs to the additional 16,573 acres results in $18,395,642 of additional production costs to replace the sugar that would be lost.

Combining the previously stated $20,904,000 of total lost revenue and the $18,395,642 in additional total production costs, brings the total in losses to $39,299,642 caused by not having chlorpyrifos as an option for sugarbeet root maggot control in sugarbeets. This is a one-year loss (2022) and will be replicated (and likely increase) in each subsequent crop year due to the use of less effective alternative insecticides.

In addition to the grower losses described above, there is reason to think ACSC would likely incur additional postharvest losses during crop storage, because damaged sugarbeet roots piled with undamaged roots can lead to the development of hotspots within storage piles thereby causing undamaged sugarbeets to store poorly and even rot during storage. It should be noted that these losses could also occur every year and, as sugarbeet root maggot incidence increases, the losses would likely increase exponentially.

On November 18th, 2020, the EPA released the "Revised Benefits of Agricultural Uses of Chlorpyrifos". This document covered sugarbeets and acknowledged the elevated pressure in the Minnesota and North Dakota growing region. In this document it is stated that they estimate yield losses of 45% from poor control.

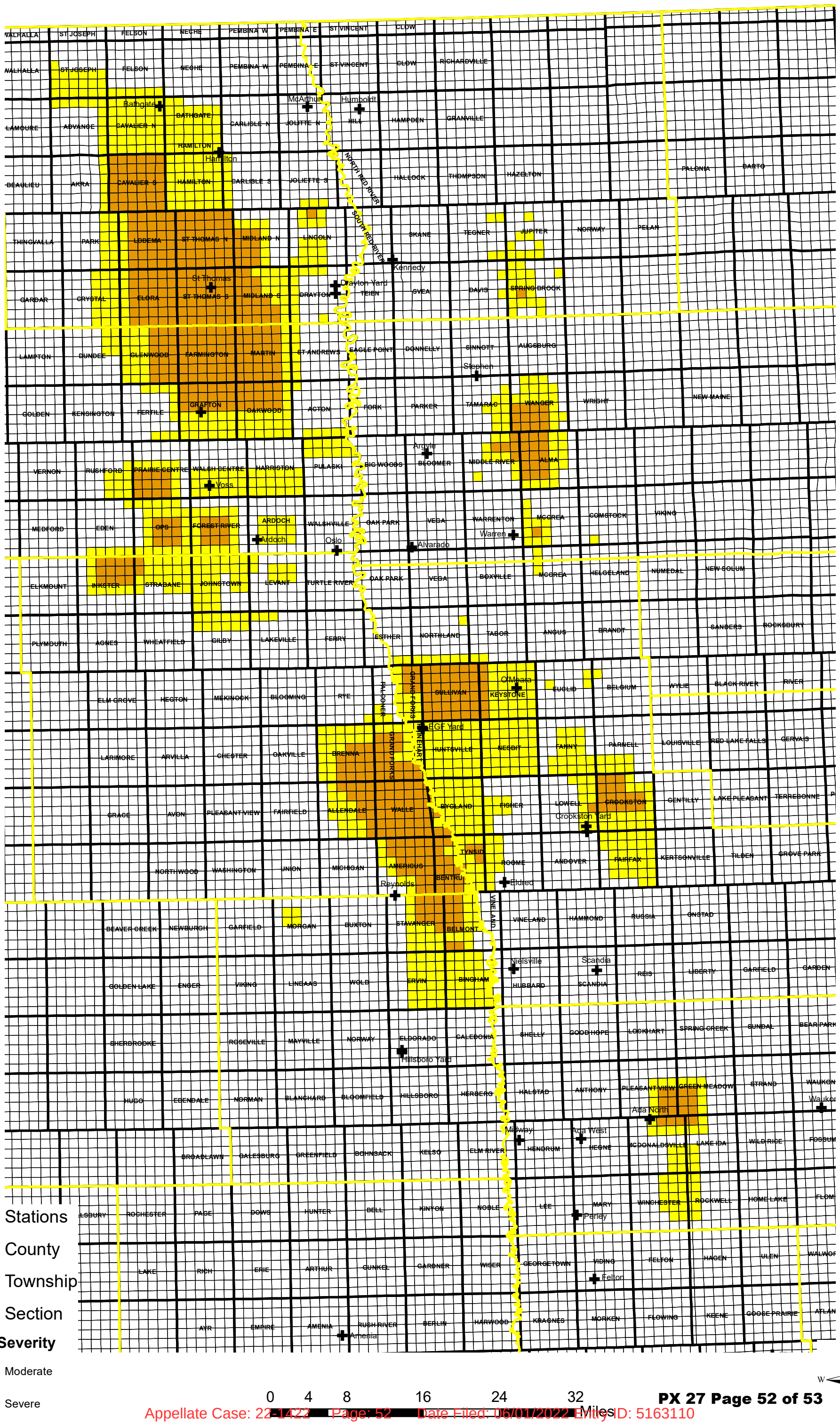
2020 Chlorpyrifos Agricultural Benefits EPA
https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969
pages 48-49.

In EPA's December 2020 Chlorpyrifos Proposed Interim Registration Review Decision, it recognized chlorpyrifos use for sugar beets as a high-benefit agricultural use that the agency has determined will not pose potential risks or concerns with an FQPA safety factor of 10X. The document went on to state that sugar beets had a potentially very high per acre benefits of almost $500 per acre in parts of Minnesota and North Dakota, leading to high-end estimated benefits of over $30 million overall.

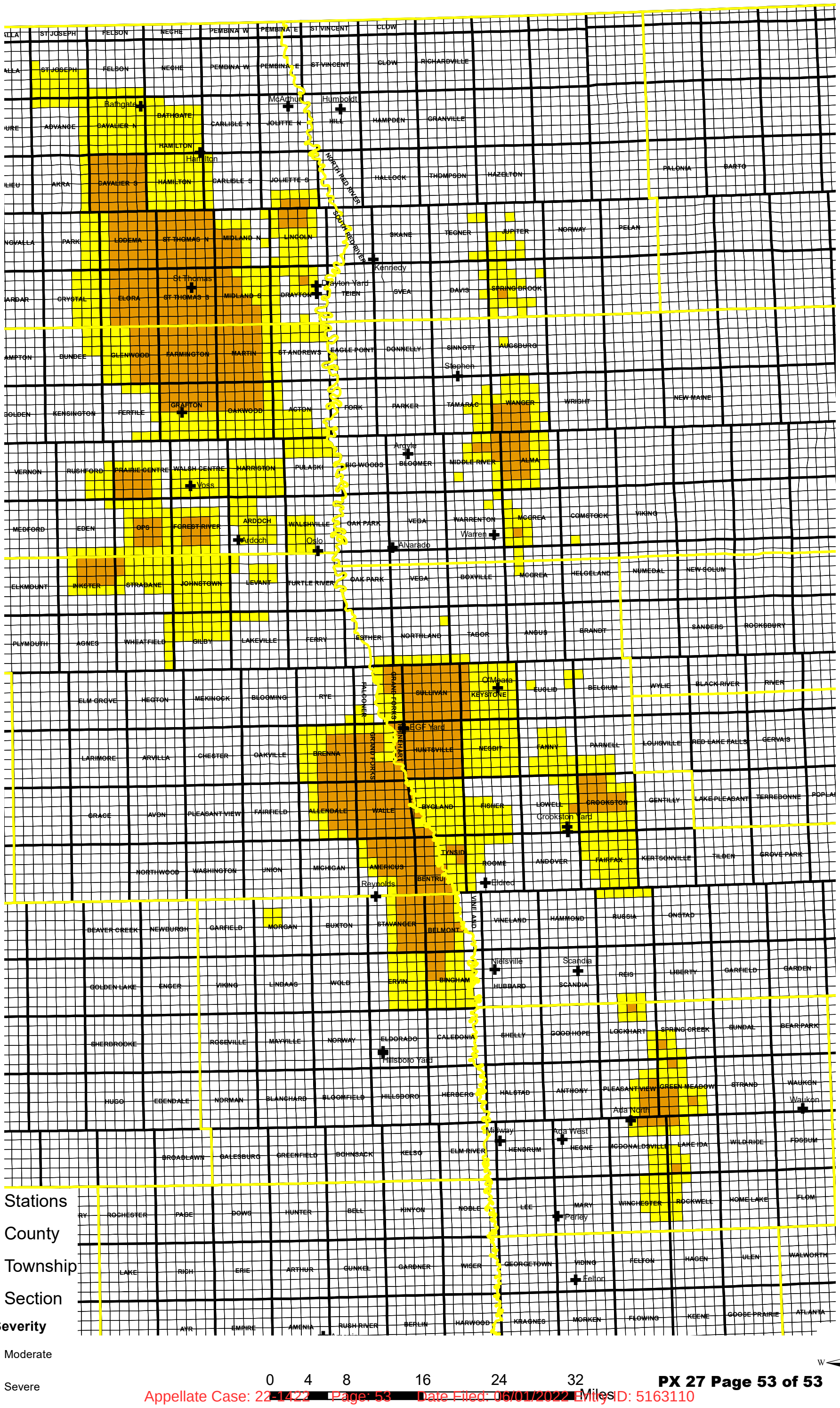
Chlorpyrifos Proposed Interim Decision
https://www.epa.gov/sites/default/files/2020-12/documents/chlorpyrifos_pid_signed_120320.pdf
pages 41-42.

The information contained in this document and its attachments makes clear the need for chlorpyrifos to control sugarbeet root maggot in sugarbeets.

Sugarbeet Root Maggot Severity
2020



Sugarbeet Root Maggot Severity
2021



Nos. 22-1422, 22-1530

In the United States Court of Appeals
For the Eighth Circuit

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, *et al.*,
Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

On Petition for Review from the U.S. Environmental Protection Agency

BRIEF FOR THE STATE OF MISSOURI AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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STATEMENT OF THE *AMICI CURIAE*'S INTEREST

The Attorney General of Missouri is Missouri's chief legal officer and has the authority to file briefs on behalf of Missouri pursuant to Federal Rule of Appellate Procedure Rule 29(a)(2). *See* Mo. Rev. Stat. § 27.060.

Missouri has a $93.7 billion agriculture industry.[1] Agriculture employs nearly 460,000 Missourians and covers 27.8 million acres of farmland. Missouri grows 290.5 million bushels of soybeans and 684,000 bales of cotton per year, making it the sixth largest producer of those crops. *Id.* In 2017, Missouri exported $1.4 billion in soybeans across the globe. [2] In 2021, Missouri shipped more than $3.1 billion in agricultural exports, including more than $600 million in soybeans and soybean meal.[3] .

Controlling pests is vital to agriculture. Chlorpyrifos has been registered for use in the United States since 1965. Add. 6. It successfully

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[1] Missouri Department of Agriculture, *Missouri agriculture at a glance*, available at https://agriculture.mo.gov/abd/intmkt/pdf/missouriag.pdf.
[2] Office of the United States Trade Representative, *State Benefits of Trade*: *Missouri*, available at https://ustr.gov/map/state-benefits/mo.
[3] Missouri Department of Agriculture, *Domestic & International Marketing Program*, Table Missouri's Top 10 Agricultural Exports, available at https://agriculture.mo.gov/abd/intmkt/.

protects a wide variety of crops against a host of insects and is cost-effective for farmers. *See, e.g.*, American Farm Bureau Federation Letter, EPQ-HQ-OPP-2015-0653-0581 (Jan. 14, 2017) ("Chlorpyrifos is effective in treating a number of Arthropod pests in soybeans, including soybean aphid, bean leaf beetle, caterpillars, grasshoppers, leafhopper, two-spotted mites and others."). Due to its success, chlorpyrifos was used for a variety of agricultural and other uses. *Id.* (stating U.S. Department of Agriculture recognized that chlorpyrifos had been part of pest management "for approximately 50 years and is used to control a wide array of primary and secondary pests in over 75 cropping systems"); Add. 6.

Missouri has a vital interest in protecting its citizens' livelihoods and their food security. Revoking all tolerances, as EPA did in the Final Rule, threatens both. As detailed by *Amici* to the Ninth Circuit case, chlorpyrifos is a leading product because in some uses, like wheat, there are "no other choices of reliable and effective products," and it prevents significant yield losses, including "up to a 40% yield loss in the Midwest" for soybeans among other uses. *Brief of Agribusiness Council of Indiana, et. al*, Nos. 19-71979 & 19-71982, *League of United Latin American*

Citizens v. Regan, Part II.A (9th Cir. Mar. 6, 2020).[4] Recent events have shown that the world's food security is more precarious than ever before. Ana Swanson, *Ukraine Invasion Threatens Global Wheat Supply*, New York Times (updated Mar. 23, 2022)[5] ("Russia and Ukraine together export more than a quarter of the world's wheat, feeding billions of people in the form of bread, pasta and packaged foods."). EPA's action poses real danger and causes even greater uncertainty in a wide array of agriculture products.

[4] Also filed in this case as Exhibit 1 to the Goldman Declaration (filed Mar. 14, 2022).

[5] *Available at* https://www.nytimes.com/2022/02/24/business/ukraine-russia-wheat-prices.html.

SUMMARY OF ARGUMENT

In 2006, EPA approved the tolerances and registrations revoked by the Final Rule, concluding that "the existing tolerances were safe and that chlorpyrifos continued to meet the FIFRA standard for registration." Add. 6. A year later, a group of non-profits petitioned EPA to undo that finding and revoke all current tolerances and cancel all registrations because the "scientific evidence now available showed that the current chlorpyrifos tolerances were not safe, especially for infants and children; indeed, they argued, 'no safe level of early-life exposure to chlorpyrifos can be supported.'" *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 682 (9th Cir. 2021). After a more than a decade of EPA reviews and orders, the scientific answer to whether the tolerances for chlorpyrifos are safe remained unclear. In 2017, the EPA denied the petition and in 2019, the EPA denied the petition after remand from the Ninth Circuit reiterating that more scientific certainty was needed to make any decision and that the 2007 petition failed to provide "reliable evidence sufficient to meet [its] burden." *Id.* at 690. The Ninth Circuit disagreed with EPA's refusal to make a safety finding on that petition,

and remanded with instructions to either revoke or modify the tolerances. *Id.* at 703.

EPA chose the path of least judicial resistance and revoked all tolerances and cancelled all relevant registrations. In doing so, EPA failed to make any finding—either that the tolerances for any food were unsafe or safe. Add. 3 ("EPA cannot make a safety finding … . EPA cannot determine that there is a reasonable certainty that no harm will result from aggregate exposure to residues."). This is contrary to the statutory text that requires EPA to make a finding. 21 U.S.C. § 346a(b)(2)(A). The Final Rule repeats the error that the Ninth Circuit identified: "refusing to make a safety finding." *LULAC*, 996 F.3d at 697. The statute explicitly requires EPA to determine a tolerance is "not safe" in order to revoke it. Without an individual determination either way, EPA cannot revoke all tolerances.

Importantly, EPA did not determine that all tolerances were unsafe because it did not reject or amend its 2020 Proposed Interim Decision (PID) that eleven high-benefit crop tolerances would be safe. *See* Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020). EPA rejected claims that it could have retained those uses by stating that it did not want to

be in the position of "picking 'winners and losers'" and that it cannot retain specific tolerances "until aggregate exposures have been reduced to acceptable levels." Add. 47. But EPA did not determine aggregate exposure once the number of tolerances reduced from 80 to 11. *Id.* Without finding that all uses are unsafe, EPA should not be allowed to revoke admittedly safe uses. EPA's all or nothing approach revoking all tolerances cannot be justified in light of the agency's failure to make a finding that no tolerance is safe.

EPA's Final Rule does not comport with its statutory obligations to make a finding and act consistent with Congress' directions. For this and all the reasons stated by Petitioners, the Court should vacate the Denial Order and Final Rule.

ARGUMENT

I. The FFDCA's text and structure require that EPA make a safety determination for each tolerance, and EPA's failure to do so is arbitrary and capricious.

Congress clearly requires EPA to make a safety finding when exercising its power to establish, leave in effect, modify, or revoke a tolerance for a pesticide chemical residue. 21 U.S.C. § 346a(b)(2)(A). All congressionally prescribed actions require "the Administrator [to]

determine[] that the tolerance is safe" or "it is not safe." *Id.* To the extent there is uncertainty based on all anticipated dietary exposures and exposures based on "reliable information," the statute requires EPA to determine a safe tolerance. The Final Rule does not do any of the foregoing, and revokes all tolerances, even those tolerances it determined would be safe. *See* Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020).

In response to a petition, EPA may only establish, modify, or revoke a tolerance for a pesticide "in or on a food" and may not "modify" the tolerance by "expanding the tolerance to cover additional foods." 21 U.S.C. § 346a(b)(1). EPA is constrained by the FFDCA to reviewing each tolerance for each food. If a petitioner wishes to add a tolerance to a food, EPA may "establish" another tolerance, but EPA may only "modify" a tolerance with respect to approved tolerances for a specific food. The FFDCA petition provisions require a tolerance-by-tolerance approach.

The FFDCA states what happens when a determination is made—and it does not leave EPA discretion to fail to make that finding, as EPA's power flows from that determination. EPA found it could not make a safety finding to support the current tolerances, Add. 3, but it similarly

did not determine that the current tolerances were unsafe. It only noted it could not determine that no harm would arise from aggregate exposures to currently registered tolerances. *Id.*

In response to Petitioners' objections, EPA stated that it is required to assess the safety of tolerances in the aggregate, thus once "one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels." Add. 47. By EPA's lights, any finding that an aggregate exposure is unsafe permits EPA to revoke all tolerances, even those that the petition does not challenge. Aside from the due process concerns that would arise by revoking tolerances not at issue in a particular petition, this reasoning runs afoul of the statutory text that focuses on individual tolerances, strengthened by the statutory term "modify."[6]

It is generally accepted that "'to modify' means to change moderately or in minor fashion." *MCI Telecommunications Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994) (collecting dictionary

[6] This structural inference is further buttressed by the extensive registration process and requirements of FIFRA. *See* Petitioners' Br. 48-55 (arguing how FFDCAA should harmonize with FIFRA registration).

definitions). The statute's express prohibition on modifying a tolerance to include other foods supports the common understanding that "modify" means an incremental change. The statute's standard similarly differentiates between "modify" and "revoke," indicating a lesser action that can be taken if EPA finds a specific tolerance to be unsafe. 21 U.S.C. § 346a(b)(2)(A); *see also Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017) (courts should give "each word its 'ordinary, contemporary, common meaning'"). Determining that a tolerance will result in harm from the aggregate exposure does not require revoking all tolerances—as EPA suggests. Indeed, under that approach EPA would never be able to "modify" or incrementally change a tolerance—every tolerance would lead to widespread revocation. Instead, EPA is limited to determining whether the individual tolerance will result in harm when included with the aggregate exposure to the pesticide chemical residue and then deciding to modify or revoke that tolerance.

EPA's revocation of all tolerances is arbitrary and capricious because it had previously found eleven high benefit use tolerances that would be safe. EPA acknowledged that these represented a subset of registered uses and that additional assessments would be needed. Add.

56. EPA rejected retaining these uses, because "it was not a complete and full assessment of the approved uses of chlorpyrifos." *Id.* Yet, in revoking all other uses, EPA's reason holds no force because the safe subset of uses would have been the universe of tolerances. Moreover, EPA's own findings show that there are tolerances at which chlorpyrifos are safe for food products—but instead of permitting those safe uses to continue, EPA has forced a disruptive change that endangers agricultural yields that are critical to Missouri's economy.

The Court cannot allow EPA to give short shrift to its statutory duties because it unduly delayed action on the previous petition for thirteen years. EPA should follow its statutory obligations and make the required finding for each individual tolerance while harmonizing its actions with its previous findings made during the FIFRA registration process.

CONCLUSION

This Court should grant the Petition and all relief requested by the Petitioners.

Dated: May 31, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this motion complies with the typeface and formatting requirements of Fed. R. App. P. 29 and 32, and that it contains 1,850 words as determined by the word-count feature of Microsoft Word. The brief has been scanned for viruses and is virus free. */s/ Jeff P. Johnson*

CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the CM/ECF system, and I will serve a copy of the foregoing on all participants in the case who are not registered CM/ECF users by mailing a copy of the same, first-class, postage paid, to the address listed on the Court's CM/ECF system.

/s/ Jeff P. Johnson

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1503

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

Petition for Review of Actions of the U.S. Environmental Protection Agency

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BRIEF OF RESPONDENTS

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GLOSSARY

APA	Administrative Procedure Act
EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

INTRODUCTION

Congress tasked EPA with establishing "tolerances," which allow maximum levels of pesticide residues in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. Under the FFDCA, EPA may establish or leave in place a tolerance for a pesticide *only* if it determines that the tolerance is "safe," and must revoke or modify an existing tolerance if EPA determines that the tolerance is not "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. "Safe" means a "reasonable certainty that no harm will result from aggregate exposure," including all anticipated dietary exposures. *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. The FFDCA's safety standard is strictly safety-based: EPA may not consider any other factors, such as economic costs or benefits, in determining whether tolerances are safe, and whether tolerances are "safe" is the exclusive basis for revoking, modifying, or setting tolerances.

In 2007, public interest groups petitioned EPA to revoke all chlorpyrifos tolerances based on neurodevelopmental impacts to infants and children, among other things. After years of administrative process and court rulings in response to the petition, the U.S. Court of Appeals for the Ninth Circuit concluded in 2021 that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 700–01 (9th Cir.

2021) (*"LULAC II"*). The Ninth Circuit chided EPA for "expos[ing] a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 702. The Court ordered EPA to, within 60 days, revoke all chlorpyrifos unless EPA could find by that time, based on the evidence regarding aggregate exposure to chlorpyrifos, that modified tolerances would be safe. *Id.* at 703.

On August 30, 2021, EPA promulgated a final rule revoking all chlorpyrifos tolerances. Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315 (Aug. 30, 2021) ("Final Rule"), AR 1, Pet'rs' Add. 1; *see also* Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222 (Feb. 28, 2022) ("Denial Order"), Pet'rs' Add. at 23. EPA determined that it could not make the safety finding necessary to leave in place the current tolerances for residues of chlorpyrifos because the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Specifically, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. In addition, there are laboratory studies and epidemiological data studying chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* Adhering to the

FFDCA's strict safety standard and the Ninth Circuit's mandate, EPA revoked all chlorpyrifos tolerances. AR 1 at 48316, Pet'rs' Add. at 2. Petitioners now ask this Court to do what both Congress and the Ninth Circuit forbade: leave *all* chlorpyrifos tolerances in place, even though the expert agency has concluded that they are not safe.

STATEMENT OF JURISDICTION

Petitioners have filed three petitions for review regarding EPA's revocation of chlorpyrifos tolerances. The Court dismissed Petitioners' first petition for lack of jurisdiction. *Red River Valley Sugarbeet Growers Ass'n v. Regan,* No. 22-1294, Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661. The Court has jurisdiction over the consolidated second and third petitions challenging EPA's Final Rule and Denial Order under FFDCA Section 408(h)(1). 21 U.S.C. § 346a(h)(1), Resp'ts' Add. at 12.

STATEMENT REGARDING ORAL ARGUMENT

Respondents agree with Petitioners that oral argument is appropriate and would be helpful to the Court. This case involves the application of important provisions of the FFDCA administered by EPA.

STATEMENT OF THE ISSUE

The Ninth Circuit ordered EPA to "immediately" revoke all chlorpyrifos tolerances unless the Agency could find, based on evidence available at that time, that modified tolerances were reasonably certain to avert harm from aggregate exposure to chlorpyrifos. EPA revoked all tolerances after determining that it could not make that finding. Was EPA's determination non-arbitrary and consistent with the FFDCA's strict-safety standard?

STATEMENT OF THE CASE

A. Statutory and regulatory background

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, Resp'ts' Add. at 1, and FIFRA, 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, EPA establishes "tolerances," which are rules establishing the maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. As originally enacted, the FFDCA instructed EPA to set tolerances that are "safe for use, to the extent necessary to protect the public health" while giving appropriate consideration to "the necessity for production of an adequate, wholesome, and economical food supply" and "the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture." H.R. Rep. No. 104-669, pt. 2 at 40 (1996). With the passage of the

Food Quality Protection Act ("FQPA") in 1996, Congress replaced that standard with a pure safety standard. *See id.* As amended, the FFDCA permits EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). EPA "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* Thus, under current law, "FFDCA review is limited to the sole issue of safety" and "explicitly prohibit[s] the EPA from balancing safety against other considerations, including economic or policy concerns." *LULAC II,* 996 F.3d at 696.

"Safe" under the FFDCA means a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. Congress understood "aggregate exposure" to include "all dietary exposures." H.R. Rep. 104–669, pt. 2, at 40 (1996). In another provision of the FFDCA describing "aggregate exposure," Congress required EPA to consider "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue . . . , including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources." 21 U.S.C. § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5. Additionally, infants

and children are given special consideration: EPA must assess the risk of the pesticide residues to infants and children utilizing a presumptive tenfold (10X) margin of safety for threshold effects (the "FQPA safety factor"), unless "reliable data" shows that a lower margin will be safe. 21 U.S.C. § 346a(b)(2)(C), Resp'ts' Add. at 4-5.

Under Section 408(*l*), EPA is to coordinate the revocation of a tolerance with any related necessary action under FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. While EPA may establish, modify, or revoke tolerances under the FFDCA, it cannot require changes to pesticide registrations (like geographic or application restrictions) under the FFDCA.

2. The Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA requires EPA approval of pesticides prior to distribution or sale and establishes a registration regime to regulate their use. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). In contrast to the FFDCA's risk-only safety standard, FIFRA's "unreasonable adverse effects" standard means "any unreasonable risk to man or the environment," taking into consideration both risks and benefits of the pesticide. *Id.* § 136(bb).

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years, starting in 2006. *Id.* § 136a(g)(1)(A). During "registration review," EPA assesses all pesticide product registrations containing an active ingredient and must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account new scientific information and changes to risk-assessment procedures, methods, and data requirements. 40 C.F.R. §§ 155.40(c)(1), 155.53(a); 7 U.S.C. § 136a(g). EPA may propose measures to mitigate identified risks, including label or registration changes, in a proposed decision or proposed interim decision. *See* 40 C.F.R. §§ 155.56, 155.58(a)-(b). EPA may issue a final interim decision. *See id.* § 155.56. In addition, or instead of, a final interim decision, EPA will issue a proposed final decision. *Id.* EPA must issue a final registration review decision to conclude registration review. *See id.*

FIFRA registrations function as product-specific licenses. *See* 7 U.S.C. § 136a(a), (c)-(e). Registrants may submit a request to modify a pesticide registration, including labeling, under FIFRA. *See* 40 C.F.R. § 152.44. Registrants may submit requests to voluntarily cancel their pesticide registrations or terminate certain registered uses under 7 U.S.C. § 136d(f), or EPA may initiate cancellation proceedings under § 136d(b). The procedures for voluntary and involuntary cancellation differ dramatically. If a registrant wishes to voluntarily

cancel its registration or terminate a specific use, it may do so at any time by submitting a request to EPA, which following publication in the Federal Register for public comment, the Agency may approve or deny. 7 U.S.C. § 136d(f)(1). By contrast, if EPA initiates cancellation proceedings, it must first provide a draft Notice of Intent to Cancel to the Secretary of Agriculture and the FIFRA Scientific Advisory Panel at least 60 days before publishing the final Notice in the Federal Register. 7 U.S.C. §§ 136d(b), 136w(d).[1] Any person adversely affected by the notice may request a hearing before an Administrative Law Judge. 7 U.S.C. §§ 136d(b). The Administrative Law Judge's decision may be appealed to the Environmental Appeals Board. 40 C.F.R. § 164.101. Registrants and other interested persons may seek judicial review of a final cancellation order within 60 days. 7 U.S.C. § 136n(b).

B. Factual background

1. 2007 petition to revoke all tolerances

Chlorpyrifos is a broad-spectrum insecticide and miticide registered for use on over 50 different food crops as well as in non-food settings, including turf. AR 40 at 11. In the 2006 Reregistration Eligibility Determination for chlorpyrifos,

[1] EPA may also issue a notice of intent to hold a hearing on cancellation instead of publishing a Notice of Intent to Cancel. 7 U.S.C. § 136d(b).

EPA determined that chlorpyrifos tolerances were safe.[2] AR 33, Resp'ts' App. at 80.

In 2007, the Pesticide Action Network North America ("PANNA") and the Natural Resources Defense Council ("NRDC") filed a Petition to Revoke all Tolerances and Cancel All Registrations for Chlorpyrifos under 21 U.S.C. § 346a(d)(1)(A) (the "2007 Petition to Revoke"). AR 1 at 48318, Pet'rs' Add. at 4. Among other things, the petition argued that chlorpyrifos causes adverse neurodevelopmental effects in children. AR 1 at 48318–19, Pet'rs' Add. at 4-5. EPA believed that these neurodevelopmental claims raised important concerns and warranted further consideration in registration review, which EPA initiated in 2009. 87 Fed. Reg. at 11235, Pet'rs' Add. at 36. In the years that followed, EPA convened multiple meetings with the FIFRA Scientific Advisory Panel, and published multiple Human Health Risk Assessments, all of which analyzed these neurodevelopmental claims. AR 1 at 48320–22, Pet'rs' Add. at 6-8.

Dissatisfied with the pace of EPA's review, PANNA and NRDC filed a petition for mandamus in 2012, seeking an order requiring EPA to respond to the 2007 Petition to Revoke. The court denied the petition without prejudice, noting that EPA intended to issue a final response by February 2014. *In re Pesticide*

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[2] EPA issued decision documents called REDs for registered pesticides as part of the pesticide review program that predated registration review. *See* 7 U.S.C. 136a-1.

Action Network N. Am., 532 Fed. Appx. 649, 650–52 (9th Cir. 2013). After EPA failed to meet its self-imposed deadline, PANNA and NRDC filed a second petition. *In re Pesticide Action Network N. Am.*, 798 F.3d 809 (9th Cir. 2015). In that case, EPA told the court that due to its concerns about drinking water contamination, the Agency planned to issue a rule by April 2016 revoking all tolerances. *Id*. at 812–13. The Ninth Circuit granted the mandamus petition and directed EPA to issue, by October 31, 2015, either a proposed or final revocation rule or a full and final response to the 2007 Petition to Revoke. *Id*. at 811, 815. EPA published a rule proposing to revoke all tolerances. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (Nov. 6, 2015), Pet'rs' App. at 995. EPA's proposed revocation was based on a determination that drinking water concentrations of chlorpyrifos in some watersheds would exceed exposure levels that EPA considered "safe." *Id*. at 69083, Pet'rs' App. at 998.

The Ninth Circuit then ordered EPA to take final action on the proposed revocation rule by December 30, 2016. *In re Pesticide Action Network N. Am.*, 808 F.3d 402 (9th Cir. 2015). In 2016, EPA developed a revised Human Health Risk Assessment, which it released for public comment as additional support for the 2015 proposal.[3] To incorporate those additional comments, EPA sought a six-

[3] 2015 Proposed Rule. Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81049 (Nov. 17, 2016).

month extension of the December 30, 2016 deadline to issue a final response to the 2007 Petition to Revoke. *In re Pesticide Action Network N. Am.*, 840 F.3d 1014 (9th Cir. 2016). The court characterized EPA's request as "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action' that has been repeated for the past nine years." *Id.* at 1015 (quoting *In re Pesticide Action Network*, 798 F.3d at 811). The court ordered EPA to take final action by March 31, 2017. *Id*. Instead of finalizing the 2015 proposal, EPA subsequently denied the 2007 Petition to Revoke on the ground that the science concerning adverse neurodevelopmental effects remained uncertain and EPA would address those issues as part of its FIFRA registration review process. Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16581, 16583 (April 5, 2017).

Several states and organizations filed objections to this denial pursuant to FFDCA § 408(g), 21 U.S.C. § 346a(g), Resp'ts' Add. at 11-12. Many of them also sought relief in the Ninth Circuit without awaiting EPA's decision on their objections. *League of United Latin Am. Citizens v. Wheeler,* 899 F.3d 814 (9th Cir. 2018). A Ninth Circuit panel ordered EPA to revoke all chlorpyrifos tolerances. *Id*. at 829. On rehearing, the court vacated the panel's opinion and ordered EPA to issue a final order responding to the objections. *League of United Latin Am. Citizens v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc). EPA

denied all objections in July 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555 (July 24, 2019). Petitions were filed challenging this denial order, which were referred to the same panel. *League of United Latin Am. Citizens v. Wheeler*, 940 F.3d 1126, 1127 (9th Cir. 2019).

2. EPA's 2020 Proposed Interim Registration Review Decision for Chlorpyrifos

Concurrent with its consideration of the petition under the FFDCA, EPA continued its FIFRA registration review. In December 2020, EPA released the Proposed Interim Registration Review Decision ("PID") for Chlorpyrifos pursuant to FIFRA. *See* AR 40, Pet'rs' App. at 366. The PID proposed to conclude that aggregate exposure (including exposures in food, drinking water, and residential settings) from all currently-registered uses of chlorpyrifos was unsafe. *Id.* at 19, Pet'rs' App. at 384. To reduce aggregate exposures to safe levels, under the FQPA's 10X safety factor, EPA proposed that uses of chlorpyrifos be limited to applications for eleven "high-benefit" uses in limited geographic areas: alfalfa, apple, asparagus, cherry (tart), citrus, cotton, peach, soybean, strawberry, sugar beet, wheat (spring and winter).[4] *Id.* at 40–41, Pet'rs' App. at 405–06. The proposal for retention of those uses also relied on application rate reductions

[4] These specific uses were identified as critical by a registrant or as high-benefit to growers by EPA. 87 Fed. Reg. at 11255, Pet'rs' Add. at 56.

consistent with rates that were assessed in EPA's 2020 drinking water assessment. *Id*. at 55-59, Pet'rs' App. at 420–24. In other words, EPA proposed that *if* use on those 11 crops was amended as indicated in the PID *and* all other uses were cancelled—both FIFRA actions—EPA could determine that the aggregate exposure to chlorpyrifos was safe and thus tolerances associated with those 11 specific uses could be left in place under the FFDCA.

As required under EPA's regulations, EPA solicited public comment on the PID. 40 C.F.R. § 155.58(a); AR 40 at 62, Pet'rs' App. at 427. Multiple groups submitted comments disagreeing with the subset of 11 uses EPA identified. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. Some commenters, including cranberry and banana growers, argued that their crops should also be retained; others, including advocacy and environmental groups, argued that a safety determination supporting even those limited 11 uses would contravene the available science. *Id.* at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not issued an interim or final registration review decision.

At the time of the issuance of the Final Rule, no chlorpyrifos registrant had submitted voluntary cancellation requests or applications for label amendments consistent with the proposed mitigation measures in the PID.

3. The Ninth Circuit's decision vacating EPA's denial of the petition

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the 2007 Petition and EPA's order denying related objections and concluded that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01 (listing six EPA and Scientific Advisory Panel assessments and notices from 2012 to 2016 that indicated that there is not a reasonable certainty of no harm under the FFDCA). Indeed, the Ninth Circuit found that since 2006, EPA had "consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of chlorpyrifos and for the susceptibility of the developing brain to chlorpyrifos." *Id.* at 697. The Ninth Circuit chided EPA for taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition," which was an "egregious delay [that] exposed a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 703. According to the Court, that EPA was in the midst of registration review under FIFRA did not justify the "total abdication of the EPA's statutory duty under the FFDCA," as registration review was "separate from [EPA's] continuous obligation to ensure safety under the FFDCA." *Id.* at 678, 691. The Ninth Circuit made clear that it was not remanding for further factfinding, as "further delay would make a

mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." *Id.* at 702.

The Ninth Circuit instructed EPA to publish a final response to the 2007 Petition within 60 days after the issuance of its mandate, without notice and comment, "that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703 ("EPA's time is now up."). Regarding modification, the Ninth Circuit stated that "[i]f, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it *may* modify chlorpyrifos registrations rather than cancelling them." *Id.* (emphasis added). The Ninth Circuit also directed EPA to modify or cancel related FIFRA registrations "in a timely fashion." *Id.* at 704.

4. EPA's attempt to negotiate voluntary cancellations with Petitioner Gharda and other registrants

Shortly after the issuance of the Ninth Circuit's decision in *LULAC II*, EPA entered into good-faith negotiations with each of the technical registrants, including Gharda, regarding the voluntary cancellation of chlorpyrifos

registrations.[5] None of the technical registrants, however, ultimately submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. Indeed, instead of proceeding quickly given the Ninth Circuit's 60-day deadline, Gharda repeatedly sought unreasonable cancellation terms:

- On May 12, 2021, Gharda stated that it was "willing to negotiate and execute an agreement with EPA" that contained nine separate terms, including allowing continued uses on several crops not listed in the PID; phasing out the production, sale, and distribution of chlorpyrifos products for certain uses through 2026; and retaining all import tolerances. Redacted Decl. of Ram Seethapathi, Ex. B, at 1–2, (Doc. ID 5133345 at 28-29), Pet'rs' App. at 1739-40.
- On June 7, 2021, Gharda committed to voluntarily cancel all currently approved agricultural uses except the subset of 11 uses identified in the PID if EPA agreed to nine other terms, including allowing: (1) use of chlorpyrifos on cotton in Texas (which was not proposed in the PID); (2) Gharda to import all finished technical product from Gharda's foreign warehouse for processing and sale in the United

[5] "Technical" or "manufacturing-use products" are intended and labeled for formulation and repackaging into other pesticide products. *See* 40 C.F.R. § 158.300.

States for all currently registered uses; and (3) Gharda to process and sell product in its possession for all currently registered uses. *Id.,* Ex. C at 1–2, Pet'rs' App. at 1743–44. Gharda also stated that it would reserve the right to withdraw from voluntarily cancelling uses in the event that the U.S. Supreme Court granted certiorari in *LULAC II*. *Id.* at 2.[6]

- On June 25, 2021, Gharda proposed new terms, including retention of nine of the 11 uses outlined in the PID; the formulation, distribution and sale of end-use products until December 31, 2022; the use of existing stocks until December 31, 2023; the use of aerial application through December 31, 2023; and retention of all import tolerances. Seethapathi Ex. G, at 1–2 (Doc. ID 513345 at 45–46), Pet'rs' App. at 1756–57. Gharda noted that "[t]erms will be set forth in a separate, written agreement" and that the company "reserves the right to withdraw from the written agreement in the event that the U.S. Supreme Court grants certiorari in the *LULAC II* case." *Id.* at 2, Pet'rs' App. at 1757.
- On July 6, 2021, Gharda stated that it was "willing to accept" the voluntary cancellation of certain uses, such as strawberry, asparagus,

[6] No petition for certiorari was ultimately filed for *LULAC II*.

cherry (tart) and cotton, that had been proposed for retention in the PID, if, "in return," EPA agreed to allow the formulation and distribution for all current uses through June 2022 and the use of existing stocks through June 2023, instead of EPA's proposals of February and August 2022. *Id.,* Ex. H, at 2 (Doc. ID 513345 at 51), Pet'rs' App. at 1762.

EPA did not agree to these conditions since they would not have adequately addressed the FFDCA requirement not to leave in place tolerances that are unsafe and due to concerns that such an extended existing stocks period would have been inconsistent with *LULAC II*. 87 Fed. Reg. at 11248, Pet'rs' Add. at 48. Ultimately, neither Gharda nor any of the other chlorpyrifos registrants submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

5. EPA's revocation rule

On August 30, 2021, EPA published a Final Rule revoking all tolerances for chlorpyrifos. AR 1, Pet'rs' Add. 1. Given the immediate deadline from the Ninth Circuit, and lack of an agreement on any new label terms or use deletions, EPA relied on its previously conducted aggregate assessments of chlorpyrifos, which

covered all registered uses and included extensive information about the potential impacts of chlorpyrifos.

More specifically, chlorpyrifos inhibits acetylcholinesterase ("AChE"), an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. Thus, exposure to chlorpyrifos can lead to neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. *Id.* There is also an extensive body of information (epidemiological, mechanistic, and laboratory animal studies) studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children (including cognitive, anxiety and emotion, social interactions, and neuromotor functions), although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38.

EPA's decision relied on the effect of AChE inhibition for assessing risks from chlorpyrifos and retained the default FQPA 10X safety factor to account for scientific uncertainties around the potential for adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11237, Pet'rs' Add. at 38. Taking into account the available data and literature and the currently registered uses of chlorpyrifos, EPA determined that it could not make the safety finding to support leaving in place current tolerances. AR 1 at 48317, Pet'rs' Add. at 3. The

Agency's analysis indicated that although exposures from food alone did not exceed safe levels, EPA concluded that aggregate exposures from food, drinking water, and residential settings due to currently registered uses exceeded safe levels. 87 Fed. Reg. at 11237–38, Pet'rs' Add. at 38–39. Because EPA could not conclude that aggregate exposure to chlorpyrifos residues was safe, the Agency revoked all chlorpyrifos tolerances as required under FFDCA section 408(b)(2). *Id.* at 11238, Pet'rs' Add. at 39; *see also* AR 1 at 48334, Pet'rs' Add. at 20 ("EPA has determined that the current U.S. tolerances for chlorpyrifos are not safe and must be revoked.").

To ease the transition away from chlorpyrifos for growers and to accommodate international trade considerations, EPA allowed the tolerances to remain in place for six months following publication of the Final Rule, setting an expiration date of February 28, 2022, for the tolerances. AR 1 at 48334, Pet'rs' Add. at 20, 87 Fed. Reg. 11238, Pet'rs' Add. at 39.

On February 28, 2022, EPA published its Denial Order objecting to the Final Rule, requests for hearing on those objections, and requests to stay the Final Rule, 87 Fed. Reg. 11222, Pet'rs' Add. at 23, which reaffirmed EPA's conclusions in the Final Rule for revoking the chlorpyrifos tolerances.

6. The petition for review

On February 9, 2022, Petitioners filed a petition for review challenging the Final Rule. *Red River Valley Sugarbeet Growers Ass'n v. Regan*, No. 22-1294, Doc. ID 5126162. The next day, Petitioners moved to stay the February 28, 2022, expiration date in the Final Rule. Doc. ID 5126280. On February 18, 2022, EPA moved to dismiss that petition for lack of jurisdiction because EPA had not yet issued a final order denying objections to the Final Rule. Doc. ID 5129068, Pet'rs' App. at 1285.

On February 28, 2022, Petitioners filed a second petition for review challenging both the Final Rule and the Denial Order, and renewed their stay motion. Doc. IDs 5131400, 5132688 (No. 22-1422). On March 14, 2022, Petitioners filed a third petition for review of the Final Rule and the Denial Order. Doc. ID 5136561 (No. 22-1530), Pet'rs' App. at 1816.

On March 15, 2022, the Court denied Petitioners' stay motion and exercised jurisdiction over the second petition. Doc. ID 5136844. The following day, the Court dismissed the first petition for lack of jurisdiction. Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661, Pet'rs' App. at 1914.

7. Cancellation status of chlorpyrifos registrations under FIFRA

On April 28, 2022, EPA published in the Federal Register requests to voluntarily cancel 16 different chlorpyrifos registrations. Requests to Voluntarily Cancel Certain Pesticide Registrations, 87 Fed. Reg. 25256, 25257–58 (Apr. 28, 2022). EPA plans to initiate involuntary cancellation proceedings for every chlorpyrifos registration for which it has not received a voluntary cancellation request.

SUMMARY OF ARGUMENT

As required under the FFDCA, in determining whether chlorpyrifos tolerances could be left in place, EPA considered "aggregate exposure . . . , including *all* anticipated dietary exposures and other exposures" of chlorpyrifos based on existing registered (*i.e.,* legally permitted) uses. 21 U.S.C. §346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added). That assessment showed that the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Accordingly, EPA revoked all chlorpyrifos tolerances. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; AR 1 at 48316, Pet'rs' Add. at 2.

The ultimate relief sought by Petitioners in this case is the retention of *all* chlorpyrifos tolerances. But Petitioners' actual legal argument is more limited.

Specifically, they argue that EPA should not have assessed safety with respect to aggregate exposures, but was required to retain a specific geographically-limited subset of 11 uses that EPA proposed for retention in the PID and purportedly determined are safe. Petitioners' argument lacks merit for five reasons.

First, no one disputes that EPA must revoke or modify a tolerance that is not safe. Regarding chlorpyrifos, EPA concluded that exposure can lead to neurotoxicity and that there is an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11231, 11237, Pet'rs' Add. at 32, 38. Based on these and other findings, EPA reasonably concluded that aggregate exposure to chlorpyrifos exceeded safe levels and revoked all tolerances. *Id.* at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3.

Second, contrary to Petitioners' claim, the PID was not "final." The PID was a *proposed* determination as part of registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's proposed scientific assessment that a particular subset of 11 high-benefit uses would not pose potential risks of concern, using the 10X safety factor, if certain mitigation was adopted, including geographic and application restrictions. AR 40 at 40, Pet'rs' App. at 405. The proposed nature of the PID means that EPA's safety

determination (and the subset of uses to be retained) might be adjusted or revised. EPA requested public comment on the PID, and some commenters disagreed with the retention of those 11 uses, while others advocated for a different combination of uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA could not fully consider those comments and reach a definitive conclusion in the timeframe the Ninth Circuit provided EPA to act under the FFDCA, and it has not yet issued an interim or final registration review decision.

Third, contrary to Petitioners' claim, the FFDCA does not require EPA to undertake a tolerance-by-tolerance analysis generally, nor is that analysis prudent in situations like this, where aggregate risk is not safe. EPA's consideration of all tolerances for a specific pesticide is consistent with the FFDCA's mandate (and the Ninth Circuit's edict) to assess "aggregate" exposure, as well as longstanding EPA policy. Moreover, Petitioners do not explain how, from a practical perspective, EPA could actually carry out a tolerance-by-tolerance approach in this case in a manner consistent with that mandate.

Fourth, EPA's consideration of all currently-registered uses, instead of only the 11 uses proposed in the PID, was entirely reasonable under the FFDCA's direction to consider "all anticipated dietary exposures." The FFDCA requires EPA to determine whether tolerances *are* safe. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. It does not allow EPA to leave tolerances in place if they *might*

be safe *if* the suite of mitigation measures proposed under FIFRA might be implemented at some indeterminate time in the future. At the time of the Final Rule, no concrete steps under FIFRA had been taken by registrants that would have altered the universe of uses EPA needed to assess: EPA had received no cancellation requests or applications to amend labels to geographically limit uses or limit applications consistent with the mitigation proposed in the PID. The proposed mitigation measures in the PID are not self-executing, and without efforts to make changes to the registrations, they do not, by themselves, support an assumption that aggregate exposures would be limited to that subset of uses. Nor would the revocation of tolerances associated with uses other than the subset of 11 alone have supported a safety determination without the necessary geographic and application restrictions occurring on those 11 uses, which would need to occur under FIFRA. Thus, EPA's consideration of all existing chlorpyrifos registrations in its assessment of "anticipated" exposures was reasonable.

Fifth, EPA was not required to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. Petitioners point to the FFDCA's direction that "[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocation of tolerances with FIFRA "[t]o the

extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704. Given the length of time an involuntary cancellation proceeding can take, Petitioners' view could force EPA to leave in effect pesticide tolerances it had found unsafe long after making that finding, contrary to the FFDCA.

Ultimately, EPA reasonably considered aggregate exposure from all anticipated sources based on all currently registered uses in determining that the continued use of chlorpyrifos did not meet the FFDCA's strict safety standard, and that all tolerances therefore must be revoked.

STANDARD OF REVIEW

The APA provides the standard of review for this case. *See* 5 U.S.C. § 706. Under this standard of review, EPA's Final Rule and Denial Order can be overturned only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A)). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). That standard requires the court to "affirm the EPA's rules if the agency has considered the relevant factors

and articulated a 'rational connection between the facts found and the choice made."' *Allied Local and Reg'l Mfrs. Caucus v. EPA,* 215 F.3d 61, 68 (D.C. Cir. 2000) (quoting *Motor Vehicles Mfrs. Ass'n,* 463 U.S. at 43).

ARGUMENT

I. EPA reasonably revoked chlorpyrifos tolerances based on its determination that those tolerances were not safe.

There is no dispute that the statutory criteria for leaving a tolerance in place or revoking a tolerance is whether the residue is "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; *see also LULAC II*, 996 F.3d at 696 (amendments to the FFDCA "explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns."). If EPA cannot conclude that a tolerance is safe, it "shall" revoke or modify it. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.

EPA's scientific analysis of chlorpyrifos is complicated, but its conclusion is not: "Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71. Because EPA concluded that aggregate exposure to chlorpyrifos residues from all registered uses was not safe, it revoked all chlorpyrifos tolerances. *Id*. As noted above, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. *Id.* Moreover, there is also an extensive body of

information studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children, although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38. Although EPA did not identify risks of concern based on exposure to residues of chlorpyrifos in food alone, it concluded, consistent with the FFDCA, that aggregate exposure to residues of chlorpyrifos in food, drinking water, and residential settings from currently registered uses exceeded safe levels. *Id.* at 11237–38, Pet'rs' Add. at 38-39.

Petitioners' claim that "the sole dietary exposure source of concern . . . is drinking water" is a red herring. Pet'rs' Br. at 39. It does not matter what the "sole" or "primary" source of exposure is that drives risk concerns. The FFDCA directs EPA to consider "aggregate" exposure in making a safety determination. If aggregate exposure—taking all the relevant sources of exposure together—is not safe, then EPA cannot find that the tolerances are safe.

Amicus curiae State of Missouri's claim that, contrary to the statute, EPA "failed to make any finding—either that the tolerances for any food were unsafe or safe" similarly misreads the Final Rule, as well as the statute. *See* Missouri Br. at 5, 7-8. First, EPA did conclude that chlorpyrifos tolerances were not safe. AR 1 at 48317, Pet'rs' Add. at 3 ("[T]he Agency's analysis indicates that aggregate

exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels. . . "). Second, the FFDCA permits EPA to "leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). Put differently, EPA is required to revoke or modify any tolerance for which it cannot make a safety finding. *LULAC II,* 996 F.3d at 694.

Petitioners and *amicus curiae* State of North Dakota attempt to undercut EPA's conclusions about adverse impacts to infants' and children's developing brains by arguing that, without chlorpyrifos, growers will experience "dramatic adverse reduction in its yield" and "crippling economic losses" that "will ultimately be felt by U.S. consumers." Pet'rs' Br. at 15-16; N. Dakota Br. at 19; *see also* Missouri Br. at 10 ("EPA has forced a disruptive change that endangers agricultural yields that are critical to Missouri's economy.") Those arguments conflate two *different* statutory standards, attempting to import FIFRA's "unreasonable adverse effects" standard—which considers economic and social costs and benefits—into the FFDCA's strict safety standard. The FFDCA, however, imposes "an uncompromisable limitation: the pesticide must be

determined to be safe for human beings." *LULAC II*, 996 F.3d at 678; *see* 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.[7]

Similarly without merit are Petitioners' and North Dakota's claims that the Final Rule and Denial Order failed to sufficiently account for their reliance interests in the continued use of chlorpyrifos. North Dakota purports to have "reasonably relied on" EPA's safety finding in the 2006 Reregistration Eligibility Determination for chlorpyrifos. N. Dakota Br. at 12–13; AR 33, Resp'ts' App. at 80. But the Ninth Circuit concluded in 2021 that, based on subsequent evidence before the Agency, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01. And in fact, since 2006, EPA's extensive scientific analyses of chlorpyrifos provided North Dakota with ample notice that EPA's 2006 safety finding could change. Moreover, the Ninth Circuit's mandate to revoke all tolerances unless the Agency could make a safety finding supporting modification left no room for EPA to consider reliance reasons, even absent such a safety

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[7] Petitioners and North Dakota rely in large part upon materials from outside of the administrative record for their economic arguments. These extra-record materials are not properly before the Court. *See Newton Cty. Wildlife Ass'n. v. Rogers,* 141 F.3d 803, 807 (8th Cir. 1998) ("APA review of agency action is normally confined to the agency's administrative record."); *CTS Corp. v. E.P.A.,* 759 F.3d 52, 64 (D.C. Cir. 2014) ("[A] reviewing court [in an APA case] should have before it neither more nor less information than did the agency when it made its decision.") (internal quotations and citations omitted).

finding. *Cf. Brachtel v. Apfel,* 132 F.3d 417, 419–20 (8th Cir. 1997) (applying law-of-the-case doctrine to administrative agencies on remand). Accordingly, North Dakota's purported reliance on the 2006 RED was unreasonable.

Petitioners' purported reliance on the 2020 PID was also unreasonable. Petitioners argue that *Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) and *Encino Motorcars, LLC v. Navarro,* 136 S. Ct. 2117, 2126 (2016) impose a more demanding requirement for justifying an action that deviates from a prior policy. Pet'rs' Br. at 61; *see also* CropLife Br. at 15–16. But both cases specifically addressed changes from "longstanding policies" that may have "engendered serious reliance interests that must be taken into account." *Encino Motorcars,* 136 S. Ct. at 2126 (quoting *F.C.C. v. Fox TV Stns., Inc.,* 129 S. Ct. 1800, 1811); *Dep't of Homeland Sec.,* 140 S. Ct. at 1913. That is not the case here. First, the PID was a *proposed* determination—not an Agency policy—signed only nine months before the Final Rule was published and heavily caveated. 40 C.F.R. § 155.58(b)(1) (the PID contained "proposed findings"); *compare* AR 40 (signed Dec. 3, 2020), Pet'rs' App. at 366, with Final Rule (published Aug. 30, 2021), Pet'rs' Add. at 1. Second, the Ninth Circuit's April 29, 2021 decision in *LULAC II* explicitly contemplated that EPA would, absent a safety finding, revoke all chlorpyrifos tolerances in response to that decision. 996 F.3d at 703.

Accordingly, any reliance by Petitioners on the PID was unreasonable, not to mention irrelevant to the Agency's safety analysis under the FFDCA.

In sum, consistent with the FFDCA's strict safety standard, EPA reasonably and properly revoked all chlorpyrifos tolerances when it found that aggregate exposure to chlorpyrifos was unsafe.

II. The PID was not final, and neither EPA nor Gharda treated it as such.

Petitioners claim that EPA "unquestionably believed that its scientific findings concerning tolerances [in the PID] were final and actionable." Pet'rs' Br. at 59. But that assertion is contradicted by the plain language of the PID itself, FIFRA regulations regarding registration review, and the APA.

The PID was a *proposed* determination as part of a registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's scientific assessment that, based on the evidence available at the time, a subset of 11 high-benefit uses with geographic and application rate restrictions would not pose potential risks of concern with the 10X safety factor, *if* other uses contributing to aggregate exposures were cancelled. AR 40 at 40. Accordingly, EPA determined that those 11 uses "may be considered for retention." *Id.*

The proposed nature of the PID means that EPA's safety determination might be adjusted or revised. EPA requested public comment on the PID, and

some commenters, including cranberry and banana growers, argued that their crops should be retained as well. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. Others, including advocacy and environmental groups, argued that a safety determination supporting even those 11 uses would contravene the available science. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not fully considered these comments and has not yet issued a final interim decision. Petitioners' contention (at 55–61) that the PID nevertheless was final disregards that the APA and FIFRA regulations require that EPA address those comments. *See* 5 U.S.C. 553(c); 40 C.F.R. § 155.58(c); *U.S. Satellite Broad. Co., Inc. v. FCC,* 740 F.2d 1177, 1188 (D.C. Cir. 1984) (Agency must respond "in a reasoned manner to significant comments received."). FIFRA regulations also contemplate that there may be changes to the mitigation measures in a proposed interim decision, which the Agency is required to explain. 40 C.F.R. § 155.58(c). As a practical matter, mitigation measures in a proposed interim decision are often modified in the final interim decision, which establishes the legally-required mitigation and label changes. For example, the Interim Registration Review Decision for oxadiazon strengthened certain mitigation measures from the proposed interim decision, including requiring thorough post-application irrigation to mitigate post-application risks of concern and designating oxadiazon as a Restricted Use Pesticide. Oxadiazon: Interim Registration Review Decision Case

Number 2485, EPA Docket No. EPA-HQ-OPP-2014-0782 (Mar. 31, 2022) at 6, Resp'ts' App. at 626.

Petitioners claim that the PID was labeled a "proposal" solely because EPA needed to complete its Endangered Species Act analysis and endocrine screening for registration review. Pet'rs' Br. at 58. Petitioners are wrong. First, EPA's regulations require EPA to publish a proposed registration review decision for every registration review case for at least 60 days of public comment. 40 C.F.R. § 155.58(a). As explained above, EPA was required to consider comments submitted on the PID, including comments on the proposed subset of 11 uses. Second, as EPA explained in the PID, the Agency still needed to consider the forthcoming 2020 FIFRA Scientific Advisory Panel's latest recommendations, which could impact the human health risk assessment and the proposed mitigation measures. AR 40 at 10, 40 ("EPA's conclusions about risk, and thus proposed mitigation measures, may be revised.").

Nor did the Ninth Circuit treat the PID as final. Recognizing EPA's proposal in the PID for modifying certain tolerances and the intervening Scientific Advisory Panel, the Ninth Circuit noted that "*[i]f*, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos

registrations rather than cancelling them." *LULAC II*, 996 F.3d at 703 (emphasis added).

Petitioners' claim (at 61) that "[a]t all times, Gharda understood that the Safe Uses would be retained" is contradicted by the record of negotiations between EPA and Gharda. At one point, Gharda asked EPA to retain cotton use in Texas (even though it was not proposed for retention in the PID), while later Gharda was willing to eliminate four uses—strawberry, asparagus, cherry (tart) and cotton—that had been proposed for retention in the PID. Seethapathi Ex. H, at 2; (Doc. ID 5133345 at 51), Pet'rs' App. at 1762; *see also* Ex. G, at 1; (Doc. ID 5133345 at 45), Pet'rs' App. at 1756.

Accordingly, the PID did not represent EPA's final position on which uses, if any, could be retained for chlorpyrifos. But ultimately that question is not the deciding one here. The PID's proposed continuation of a limited subset of chlorpyrifos uses was conditioned on the cancellation of all other uses under FIFRA and the implementation of new geographic and application restrictions. AR 40 at 40, 55. At the time of the Final Rule, EPA had not received a single voluntary cancellation request or label amendment from any of the chlorpyrifos registrants, and, as discussed *infra* at 54, FIFRA does not provide EPA with another way to quickly cancel or modify existing registrations. With the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision

based upon an assessment of the science and facts that actually existed. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49.

In sum, the PID was not final, and neither EPA nor Gharda treated it as such. And, even if it were final, because EPA had not received any voluntary cancellation requests or label amendments at the time of the Final Rule, it reasonably made a decision based on its scientific assessment of the registrations that actually existed.

III. EPA reasonably assessed "aggregate" exposure under the FFDCA.

Petitioners argue that the Final Rule and Final Order were arbitrary and capricious because EPA did not utilize a "tolerance-by-tolerance approach." *See* Pet'rs' Br. at 43–46. Petitioners are wrong. EPA's consideration of all tolerances together is consistent with the FFDCA's mandate to assess "aggregate" exposure, as well as longstanding EPA practice. While tolerances may be established or modified individually, the assessment of exposures required to support such actions necessarily includes exposures from all tolerances and other drinking water and residential exposures from registered uses of the pesticide, and this is especially true in the case of a decision to "leave" tolerances "in place." *See supra* at 5 (describing the aggregate exposure assessment required by the FFDCA).

A. EPA's approach is consistent with the text of the FFDCA.

Petitioners and CropLife argue that the plain text of the FFDCA commands an individual tolerance-by-tolerance approach. Pet'rs' Br. at 43–47; CropLife Br. at 15–16. As an initial matter, they have waived this statutory argument because they did not raise it in their objections to the Final Rule. *See Friends of the Norbeck v. U.S. Forest Serv.,* 661 F.3d 969, 974 (8th Cir. 2011). Petitioners and CropLife also fail to explain what, in their view, such an approach would entail. Most importantly, they ignore that the FFDCA explicitly directs EPA to assess "*aggregate* exposure to the pesticide chemical residue" based on "*all* anticipated dietary exposures and *all* other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added); *see also id.* at § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5 (requiring EPA to consider when leaving in effect or revoking a tolerance, "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue*, and exposure from other non-occupational sources.") (emphasis added). Congress's use of the word "aggregate" and the plural for both "all anticipated dietary exposure***s***" and "all other exposure***s***" plainly indicates that something more than any one tolerance for a specific pesticide is to be considered at a time. For this reason, EPA's standard

practice is to assess all exposures from all tolerances for a specific pesticide chemical (as well as from drinking water and residential uses) whenever making a safety determination for any given pesticide. AR 16 at 25, Resp'ts' App. at 26.

Nowhere does the FFDCA instruct EPA to employ a tolerance-by-tolerance approach. Petitioners nevertheless argue, without explanation, that the statute's use of "*a* tolerance" instead of "*the* tolerances" mandates such an approach. *See* Pet'rs' Br. at 44; *but cf.* 1 U.S.C. § 1 ("unless the context indicates otherwise—words importing the singular include and apply to several persons, parties or things."). But the use of singular versus plural in this case is irrelevant, as the statute mandates EPA to assess aggregate exposure. *See* 21 U.S.C. §§ 346a(b)(2)(A)(ii), (D)(vi), Resp'ts' Add. at 2-3, 5. Accordingly, the safety finding for any particular tolerance would be the same as for all tolerances together—either way, EPA is required to assess the aggregate exposure caused by *all* tolerances. *See* Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59608, 59675 (Nov. 18, 2009) ("The consequence of this requirement [to consider aggregate exposures] is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels.")

Petitioners also argue that the FFDCA's provision for modifying a tolerance if it is not safe further supports their argument that the text of the FFDCA requires

an individual tolerance-by-tolerance approach. Pet'rs' Br. at 45. Specifically, they argue that because the statute provides that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," 21 U.S.C. § 346a(b)(1), Resp'ts' Add. at 2, the term "modify" can only mean "to narrow permissible uses." Pet'rs' Br. at 45. Thus, Petitioners argue, "EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe." *Id.* at 45–46. This, too, misses the mark.

Just because EPA has the authority to lower or revoke tolerances to reduce the number of approved uses for a pesticide does not mean that the FFDCA compels the Agency to do so, nor does the statute automatically provide the Agency with all of the necessary criteria or tools.[8] Instead, this record needs to be developed and evaluated by EPA in the context of each relevant action. As discussed above, at the judicially-mandated time for EPA's decision here, the Agency lacked an appropriate record basis to make such a decision. Finally, if EPA were to revoke certain tolerances and leave others in place consistent with the PID, EPA would still need to find that the tolerances left in place were safe, which EPA could not do in this case because no changes had been made to (nor had

[8] The term "modify" can also mean to lower a tolerance level. *See, e.g.,* MCPA; Pesticide Tolerances, 86 Fed. Reg. 71152 (Dec. 15, 2021) (reducing MCPA tolerances for clover commodities).

applications been submitted for) the underlying registrations to incorporate the PID's geographic, rate and application restrictions at the time of the Final Rule.

Petitioners do not explain, from a practical perspective, how EPA could conduct, for a pesticide with multiple tolerances, a tolerance-by-tolerance analysis in a manner consistent with the FFDCA's requirement to assess aggregate exposure. With regard to chlorpyrifos, the PID proposed a subset of uses that could fit within the "risk cup,"[9] subject to geographic, rate and application method restrictions, as part of the FIFRA registration review process. But there were likely other possible combinations of uses and restrictions that could have resulted in safe levels of aggregate exposure. 87 Fed. Reg. at 11245, Pet'rs' Add. at 46. EPA specifically noted in its 2020 Drinking Water Assessment that the analysis focused solely on the limited subset of 11 crops to assess whether there were any areas where the estimated drinking water concentrations would not exceed EPA's safe levels of exposures; it did not evaluate every possible combination of uses and restrictions to assess whether a different subset could also result in safe aggregate exposures. *Id.* EPA's 2016 Refined Drinking Water Assessment had already shown that estimated concentrations of chlorpyrifos in drinking water from all uses

[9] The "risk cup" is the total exposure allowed for a pesticide considering its toxicity and required safety factors and is equal to the maximum safe exposure for the duration and population being considered. 87 Fed. Reg. at 11222, Pet'rs' Add. at 23.

would exceed levels of concern, *see* AR 37 at 124, Resp'ts' App. at 464; therefore, EPA's 2020 Drinking Water Assessment focused on whether aggregate exposures might be safe if only some uses were retained. Given the large number of registered chlorpyrifos uses, EPA focused its registration review resources on a subset of potentially higher-benefit uses. AR 38 at 8, Resp'ts' App. at 473.

Even if EPA had adopted the proposed subset of 11 uses from the PID in its tolerance action under the FFDCA, as Petitioners advocate, it is not clear that all stakeholders would agree that EPA had selected the appropriate combination of chlorpyrifos tolerances. For example, some commenters on the PID advocated that bananas and cranberry be included in the list of continued uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. And in its negotiations with EPA, Gharda proposed the retention of uses for corn, mint, and grapes. Seethapathi Ex. B at 2. (Doc. ID 5133345 at 29), Pet'rs' App. at 1740. Critically, the FFDCA, which does not permit the consideration of benefits in determining whether to leave a tolerance in place, provides no basis for EPA to unilaterally choose one tolerance over another where aggregate exposures for tolerances overall are unsafe.

FIFRA and the FFDCA are complementary but different statutes with separate requirements. As it did under FIFRA, EPA may propose in the PID (and specify in the Interim Decision) label modifications and product or use cancellations that are necessary in order for the product to meet FIFRA's

unreasonable adverse effects standard. 40 C.F.R. § 155.56. Consistent with FIFRA, the proposed measures consider the benefits of those uses. AR 40 at 41–42. When registrants comply with EPA's requirements in an interim decision to voluntarily cancel registrations or amend pesticide product labels, then the pesticide, as assessed, is one step closer to meeting the FIFRA registration standard because the aspects found to cause unreasonable adverse effects no longer exist. *See*, *e.g.*, Oxadiazon: Interim Registration Review Decision Case Number 2485 (Mar. 31, 2022) at 70, Resp'ts' App. at 690 (finding that oxadiazon does not meet the FIFRA registration standard without the specified changes to the affected registrations and their labeling).

By contrast, in assessing the safety of a tolerance under the FFDCA, EPA is required to consider whether aggregate exposures from all anticipated dietary exposures and all other exposures *are* safe. *See* 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. When EPA finds that tolerances are not safe, EPA's sole option under the FFDCA is to modify or revoke tolerances; EPA cannot modify the underlying registrations. Any changes to underlying registrations to reduce aggregate exposures to safe levels occur under FIFRA, not under the FFDCA. *See* 40 C.F.R. § 152.44. Since that is not what happened here, *see supra* at 18, EPA could not base its FFDCA safety analysis on a potentially more limited universe of uses that did not actually exist yet in the real world. In sum, because the sole

consideration under the FFDCA is safety, and safety requires consideration of aggregate exposures, the statute does not provide EPA with any basis upon which to choose which uses to retain. As the Ninth Circuit explained in *LULAC II*, although FIFRA review includes a safety assessment under the FFDCA, it also requires EPA to assess a pesticide's economic, social, and environmental costs and benefits, including impacts on agricultural production and food prices. 996 F.3d at 692–93. But "Congress's decision to give the EPA discretion to set FIFRA priorities does not translate to the FFDCA." *Id.* at 693. Thus, while EPA might be able to conclude that some uses contribute lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment, consideration of those relative benefits is not permitted under the FFDCA in determining whether a tolerance is safe.

B. EPA's approach in the Final Rule and Denial Order is consistent with Agency practice for assessing aggregate exposures when determining whether tolerances are safe.

Contrary to Petitioners' and CropLife's claims (at 44–45, 47 and 16–17), it has not been EPA's practice to conduct a tolerance-by-tolerance analysis along the lines suggested by Petitioners, particularly where the aggregate exposure level is unsafe. To the contrary, as EPA has previously explained, the FFDCA "does not compel EPA to determine the appropriate subset [of tolerances] that would meet

the safety standard." Carbofuran Order, 74 Fed. Reg. at 59675[10]; *see also* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 Fed. Reg. 3421, 3423 (Jan. 19, 2011) (proposing to grant request to stay promulgation of sulfuryl fluoride tolerances because aggregate exposure was unsafe). Indeed, EPA's general practice when the Agency has determined that aggregate exposures are unsafe (making tolerances overall not safe) is not to independently select a subset of uses that meets the safety standard, but instead to engage in a public process that allows registrants and the public to indicate which of the various subsets of tolerances are of sufficient importance to warrant retention. 74 Fed. Reg. at 59675; *see also* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. EPA attempted to work in this way with Gharda and other chlorpyrifos registrants here, but ultimately was unable to reach an agreement with any registrant regarding voluntary cancellations and label amendments before the Ninth Circuit's 60-day deadline. *See supra* at 15–18.

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[10] The U.S. Court of Appeals for the D.C. Circuit denied the portion of a petition for review that challenged EPA's revocation of domestic carbofuran tolerances, but granted the portion challenging EPA's revocation of import tolerances for carbofuran. *Nat'l Corn Growers Ass'n v. EPA,* 613 F.3d 266 (D.C. Cir. 2010). There, EPA had concluded that carbofuran exposure from import tolerances alone would be safe. *Id.* at 275. EPA has made no such conclusion with regard to import tolerances for chlorpyrifos nor has EPA determined that the subset of 11 uses would be safe in the absence of changes to the registrations under FIFRA.

Despite EPA's consistency in addressing tolerances for which aggregate exposures are unsafe, Petitioners and CropLife claim that EPA's tolerance actions on flonicamid, tebuconazole, fludioxonil, and ethalfluralin show that "tolerances do not have to rise or fall together." *See* Pet'rs' Br. at 46-47; CropLife Br. at 11–12. Petitioners and CropLife's examples miss the point, as the individual tolerances to which Petitioners and CropLife refer were not assessed in a vacuum; instead, EPA assessed all tolerances together as part of an aggregate exposure analysis in response to petitions requesting new tolerances. In EPA's tolerance actions for those pesticides, the Agency was able to increase or decrease existing tolerances and/or establish new tolerances because aggregate exposure levels—*i.e.,* exposures from the newly requested tolerance plus all existing tolerances and uses contributing to aggregate exposure—fit within the "risk cup."[11] Put differently, EPA could establish tolerances requested by those petitioners because aggregate exposure levels were safe. By contrast, EPA determined that aggregate exposure to chlorpyrifos was unsafe. Therefore, none of these examples contradicts EPA's position of not independently selecting the subset of uses that meets the safety standard, when, as is the case with chlorpyrifos, aggregate exposure levels are

[11] Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30425 (May 19, 2022); Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60932 (Nov. 12, 2019); Fludioxonil; Pesticide Tolerances, 85 Fed. Reg. 51354 (Aug. 20, 2020); Ethalfluralin; Pesticide Tolerances, 85 Fed. Reg. 45336 (July 28, 2020).

unsafe. If anything, they support the general principle that EPA considers aggregate exposures when assessing whether tolerances are safe. *See* 21 U.S.C. § 346a(b)(2), Resp'ts' Add. at 2-3.

CropLife argues that "with the EPA's new policy of revoking all tolerances whenever the risk cup overflows—even though modification of tolerances would achieve a safe risk cup—registrants and other stakeholders would have no basis to rely on EPA's ability to negotiate and work with them to determine what specific subsets of uses warrant retention." CropLife Br. at 19. CropLife's characterization of EPA's course of action with regard to chlorpyrifos as a "new policy" is incorrect.

First, EPA had a tight timeframe to revoke or modify tolerances as a result of the Ninth Circuit's order, much of which Gharda spent repeatedly seeking unreasonable terms for cancellations and label amendments under FIFRA. Second, as explained above, EPA's actions regarding chlorpyrifos are fully consistent with longstanding Agency policy. Third, where changes to registrations need to occur under FIFRA for remaining tolerances to be found safe by a date certain, EPA cannot leave those tolerances in place when it has no reason to believe that those changes are imminent. Finally, EPA does attempt to work with registrants to cancel or modify registrations and labels in order to lower aggregate exposure where aggregate exposure exceeds the risk cup. For example, in the case of

bifenthrin, registrants cancelled certain registrations and amended others to address residential application risks identified during registration review. *See* Bifenthrin; Pesticide Tolerances, 86 Fed. Reg. 68150, 68154 (Dec. 1, 2021); Product Cancellation Order for Certain Pesticide Registrations, 86 Fed. Reg. 38339 (July 20, 2021). These actions created sufficient room in the risk cup for EPA to establish tolerances for certain food uses. *See* 86 Fed. Reg. at 68151, 68154. The tolerance actions for bifenthrin also contradict Petitioners', CropLife's, and Missouri's claims that EPA's approach effectively reads the term "modify" out of the FFDCA. Pet'r's Br. at 46; CropLife Br. at 12-13, Missouri Br. at 9.

In sum, EPA's process for considering aggregate exposure was consistent with the FFDCA and past policy and practice and, therefore, reasonable.

IV. When assessing all "anticipated" exposures, EPA reasonably considered all currently registered uses of chlorpyrifos.

Petitioners argue (at 43) that by evaluating exposure from all registered chlorpyrifos uses, EPA essentially replaced the statute's use of the word "anticipated" with the word "existing." This argument misinterprets the FFDCA's mandate to assess *all anticipated exposures* in making EPA's safety determination. 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. In guidance developed after the FQPA amendments to the FFDCA, EPA established that "[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure

assessment is the universe of *proposed* and *approved* uses for the pesticide,"[12] which are determined by use patterns on labels of the proposed and registered products. AR 16 at 44–45, Resp'ts' App. at 45-46 (emphasis added); *see, e.g.,* Fluoxastrobin; Pesticide Tolerances, 84 Fed. Reg. 38138, 38140 (Aug. 6, 2019) (considering petitioned-for tolerances and existing tolerances). Accordingly, EPA's consideration of all registered chlorpyrifos uses when determining which exposures are "anticipated" was consistent with the ordinary reading of the statute and long-standing Agency guidance and practice.

Citing EPA's tolerance action on benzobicyclon, Petitioners assert that EPA's consideration of registered uses for chlorpyrifos was not a consideration of "anticipated uses." *See* Pet'rs' Br. at 46–47 (citing Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60368 (Nov. 2, 2021)). Petitioners again misunderstand how EPA assesses tolerances and implements the aggregate exposure directive of the FFDCA. For benzobicyclon, EPA received a petition to increase one tolerance. In response, the Agency considered the "anticipated" aggregate exposures, which included exposures from uses already registered as well as what was anticipated from the new use if it was approved. 86 Fed. Reg. at 60370–71. This example is

[12] The term "approved uses" refers to uses that have already been approved or registered by EPA, *see* 40 C.F.R. § 152.112; "proposed uses" refers to new uses for which an application has been submitted for registration. *See* 40 C.F.R. § 152.3 (definition of "new use" referring to "proposed use pattern").

consistent with EPA's chlorpyrifos action. The "anticipated exposures" for chlorpyrifos reasonably included exposures from registered uses because no registrant had submitted any label amendment applications to align uses with the Agency's proposal in the PID to potentially retain certain tolerances.

Critically, EPA cannot require changes to registered pesticides under the FFDCA. Changes such as application rate restrictions or geographical limitations can only be accomplished through amendments to the label approved under FIFRA, which EPA cannot do unilaterally. *See infra* at 54, n.13. When a tolerance for residues of a pesticide on a particular food is revoked, that pesticide may no longer be registered for use on that food. *See* 21 U.S.C. § 346a(a), Resp'ts' Add. at 1; 7 U.S.C. § 136(bb). However, for chlorpyrifos, it would not be as simple as revoking all but the 11 uses proposed for retention in the PID. Aside from the fact that it was not a final determination, EPA's proposal to find the 11 uses safe was also contingent on restrictions being made to the underlying labels under FIFRA, *i.e.*, restricting applications to specific geographic areas and ensuring that application rates reflected the usage rates assessed in EPA's 2020 Drinking Water Assessment. Without those labeling changes, the 11 uses EPA identified would not be consistent with the proposal in the PID. *See* 87 Fed. Reg. 11246, Pet'rs' Add. at 47 (explaining that tolerances are broadly applicable rules without geographic limitations, and in order to limit geographic use, associated

FIFRA labels would need to be amended). Put differently, EPA could not modify tolerances under the FFDCA in a way that would render those 11 proposed uses safe, because additional changes to associated labeling would still need to occur under FIFRA, and at the time of the Final Rule no applications for label revisions had been submitted or approved under FIFRA. Until the universe of chlorpyrifos uses reflected the subset proposed in the PID—or at least until EPA had a reasonable basis to believe that would happen—the Agency could not conclude that the subset of 11 geographically restricted uses proposed in the PID comprised the "anticipated" exposures under the FFDCA. *Id.*

Gharda's argument to the contrary portrays its negotiations with EPA as final and complete because it "had submitted to EPA a written commitment to conform its registration to EPA's safety finding." *See* Pet'rs' Br. at 52. Typically, a formal request for voluntary cancellation of registered uses includes a letter requesting cancellation of product or uses along with applications to amend relevant labels. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. EPA received neither from Gharda. *Id.* Even Gharda's final proposal to EPA stated only that it was "willing to accept" certain voluntary cancellations if, "in return," EPA agreed to extended terms for formulation, sale, distribution, and use of existing stocks. Seethapathi Decl. Ex. H, at 2, (Doc. ID 5133345 at 51), Pet'rs' App. at 1762.

Conditional proposals such as Gharda's do not provide EPA with a reasonable basis to conclude that uses will be cancelled and exposures reduced. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. Gharda defends its inaction by claiming that it was merely "standing by awaiting word from EPA on when to submit a formal voluntary cancellation request." Pet'rs' Br. at 53. But there was no need to wait: FIFRA permits any registrant to submit a voluntary cancellation request to EPA at any time. 7 U.S.C. § 136d(f)(1).

EPA also could not have completed involuntary cancellation proceedings prior to the Ninth Circuit's 60-day deadline. *See supra* at 8. Without cancellation and label amendment requests in hand from Gharda and the other chlorpyrifos registrants, or the ability to quickly complete involuntary cancellation proceedings, EPA lacked a reasonable basis for concluding that chlorpyrifos uses would be limited as proposed in the PID. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

Gharda is not without a remedy. Namely, it may petition to establish new chlorpyrifos tolerances, and EPA would be required to evaluate any such request. Instead, Petitioners ask this Court to restore *all unsafe* chlorpyrifos tolerances (by vacating EPA's revocation). Restoring all chlorpyrifos tolerances would also undermine judicial comity among sister circuits and stand in considerable tension with the Ninth Circuit's explicit instruction to immediately revoke or modify all tolerances.

Finally, Gharda's suggestion (at 28–29) that EPA did not permit it to meaningfully participate in the revocation process rings hollow. Since the petition to revoke chlorpyrifos tolerances was filed nearly 15 years ago, EPA has solicited comments on revocation multiple times. After years of administrative process in response to the 2007 Petition to Revoke, in which registrants were afforded numerous opportunities to participate, and in light of the extensive scientific record EPA developed indicating chlorpyrifos is unsafe at current exposures, the Ninth Circuit said enough is enough and directed EPA to modify or revoke the chlorpyrifos tolerances "immediately" and without notice and comment. *LULAC II*, 996 F.3d at 702–03. No additional notice of its decision to revoke tolerances was required. *See* 21 U.S.C. § 346a(d)(4)(A)(i), Resp'ts' Add. at 9 (authorizing EPA to issue a "final regulation" without notice and comment in response to a petition to revoke).

For these reasons, EPA's assessment of registered uses in its aggregate exposure analysis was reasonable.

V. The FFDCA does not require EPA to cancel chlorpyrifos registrations before revoking tolerances.

Petitioners appear to argue that the FFDCA required EPA to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. *See* Pet'rs' Br. at 45-48. This argument misreads the FFDCA.

In support of their argument, Petitioners point to the FFDCA's direction that "the Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Thus, the FFDCA does not require EPA to cancel registrations *before* revoking tolerances. *See* Carbofuran; Final Tolerance Revocations Rule, 74 Fed. Reg. 23046, 23069 (May 15, 2009) ("Nothing in this provision establishes a predetermined order for how the Agency is to proceed to resolve dietary risks.") Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704.

Petitioners accuse EPA of trying to "have it both ways" by "claim[ing] that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses." Pet'rs' Br. at 49-50. Petitioners' apparent suggestion that the FFDCA requires EPA to utilize any FIFRA-specific process or considerations prior to revoking tolerances lacks any basis under the statute. And, in these particular circumstances, where the Ninth Circuit gave EPA a 60-day deadline to act and

rejected EPA's argument that a decision on tolerances should be delayed pending completion of registration review, EPA reasonably assessed the registrations that existed at the time. *See LULAC II,* 996 F.3d at 678, 691, 702. That assessment led to the Final Rule revoking all tolerances, *see supra* at 18–20, and then, after issuing the Final Rule, EPA began the extensive process under FIFRA of conforming registrations to the Final Rule.

Similarly without merit is Petitioners' suggestion (at 50–52) that EPA may modify registrations quickly without registrants' consent, such that the Agency could have cancelled or modified all registrations before the 60-day deadline to leave in place tolerances for the proposed subset of 11 uses. To the contrary, registrants whose registrations are subject to involuntary cancellation have substantial process rights, including the right to a hearing, appeal to the Environmental Appeals Board, all *before* the registration is actually cancelled, and judicial review. *See supra* at 8.[13]

Petitioners also ignore that EPA is proceeding with the cancellation of chlorpyrifos registrations in a timely manner. Following the expiration of

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[13] Relatedly, EPA lacks the authority to unilaterally modify pesticide labels. Instead, the registrant must submit an application to amend the label, which EPA may then approve. *See* 40 C.F.R. § 152.44(a). Where registrants do not submit revised labels for approval, EPA may take appropriate action under FIFRA, which may include initiating cancellation. *See* 7 U.S.C. § 136d(b); 40 C.F.R. § 155.58(d).

chlorpyrifos tolerances, EPA received several requests for voluntary cancellation of chlorpyrifos registrations and published a notice regarding 16 voluntary cancellations. 87 Fed. Reg. 25256 (Apr. 28, 2022). Moreover, EPA has consistently stated its intention to initiate involuntary cancellation proceedings for all registrations for which it does not receive a voluntary cancellation request.

Petitioners claim (at 53) that EPA's practice has been to modify or revoke tolerances to reflect analyses that a subset of uses are safe, and then modify registrations to reflect changes to those tolerances. Petitioners are wrong. For example, in the case of bifenthrin, after the registrants cancelled certain uses and amended labels to address residential application risks, there was sufficient room in the "risk cup" to establish new tolerances. *See* Bifenthrin, 86 Fed. Reg. at 68154; 86 Fed. Reg. at 38339. Petitioners cite (at 54) dicloran as a contrary example, claiming that there EPA first modified the tolerances for dicloran and later modified the registrations to reflect the tolerance modifications. But, in fact, EPA first terminated the uses of dicloran on potatoes and carrots in response to voluntary cancellation requests by the registrant. Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71022 (Nov. 16, 2011); Dicloran; Cancellation Order for Amendment to Terminate a Use of DCNA Pesticide Registrations, 75 Fed. Reg. 16105 (March 31, 2010). EPA subsequently revoked the tolerances for dicloran on potatoes and carrots. Dicloran and

Formetanate; Tolerance Actions, 77 Fed. Reg. 40812 (July 11, 2012).[14] Moreover, the dicloran tolerance actions were not taken to address safety, and instead served only to remove tolerances that were no longer necessary because of action by the registrant.

In sum, the FFDCA does not require that EPA cancel chlorpyrifos registrations before revoking tolerances.

CONCLUSION

For the foregoing reasons, EPA respectfully requests that the Court deny Petitioners' request to vacate the Final Rule and Denial Order. Petitioners' request for vacatur would leave all chlorpyrifos tolerances in place, despite the expert agency's conclusion that they are unsafe.

[14] Petitioners also cite Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4651 (Feb. 1, 2018) in support of their claim, however that order canceled uses unrelated to the cited tolerance actions.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1503

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

Petition for Review of Actions of the U.S. Environmental Protection Agency

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RESPONDENTS' ADDENDUM

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Current through Public Law 117-159, approved June 25, 2022.

§ 346a. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption.

(1) General rule. Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) Processed food. Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)].

(3) Residues of degradation products. If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a

residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) [21 USCS § 342(a)(2)(B)] despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) Effect of tolerance or exemption. While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1) [21 USCS § 342(a)(1)].

(b) Authority and standard for tolerance.

(1) Authority. The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) Standard.

(A) General rule.

(i) Standard. The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety. As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm

will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) Rule of construction. With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) Tolerances for eligible pesticide chemical residues.

(i) Definition. As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) Determination of tolerance. Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) Conditions regarding use. For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk. For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) Review. Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) Infants and children. Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children. In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold

effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) Factors. In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) Data and information regarding anticipated and actual residue levels.

(i) Authority. In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) Requirement. If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) Percent of food actually treated. In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) Detection methods.

(A) General rule. A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) Detection limit. A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) International standards. In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level,

the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) Authority and standard for exemptions.

(1) Authority. The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) Standard.

(A) General rule.

(i) Standard. The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) Determination of safety. The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) Factors. In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) Limitation. An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) Petition for tolerance or exemption.

(1) Petitions and petitioners. Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) Petition contents.

(A) Establishment. A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)

(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) Modification or revocation. The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) Notice. A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) Actions by the Administrator.

(A) In general. The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) Priorities. The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) Expedited review of certain petitions.

(i) Date certain for review. If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) Required determinations. If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) Action on Administrator's own initiative.

(1) General rule. The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) Notice. Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) Special data requirements.

(1) Requiring submission of additional data. If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS § 136a(c)(2)(B)];

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act [15 USCS § 2603]; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act [7 USCS § 136a(c)(2)(B) or 15 USCS § 2603];

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) Noncompliance. If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) Effective date, objections, hearings, and administrative review.

(1) Effective date. A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) Further proceedings.

(A) Objections. Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) Hearing. An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues

of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) Final decision. As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) Judicial review.

(1) Petition. In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) Record and jurisdiction. A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) Additional evidence. If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the

additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) Final judgment; Supreme Court review. The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) Application. Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) Confidentiality and use of data.

(1) General rule. Data and information that are or have been submitted to the Administrator under this section or section 409 [21 USCS § 349] in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS §§ 136a, 136h].

(2) Exceptions.

(A) In general. Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act [21 USCS §§ 301 et seq.] or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act [21 USCS §§ 301 et seq.] or such statutes.

(B) Congress. This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) Summaries. Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) Status of previously issued regulations.

(1) Regulations under section 406 [21 USCS § 346]. Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e) [21 USCS § 371(e)], under the authority of section 406(a) [21

USCS § 346(a)] upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) Regulations under section 409 [21 USCS § 349]. Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 [21 USCS § 349] on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) Regulations under section 408 [21 USCS § 348]. Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph [enacted Aug. 3, 1996] shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(4) Certain substances. With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 201(q)(1) [21 USCS § 321(q)(1)] but was so included on the day before the date of the enactment of the Antimicrobial Regulation Technical Corrections Act of 1998 [enacted Oct. 30, 1998], the following applies as of such date of enactment:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409 [21 USCS § 348].

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996 [enacted Aug. 3, 1996]) is deemed to have been issued under section 409 [21 USCS § 348].

(k) Transitional provision. If, on the day before the date of the enactment of this subsection [enacted Aug. 3, 1996], a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) [21 USCS § 321(s)] as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4) [21 USCS § 321(s)(4)];

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection [enacted Aug. 3, 1996]. The Administrator shall by regulation indicate which substances are described by this

subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) Harmonization with action under other laws.

(1) Coordination with FIFRA. To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS §§ 136 et seq.].

(2) Revocation of tolerance or exemption following cancellation of associated registrations. If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS §§ 136 et seq.], cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) Suspension of tolerance or exemption following suspension of associated registrations.

(A) Suspension. If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS §§ 136 et seq.], suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) Effect of suspension. The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act [7 USCS §§ 136 et seq.]. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be

In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review of an Order of the
U.S. Environmental Protection Agency

PETITIONERS' REPLY BRIEF

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INTRODUCTION

After working with registrants in 2019 to identify key U.S. crop uses for chlorpyrifos, the Environmental Protection Agency ("EPA" or the "Agency") used up-to-date science to determine that the tolerances for a subset of uses, on eleven crops, meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act ("FFDCA") (the "Safe Uses"). Despite that finding, which EPA announced in its Proposed Interim Decision ("PID") in 2020 and reaffirmed in the Final Rule and several times since, EPA elected to revoke ***all*** tolerances, including those the Agency found safe, at the expense of farmers across the country. Petitioners brought this action to preserve the Safe Uses and uphold EPA's own scientific analysis supporting them.[1]

EPA's various explanations for its overbroad decision all fail to meet the standard of reasonableness the Administrative Procedure Act ("APA") demands. EPA claims it could not have modified the tolerances

[1] EPA claims that Petitioners ask the Court to leave *all* chlorpyrifos tolerances in place. EPA Br. at 22 ("The ultimate relief sought by Petitioners in this case is the retention of *all* chlorpyrifos uses."). But Petitioners' request is more limited: that the Court direct EPA to act consistent with its safety finding and retain the Safe Uses, which Petitioners have made clear is a subset of all the tolerances. Pet'rs' Br. at 34.

consistent with its pre-existing safety finding in a timely fashion as directed by the Ninth Circuit, even though EPA had already done the necessary work to specify where and how chlorpyrifos can be used safely. The FFDCA's plain text required EPA to consider that safety determination and the underlying scientific data supporting it in issuing the Final Rule.

EPA seeks to distinguish that safety finding by advancing a new reading of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and FFDCA as entirely separate statutory regimes. But Congress linked the two statutory regimes in the Food Quality Protection Act ("FQPA"), mandating that the two statutes have ***the same safety standard*** for food use pesticides. There is no basis for EPA to claim its safety finding for chlorpyrifos applied only to FIFRA registration reviews and not to FFDCA tolerance decisions.

EPA also argues modification of tolerances under the FFDCA consistent with its safety finding was impossible without cancellations and label amendments under FIFRA. But neither FIFRA nor FFDCA require the Agency to have cancellation and label amendment requests in hand before modifying tolerances. As the Ninth Circuit recognized,

modification of tolerances could be followed by appropriate and orderly registration action. *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 703–04 (9th Cir. 2021) ("*LULAC II*"). Contrary to EPA's argument, the Ninth Circuit set no deadline for such action. *Id.*

Next, EPA shifts its position in this litigation regarding its obligations under the FFDCA. Although EPA first said it had no authority to allow continuation of a subset of tolerances that meet the safety standard, EPA now ***admits*** in its opposition brief it "has the authority to lower or revoke tolerances to reduce the number of approved uses for a pesticide." EPA Br. at 39. Nevertheless, EPA claims it could not do so "when it [had] no reason to believe that . . . changes [to the registrations were] imminent." EPA Br. at 46.

EPA's attempt to reframe the issue, from a matter of law to whether it had an "appropriate record" upon which to act, also fails. Revocation of tolerances means the pesticide can no longer be used on food crops, and is tantamount to cancellation of associated registrations under FIFRA. EPA should have reasonably expected growers to follow the law and that registrants would submit the corresponding label amendments. In any event, if EPA genuinely believed registration

amendments were needed to support a safety finding, it was obligated under 21 U.S.C. § 346a(f)(1) to formally request such amendments from the registrants, subject to revocation of all tolerances for non-compliance. In disregard of the statute, EPA never did so. Instead, EPA cut off discussions with Gharda at the last minute in an apparent attempt to ensure the record did not contain a "reasonable basis" on which the Agency could rely. This was neither lawful nor reasonable.

At the end of the day, this Court has a legal question to decide—not a scientific one: may EPA cast aside its own science, the language of the FFDCA, and its prior practice, to make a counterfactual finding that no use of chlorpyrifos would be safe? EPA agrees "this is ultimately a question of law and not one of fact." Pet. Add. 42. For the reasons set forth in Petitioners' Opening Brief and those set forth below, the answer to this legal question is clear: EPA cannot do so.

The Court should vacate the Final Rule and remand it with instructions to issue a rule conforming to the evidence and retaining tolerances for the Safe Uses.

ARGUMENT

I. EPA made the required safety finding, determining eleven food uses for chlorpyrifos are safe.

A. EPA's safety finding, announced in the PID as a determination made by the Agency, was the product of rigorous scientific analysis that EPA does not dispute.

In its 2020 PID, EPA announced it had identified eleven Safe Uses of chlorpyrifos "that the agency has determined will not pose potential risks of concern" within the ten-fold margin of safety required by the FQPA. A.R. 40 at 40; Pet. App. 405.[2] EPA had a well-reasoned basis for focusing its safety analyses on the eleven uses, following a fulsome, methodical process for selecting those uses.[3] EPA based its PID determination that the Safe Uses are safe on, among other findings, the conclusions in EPA's third revised human health risk assessment and

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[2] As discussed below, the FQPA established a unified safety standard under FFDCA and FIFRA for food use pesticides such as chlorpyrifos. *Infra* at Part I.C.

[3] Six uses (alfalfa, citrus, cotton, soybean, sugarbeet, and wheat) were identified as "critical" in EPA's meetings with the lead registrant in 2019. *See* A.R. 40 at 41–42; Pet. App. 406–07; *see also* Supp. Pet. App. 1 (summarizing three EPA meetings with then-lead registrant Corteva regarding "critical uses" of chlorpyrifos). EPA identified the remaining uses (apple, asparagus, cherry, peach, and strawberry) as high-benefit uses, based on its own analyses.

its 2020 drinking water assessment ("the Scientific Assessments") concerning what uses of chlorpyrifos had "reasonable certainty of no harm" for human health. A.R. 40 at 12–19; Pet. App. 377-84. The Scientific Assessments were the result of extensive analysis by EPA's expert scientists, and underwent an unprecedented level of peer review. A.R. 2, 38; Pet. App. 1, 157. EPA's Scientific Assessments were complete and detailed in Agency memoranda spanning hundreds of pages. A.R. 2, 38; Pet. App. 1, 157. Because the Agency considered the scientific evidence final, EPA stated in the PID that "the agency has determined" the Safe Uses would pose no potential risks of concern under the FQPA's most protective safety standard. A.R. 40 at 40; Pet. App. 405. Even now, EPA does not question the findings of its Scientific Assessments.

> EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [the Safe Uses]. . . .

Pet. Add. 42.

EPA's decision to strike down the tolerances associated with the Safe Uses had nothing to do with the state of the science. Nowhere does

EPA make the argument that the relief requested by Petitioners—preservation of the Safe Uses—would not be safe. In fact, EPA has suggested ***additional*** uses could also be found safe. A.R. 40 at 40; Pet. App. 405.

Although EPA's Brief references studies claiming associations between chlorpyrifos and neurodevelopmental effects in an effort to defend the Final Rule, EPA Br. at 27–28, that is not what EPA's science or EPA's scientists say. The Final Rule and Denial Order, Pet. Add. 23–74, did nothing to retreat from the PID's safety finding and EPA's determination that studies on alleged neurodevelopmental effects are not strong enough to change the current regulatory standard, A.R. 40 at 40. Applying that standard and a ten-fold margin of safety to protect infants and children, EPA's scientists found the Safe Uses are indeed safe. A.R. 40 at 10, 40; Pet. App. 375, 405.

B. EPA cannot disregard its own scientific conclusions and findings as a mere "proposal."

EPA would have this Court cast aside the Scientific Assessments underpinning the PID because EPA summarized them and announced its safety determination in a document labeled as a "proposed" decision. EPA Br. at 32–36. Such a label cannot mask the truth: EPA "does not

dispute its own scientific conclusions and findings" announced in the PID and agrees they "could support a safety determination" for the Safe Uses at the time it issued the Final Rule. Pet. Add. 42.

Moreover, invoking the "proposed" label cannot cure EPA's violation of law by ignoring its own scientific conclusions and findings described in the PID. 21 U.S.C. § 346a(b)(2)(D), which identifies the "factors" EPA must consider in making tolerance decisions, states no fewer than six times EPA "shall" base such decisions on "available data" and "available information." 21 U.S.C. §§ 346a(b)(2)(D)(i), (iii), (iv), (v), (vi), and (vii); *see also* Pet'rs' Br. at 8. This repeated statutory command is not qualified—if the specified information and data are available, then EPA must consider them regardless of whether such data and information have been through notice and comment rulemaking. Those repeated commands are reinforced by the plain text of § 346a(d)(4)(A)(i). That section, applicable to the Final Rule, requires EPA to consider "***any*** other information available to the Administrator" in issuing a final rule in response to a petition, and to do so "***without*** further notice and ***without*** further period for public comment." *Id.* § 346a(d)(4)(A)(i)

(emphases added); *see* A.R. 1 at 48,316; Pet. Add. 2 (purporting to proceed under 21 U.S.C. § 346a(d)(4)(A)(i)).

The "available data" and "available information" when EPA issued the Final Rule plainly include the Scientific Assessments underlying the PID and EPA's determination that the Safe Uses meet the FFDCA safety standard. Pet'rs' Br. at 56. The FFDCA therefore ***required*** EPA to consider the Scientific Assessments and EPA's safety determination, even though EPA claims it had not completed review of comments on the PID. 21 U.S.C. § 346a(d)(4)(A)(i) (EPA "shall" consider "***any*** other information available" (emphasis added)); *see Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) ("[r]ead naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'"). The FFDCA's plain text defeats EPA's argument that EPA could ignore the PID as a "proposal."[4]

[4] Similarly, the Ninth Circuit acknowledged the PID and noted that if, on this basis, EPA could conclude certain tolerances were safe, EPA could then modify chlorpyrifos tolerances rather than cancelling them. *LULAC II*, 996 F.3d at 702–03. The Ninth Circuit, with full knowledge of the PID, ordered the Agency to act on the available evidence ***without*** going through any further notice and comment procedures. *Id.*

Moreover, EPA's argument conflates the process through which the Agency announced its safety determination (the PID) with the determination itself and the Scientific Assessments undergirding it. This is clear in the text of the PID, which refers to a determination the Agency has made on the safety of the Safe Uses, A.R. 40 at 40; Pet. App. 405, and announced EPA would take comment on whether ***additional*** uses could also be found safe under the FFDCA safety standard. A.R. 40 at 40; Pet. App. 405. EPA cannot ignore its Scientific Assessments and safety determination just because they are part of a proposal made under FIFRA to narrow the uses of chlorpyrifos.[5]

In any event, as Petitioners have explained, EPA often takes action based on proposed interim registration review decisions. For example, in the case of the fungicide famoxadone, "a registrant agreed to make certain changes to uses . . . based on EPA's proposed interim registration review decision." Pet'rs' Br. at 59. To this point, EPA's brief has no response. Nor could it, because this was precisely the course of dealing EPA followed with Gharda, in the extensive

[5] As explained below, EPA's settled approach is to make FFDCA safety findings on the basis of "proposed" uses—the very thing set forth in the PID. *Infra* at pp. 17–18, 19 n.13.

negotiations that occurred between issuance of the *LULAC II* order and EPA's silent termination of discussions in the weeks leading up to the revocation of all tolerances. Pet. App. 1611–25. If the PID's safety determination was meaningless, EPA would not have used it as a baseline for negotiation with Gharda on narrowing uses in the record leading up to the Final Rule. Pet'rs' Br. at 60–61. EPA's response makes no attempt to reconcile this course of dealing with its litigation position.[6]

C. EPA's PID safety finding applies to action on tolerances under the FFDCA.

Unable to sideline the PID's safety finding and EPA's scientific conclusions as a "proposal," EPA tries to distinguish them instead—claiming incorrectly that the PID was a FIFRA-based analysis, separate from the "reasonable certainty of no harm" safety standard applicable to tolerances under the FFDCA. EPA Br. at 23, 32. But under both

[6] EPA cites the example of oxadiazon in an attempt to justify ignoring the PID and its scientific conclusions. EPA Br. at 33–34 (noting a change from the PID to the final decision). But oxadiazon has no tolerances because it is not a food use pesticide. Resp'ts' App. 647, 656, 689. It therefore has nothing to do with the question presented here: what the FFDCA requires EPA to consider in making a tolerance decision.

FIFRA and FFDCA, there is only one definition of "safe" applicable to food use pesticides such as chlorpyrifos. Congress, in passage of the FQPA in 1996, required the same safety standard for food use pesticides for both FIFRA and FFDCA. Food Quality Protection Act, 110 Stat. 1489 (1996). Congress did so by making the FIFRA "unreasonable adverse effects" standard expressly incorporate the FFDCA's "reasonable certainty of no harm" standard. 7 U.S.C. § 136(bb)(2). There has been no "separate" definition for the safety of food use pesticides under FIFRA and FFDCA, as EPA claims, EPA Br. at 41, since passage of the FQPA in 1996. *LULAC II*, 996 F.3d at 680 ("FIFRA incorporates the FFDCA safety standard for food uses . . . ."). When EPA announced in the PID it had determined the Safe Uses "will not pose potential risks of concern with an FQPA safety factor of 10X [i.e., a ten-fold margin of safety]," A.R. 40 at 40, Pet. App. 405, that finding satisfies both FIFRA's and FFDCA's requirements concerning safety.

EPA cannot now claim otherwise. It acknowledged the relevance of the PID to the FFDCA safety determination when it brought the PID to the attention of the Ninth Circuit using FRAP 28(j)—reserved for "pertinent and significant authorit[y]" on issues before an appellate

court. Fed. R. App. P. 28(j); Supp. Pet. App. 33. And the Ninth Circuit clearly understood the "pertinen[ce]" and "significan[ce]" of the PID, as EPA intended: referencing the PID and noting EPA could, based upon this "further research," "modify chlorpyrifos registrations rather than cancelling them." *LULAC II*, 996 F.3d at 703.[7]

The PID announced the necessary safety determination that would support continuation of the tolerances associated with the Safe Uses. Pet. Add. 42 (EPA's "own scientific conclusions and findings in the 2020 PID . . . could support a safety determination" for the Safe Uses). EPA's attempt to distinguish the PID's safety determination simply has no basis.

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[7] Although EPA implies *LULAC II* supports its new paradigm of FIFRA/FFDCA "separat[ion]," EPA Br. at 14, that is not the case. In *LULAC II*, the Ninth Circuit admonished EPA for deferring action on a petition raising safety concerns until completion of registration review. 996 F.3d at 678, 691. Here, in contrast, EPA had ***already made*** a safety determination as to the Safe Uses, consistent with its obligations under the FFDCA. The Ninth Circuit's timing concerns related to a petition do not justify EPA's inaction on an existing safety determination. The Ninth's Circuit's recognition that the FFDCA "requires that the EPA make a safety determination based on whatever 'information' is 'available'," *id.* at 698, and that EPA could modify chlorpyrifos tolerances on the basis of the PID, *id.* at 703, confirms EPA should have considered the PID in the Final Rule.

II. The FFDCA and APA required EPA to act on its safety finding and modify the chlorpyrifos tolerances accordingly.

A. EPA must make tolerance decisions individually based on the available scientific evidence.

As Petitioners have shown, the text of the FFDCA requires EPA to make tolerance decisions individually and on the basis of available data and information—not "in gross" or in a counterfactual manner. Pet'rs' Br. at 42–47.[8] The FFDCA requires EPA to "modify or revoke ***a*** tolerance if the Administrator determines ***it*** is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). This clearly prescribes aligning specific tolerances with EPA's safety determination—leaving in effect those individual tolerances found safe and modifying or revoking the remainder. Pet'rs' Br. at 43–44. EPA's position would rewrite the FFDCA to say EPA may

[8] EPA claims Petitioners waived the argument that EPA violated the FFDCA by not taking a tolerance-by-tolerance approach. EPA Br. at 37. Not true. Petitioners made that argument and quoted to EPA the same sections of the FFDCA relied upon here. "To fail to leave in effect the 11 tolerances for which the PID's science-based conclusions have already supported a safety finding runs afoul of the express direction in Section 408(b)(2)." A.R. 45 at 6; Pet. App. 1150. As explained earlier in that discussion, "Section 408(b)(2) of the FFDCA directs that EPA may 'leave in effect a tolerance . . . if the Administrator determines that the tolerance is safe.' And '[t]he Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.'" A.R. 45 at 6; Pet. App. 1150; *see also* Pet. App. 1653–54, 1669–70.

"revoke ***all*** tolerances if the Administrator determines that ***any*** is not safe." Such text is nowhere in the statute. Moreover, that interpretation would read out of the statute the provisions on modification of tolerances. *Id.* 42–47.[9] Because EPA did not consider the available evidence and its safety determination for the Safe Uses—revoking all tolerances instead of modifying them to conform to its existing safety determination—EPA violated the FFDCA.

EPA attempts to justify ignoring the available data and information, and making the counterfactual finding that no tolerance would be safe, by advancing novel and erroneous interpretations of the FFDCA. In the course of this case, EPA has contradicted itself numerous times on the meaning of the FFDCA. EPA previously argued the FFDCA prohibited it from eliminating certain uses and making a safety finding for the remainder. Supp. Pet. App. 22. EPA now ***agrees*** the FFDCA allows it to do just that—abandoning its prior position—while trying to maintain it is not required to do so. EPA Br. at 39.

[9] EPA argues its regulation of carbofuran supports its decision here. EPA Br. at 38, 43–44. But there, EPA did not have a PID concluding that a subset of uses were safe. The carbofuran example provides no support for EPA's Final Rule.

EPA's new litigation position that it is not required to eliminate certain uses while maintaining those it found safe is just as flawed, as discussed below.

B. The FFDCA does not confine EPA to assess tolerance safety based on "existing registered uses" alone.

EPA claims the FFDCA requires it to consider aggregate exposure "based on existing registered (i.e., legally permitted) uses." EPA Br. at 22. But the language quoted from EPA's brief is not found in the statute. *See Lamie v. U.S. Tr.*, 540 U.S. 526, 538 (2004) (rejecting construction that "would have us read an absent word into the statute"). Instead, the FFDCA refers to safety decisions based upon "anticipated" exposures. 21 U.S.C. § 346a(b)(2)(A)(ii). "Anticipated" has a plain meaning—something "expected" or "looked forward to."[10] It does not mean "existing." If EPA could consider only existing uses, and on that basis had to make a single up-or-down safety determination applicable to the entire set, then EPA could never revoke or modify tolerances

[10] Anticipated, Merriamwebster.com, https://www.merriam-webster.com/dictionary/anticipated (last visited Sept. 1, 2022).

selectively to reduce the number of uses. But EPA now admits it can do just that. EPA Br. at 39.

EPA points to another provision of the FFDCA, 21 U.S.C § 346a(b)(2)(D)(vi), as support for its argument that anticipated exposures means exposures from existing registered uses. EPA Br. at 37. But the FFDCA's structure makes clear that consideration of existing approved uses is only the starting point for a safety determination—including this as one of nine factors EPA should consider in addition to available data and information in 21 U.S.C. §§ 346a(b)(2)(D)(i)-(ix), along with "anticipated" exposures, *id.* § 346a(b)(2)(A)(ii). EPA has elsewhere confirmed the universe of approved uses is just the "***starting point***" for EPA's risk assessment, which will also consider "proposed uses." A.R. 16 at 44–45; Resp'ts' App. 46–47 (emphasis added).[11]

Although the FFDCA requires EPA to assess "aggregate exposure" in making the safety determination, this cannot be read as code that re-

[11] The PID provided just such a proposal for limited uses. A.R. 40 at 40; Pet. App. 405. No authority exists for the proposition that only registrants have the power to define the "proposed" uses for EPA's FFDCA safety finding, or a formal proposal issued by EPA limiting such uses must be ignored.

writes the explicit text of the statute. The FFDCA requires EPA to make individualized safety determinations, 21 U.S.C. § 346a(b)(2)(A)(i), on the basis of available data and information, *id.* § 346a(b)(2)(D)(i), including any proposed uses and the corresponding "anticipated" exposures, *id.* § 346a(b)(2)(A)(ii). The reference to "aggregate exposure" naturally fits with these other provisions of the statute to instruct EPA to consider, in making its individual tolerance determinations, all the exposures a person is anticipated to encounter.[12]

This is in fact the approach EPA employed in the PID. EPA considered all chlorpyrifos tolerances "in effect" and concluded those uses would not fit within the metaphorical "risk cup." EPA then analyzed a subset of uses—the eleven Safe Uses—which would reduce

[12] EPA wisely elects not to invoke *Chevron* or any other argument for deference to its litigation position. Where an agency ignores the plain text of the statute and its settled application, and advances inconsistent interpretations in the very course of litigation, it can make no claim to deference. *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (collecting cases). And because EPA does not seek deference, this Court can provide none. *See Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 140 S. Ct. 789, 790 (2020) (court should not apply *Chevron* deference where agency fails to invoke it).

risk to acceptable levels, made a safety finding as to those uses, and set forth its conclusions in the PID.[13]

C. EPA does not need cancellations and label amendments from registrants to act on its FFDCA safety finding.

EPA argues it had to have cancellation and label amendment requests from all registrants in hand, narrowing the permitted uses to those set forth in the PID, before acting on its safety finding. EPA Br. at 49. This ignores the plain text of the FFDCA and FIFRA and the legal and practical effect of tolerance modification.

The FFDCA says EPA must consider "anticipated" exposures. If a tolerance does not satisfy the "reasonable certainty of no harm" safety standard, the FIFRA registration standard for that use is also not satisfied. *See* 7 U.S.C. § 136(bb)(2). Without a tolerance or existing stocks provision in place, it is illegal to distribute and sell a product

[13] Petitioners have pointed to several examples in which EPA made individual tolerance determinations for other pesticides. Pet'rs' Br. at 46–47. EPA claims these examples are distinguishable, because in those instances aggregate exposures did not exceed levels of concern. EPA Br. at 45. EPA ignores the fact that the FFDCA's text and structure do not change depending upon whether the "risk cup" overflows. Congress mandated that EPA make individual tolerance determinations based upon the available science and "anticipated" exposures, which requires EPA to analyze proposed uses.

labeled for that use. *See, e.g.*, 7 U.S.C. § 136j(a)(2)(S) (unlawful to violate regulation issued under FIFRA); 40 C.F.R. § 152.50(i) (establishing a tolerance as a requirement for registration of a food use pesticide). Moreover, foods containing residues not covered by a tolerance are deemed adulterated and may not be distributed in interstate commerce. 21 U.S.C. § 331(a); *id.* § 342(a)(2)(B). Thus, if EPA had in the Final Rule followed the science and revoked all tolerances other than those corresponding to the Safe Uses, it would have effectively banned any food uses other than the Safe Uses. EPA confirmed this in a Federal Register notice on the cancellation of some chlorpyrifos registrations. Cancellation Order for Certain Chlorpyrifos Registrations, 87 Fed. Reg. 53,471, 53,472 (Aug. 31, 2022) ("Once the tolerances expired, pesticide products containing chlorpyrifos could no longer be used on food crops."). EPA therefore certainly should have "anticipated" that regulated parties would follow the law and give up uses made unlawful by a tolerance revocation. Indeed, it would have been unreasonable and arbitrary and capricious for an agency to assume otherwise. *See Shays v. FEC*, 511 F. Supp. 2d 19, 28–29

(D.D.C. 2007) (rejecting agency argument that assumed regulated entities would not comply with rules unless prosecuted).

D. EPA's failure to act on its safety finding violates the APA.

Petitioners maintain the FFDCA by its plain terms required EPA to follow the science (specifically, the "available data" and "available information" on risk) and make safety decisions on individual tolerances by continuing those associated with the Safe Uses and revoking the rest. *Supra* at Part I.B. Importantly, however, this Court does not need to reach that issue in order for Petitioners to prevail. EPA's concession that it has the authority under the FFDCA to eliminate uses and make a safety finding on tolerances for the remainder, EPA Br. at 39, means EPA's failure to do so in this instance violated the APA.

The APA deems arbitrary and capricious agency actions that "run[] counter to the evidence." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must "examine the relevant data and articulate a satisfactory explanation for its action"); 5 U.S.C. § 706(2)(A). EPA had at its disposal scientific evidence—developed by expert Agency scientists in highly sophisticated, peer-reviewed risk assessments—that the Safe Uses are

safe within the meaning of the FFDCA. *Supra* at Part I.A. EPA was required by the FFDCA and the APA (and the Ninth Circuit decision in *LULAC II*) to act on the evidence before it, which included the Scientific Assessments. 21 U.S.C. § 346a(b)(2)(D)(i); 5 U.S.C. § 706(2)(A); 996 F.3d at 703. Based on these Scientific Assessments, EPA "determined" in 2020 the Safe Uses met the FFDCA safety standard with a tenfold margin of safety. A.R. 40 at 40. EPA's decision to disregard the best available scientific evidence and its existing safety determination, and therefore revoke all tolerances, is arbitrary and capricious.[14]

III. EPA's new argument that it lacked the necessary record basis to act on its safety finding ignores the plain language of the statute and the undisputed facts.

As noted above, the latest evolution in EPA's argument concedes the FFDCA allows EPA to revoke or modify tolerances to conform to its safety finding, but contends it did not have a sufficient record upon which to do so. Specifically, EPA now claims it could modify tolerances to conform them to its PID safety finding as long as it had a "reasonable

[14] EPA's response ignores the case law cited in Petitioners' brief making it clear an agency may not disregard scientific evidence just because it may later be revised. *See* Pet'rs' Br. at 40–41, 56.

basis" to believe FIFRA registrations would be modified accordingly and within the time prescribed by the Ninth Circuit. EPA Br. at 49–51. The Ninth Circuit set no deadline for action on FIFRA registrations, ordering instead that they follow the tolerance decisions "in a timely fashion" after action on the tolerances. 996 F.3d at 704.[15] This "deciding question," as EPA characterizes it, thus boils down to whether some "reasonable basis" existed to believe registrations would be modified to eliminate all but the Safe Uses.

There is no question EPA had a "reasonable basis" to expect modification of chlorpyrifos registrations. As explained above, the practical effect of tolerance revocation is a ban on the use of the pesticide. *Supra* at pp. 19–20. For that reason, conforming voluntary cancellations and label amendment requests follow tolerance decisions with no less regularity than night following day. Indeed, that is just what occurred here. EPA Br. at 54–55 ("Following the expiration of

[15] EPA's argument that registration changes would have to occur before tolerance decisions is contrary to the Ninth Circuit's order. It also ignores the central issue decided by the Ninth Circuit against EPA in *LULAC II*: EPA cannot require that tolerance decisions under FFDCA in response to a petition be "synchronize[d]" with FIFRA processes. 996 F.3d at 696.

chlorpyrifos tolerances, EPA received several requests for voluntary cancellation of chlorpyrifos registrations and published a notice regarding the 16 voluntary cancellations.") (citing 87 Fed. Reg. 25,256 (Apr. 28, 2022)). ***After*** revoking all chlorpyrifos tolerances, EPA sent a letter to registrants setting a deadline for registrants to submit cancellation requests and label amendments removing all food uses.[16] It would have been a simple matter for EPA to respond to *LULAC II* by issuing a final rule revoking all tolerances other than those associated with the Safe Uses, then issue a similar letter requiring registrants to make the necessary label amendments or cancel the registrations. Although EPA says additional geographic and application restrictions would need to be incorporated into the revised labels to conform to its safety finding, that is easily done. EPA had all the necessary information, including the geographic restrictions, A.R. 40 at 40; Pet.

[16] EPA posted some of the cancellation request letters to a public docket, available here: https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0223; *see, e.g.,* EPA-HQ-OPP-2022-0223-0017 (registrant letter referencing EPA March 3, 2022 letter). EPA omitted from this docket the voluntary cancellation request Gharda submitted, agreeing to voluntary cancellation for all but the Safe Uses. Pending the outcome of this litigation, Gharda also agreed not to sell any chlorpyrifos products labeled for food use.

App. 405, and application rates, A.R. 38 at 33–34; Pet. App. 34-35. Similar to other use changes, these modifications can be accomplished by amendments to the label through EPA's standardized Fast Track amendment process, through which EPA approves over a thousand amendments each year.

Ignoring these facts, EPA claims it would have a "reasonable basis" to anticipate narrowing of the uses only if it has cancellation and label amendment requests in hand to amend the underlying registrations to incorporate the PID's description of the Safe Uses. EPA Br. at 39–40, 51. In other words, EPA does not stop with asking the Court to insert an additional phrase ("reasonable basis") into the FFDCA—it then immediately asks the Court to translate that insertion into an "cancellation/amendments in hand" requirement. Without having those cancellation and label amendment requests in hand when the deadline arrived for a decision, EPA claims, it could do nothing other than declare everything unsafe. *Id.* Of course, EPA cites no statute, no regulation, and no case law for this proposition. Nor can EPA cite any example in which a Court countenanced such exponential rewriting of clear statutory text.

If the "cancellation/amendments in hand" requirement actually existed, one would think EPA could find some legal authority for it. One would also think EPA would have noted the existence of this requirement in its discussions with Gharda and specified the deadline. That never happened. Rather than telling Gharda what was required and setting a deadline for its submission, EPA mysteriously stopped communicating with Gharda entirely. Pet. App. 1611–25. No clearer evidence could exist that EPA's "cancellation/amendments in hand" requirement is a made up litigation position.

EPA's problems with its argument for a "cancellation/amendments in hand" requirement go beyond its dubious origin and lack of legal foundation. Even if it were credible, this argument runs headlong into the FFDCA's plain text, which places ***upon EPA*** the statutory duty to obtain from registrants the information necessary to determine whether existing tolerances can continue. The FFDCA requires EPA to take affirmative steps to request any "information" from registrants necessary to support continuation of an existing tolerance. "If the Administrator determines that additional data ***or information*** are reasonably required to support the continuation of a tolerance . . . . the

Administrator ***shall*** – [inter alia] (A) issue a notice requiring the [registrant] to submit the data or information . . . ." 21 U.S.C. § 346a(f)(1) (emphases added). This provision plainly applies to the decision EPA was making here—whether any existing chlorpyrifos tolerances could continue. The "information" EPA may demand from registrants in this circumstance includes information concerning the product label. *See* 40 C.F.R. § 156.10 (EPA regulation referring to label contents as "information"); 7 U.S.C. § 136(q)(1)(E) (FIFRA provision specifying label contents as "information"). If registrants do not provide EPA with the information required—which may include label amendments—the tolerances will be revoked. 21 U.S.C. §346a(f)(2). EPA's claim that it lacked the "tools" in the FFDCA necessary to get the information that would provide it a "reasonable basis" to reduce the number of approved uses, EPA Br. at 39, is false.

Not only did EPA have the tools to obtain the necessary information from registrants—it had the statutory obligation to use them as necessary to make its decision on continuing existing tolerances. 21 U.S.C. § 346a(f)(1) (EPA "shall" take one of the

enumerated steps to obtain information "reasonably required").[17] But EPA did no such thing. Thus, even if it was true that the record lacked information concerning label amendments "reasonably required" for EPA to make a decision on tolerances, as EPA now contends, that would be due to EPA's violation of the FFDCA—not the fault of Gharda or any registrant.

The record evidence makes this clear. EPA and Gharda communicated for months about potential narrowing of uses, EPA's issuance of a safety finding on those narrowed uses consistent with the PID, and EPA's promulgation of an existing stocks order to cover the revoked uses. These negotiations were drawn out and complicated by EPA, not by Gharda. Pet'rs' Br. at 52–53. Throughout all these discussions, EPA never set a deadline for Gharda to submit a voluntary cancellation request, and never notified Gharda this was the only way EPA would be able to "anticipate" narrowing of uses in making a safety finding. EPA implies Gharda made an informed decision not to submit

[17] Congress sensibly provided EPA the tools to obtain information and obligated the Agency to use them when necessary to support continuation of a tolerance. This protects the reliance interests of third parties such as Grower Petitioners, and the public at large, in a reliable and safe food supply.

a voluntary cancellation decision at its peril. EPA Br. at 51. Not true. The parties were nearing the final stages of months of negotiations on an agreement to retain a subset of uses—consistent with the PID—when EPA abruptly stopped communicating with Gharda about the process and what was required. Pet. App. 1611–25.[18] EPA advised Gharda to standby until EPA requested a voluntary cancellation letter memorializing the agreed terms, Pet. App. 1622–25; then EPA revoked all tolerances, claiming it had to do so in the absence of additional information from the registrants. That is contrary to what Congress commanded EPA do. *See* 21 U.S.C. § 346a(f)(1). And that is not the "fair" harmonization of the FFDCA and FIFRA Congress intended. H.R. Rep. No. 104-669(II), 104th Cong. at 51 (1996). Not only did EPA's unlawful actions harm Gharda; its actions unfairly deprived Grower

[18] EPA acknowledges these types of informal discussions with registrants are customary and how registrations are often amended to conform to tolerance determinations. *See* EPA Br. at 46. The Agency is not without authority to act on its own, however, if it genuinely believes it needs additional information to support its action. *Supra* at pp. 26–28.

Petitioners of a critical crop protection tool upon which Grower Petitioners depend.[19]

CONCLUSION

EPA's Final Rule violated the FFDCA and the APA. EPA's attempts to defend it have no support in the FFDCA, the regulations, or the case law—including *LULAC II*. In fact, EPA violated the remand instructions of *LULAC II* by refusing to act on the available evidence, and continues to ignore *LULAC II*'s central holding by arguing that FIFRA registration proceedings should conclude before making tolerance safety decisions.

Petitioners respectfully request that the Court grant Petitioners' request to vacate the Final Rule and Denial Order and remand with instructions that EPA issue a final rule conforming to the FFDCA and its mandate to consider the "available" scientific evidence and the "anticipated" exposures from the "proposed" uses identified in the PID.

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[19] EPA's suggestion that Gharda is not without a remedy because it can simply petition for new tolerances is not reasonable. First, this ignores the time and expense involved for Gharda. *See* Pet. App. 1795 ¶¶5–6. Second, that would do nothing for the Grower Petitioners whose crops will be severely damaged by pests without the immediate use of chlorpyrifos.

Contrary to EPA's claim, those instructions would not require EPA to retain all tolerances. EPA Br. at 22, 56. Instead, Petitioners request that the Court direct EPA to act consistent with its safety finding and retain the tolerances for the Safe Uses. Consistent with the Ninth Circuit's remand instructions, this Court should order EPA to do so immediately and without further notice and comment, under 21 U.S.C. § 346a(d)(4)(A)(i).

September 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply Brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 6380 words.

I further certify that Petitioners' Brief complies with the typeface and type style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), as it was prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Pursuant to Eighth Circuit Rule 28A(h)(2), I certify that the electronic version of this Brief has been scanned for viruses and is virus-free.

September 2, 2022

s/ Nash E. Long
Nash E. Long

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 2, 2022, a true and accurate copy of the foregoing Reply Brief was electronically filed with the United States Court of Appeals for the Eighth Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, Petitioners will serve each party separately represented with a paper copy of the brief.

I further certify that ten (10) paper copies of the foregoing Brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Rule 28A(d).

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December 14, 2022

VIA ELECTRONIC FILING

Michael E. Gans, Clerk of Court
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton United States Courthouse
111 South 10th Street
St. Louis, MO 63102

Re: Federal Rule of Appellate Procedure 28(j) Letter for *Red River Valley Sugarbeet Growers Association, et al. v. Michael Regan, et al.*
Nos. 22-1422(lead), 22-1530

Dear Mr. Gans:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, Petitioners write to alert the Court to "pertinent and significant authorities" that have come to their attention since filing their brief.

On December 14, 2022, the U.S. Environmental Protection Agency ("EPA") announced in the Federal Register its intent to cancel registrations of three pesticide products for which Petitioner Gharda is the registrant due to the tolerance revocation at issue here. *Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations*, 87 Fed. Reg. 76,474 (Dec. 14, 2022) (Ex. A).

The Notice supports Petitioners' arguments for at least five reasons. First, the Notice reaffirms EPA's determination that the 11 Safe Uses are safe. Ex. A at 76,479–80. Second, EPA's action confirms that registration changes did not have to precede tolerance decisions as EPA contends. Third, the Notice shows that all chlorpyrifos registrations have been withdrawn, except those for the Safe Uses

held by Gharda that are the subject of the Notice,[1] further demonstrating that EPA could have reasonably anticipated that registration changes would have followed tolerance revocation since treated food cannot enter interstate commerce without tolerances in place. Ex A. at 76,475, 76,476. Fourth, the Notice shows that the U.S. Department of Agriculture ("USDA") has "major concerns" about EPA's decision, including that EPA should have retained the 11 Safe Uses. *Id.* at 76,478. In fact, USDA challenged EPA's tolerance revocation action as inconsistent with settled Agency practice and urged EPA "to follow the science and maintain safe use of chlorpyrifos for [the] 11 crops." Ex. C at 3; *see also* Ex. D (Secretary Vilsack expressing that USDA scientists believe tolerances for the 11 Safe Uses should be retained). Fifth, EPA's Notice improperly attempts to leverage the unlawful tolerance revocation in the final rule while it remains subject to this Court's review. Ex. A at 76,476.

Respectfully submitted,

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[1] The Notice implies that Gharda is still selling chlorpyrifos products labeled for food use, omitting that Gharda has not done so and committed in writing to EPA to not do so while the litigation is pending. *See* Ex. B.

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CERTIFICATE OF SERVICE

I certify that on this 14th day of December, 2022, a copy of the foregoing Federal Rule of Appellate Procedure 28(j) Letter was served electronically through the Court's CM/ECF system on all registered counsel.

s/ Nash E. Long
Nash E. Long

EXHIBIT A

Chlorpyrifos: Notice of Intent to Cancel Pesticide Registrations
87 Fed. Reg. 76,747
December 14, 2022

of Environmental Conservation (DEC) of the following:

Date of Receipt of the Certification Request: November 30, 2022.

Reasonable Period of Time to Act on the Certification Request: One year (November 30, 2023).

If the New York DEC fails or refuses to act on the water quality certification request on or before the above date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: December 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–27127 Filed 12–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Denial of Water Quality Certification

	Project No.
Eagle Creek Hydro Power, LLC Eagle Creek Water Resources, LLC. Eagle Creek Land Resources, LLC.	9690–115
Eagle Creek Hydro Power, LLC Eagle Creek Water Resources, LLC. Eagle Creek Land Resources, LLC.	10481–069
Eagle Creek Hydro Power, LLC Eagle Creek Water Resources, LLC. Eagle Creek Land Resources, LLC.	10482–122

On March 31, 2020, Eagle Creek Hydro Power, LLC, Eagle Creek Water Resources, LLC, and Eagle Creek Land Resources, LLC (co-licensees collectively referred to as Eagle Creek) jointly filed an application for a new license for each of the ''Mongaup River Projects'' consisting of the Swinging Bridge Hydroelectric Project (P–10482), Mongaup Falls Hydroelectric Project (P–10481), and the Rio Hydroelectric Project (P–9690). Eagle Creek filed with the New York Department of Environmental Conservation (New York DEC) a request for water quality certification for the Mongaup River Projects under section 401(a)(1) of the Clean Water Act on March 30, 2021. On March 24, 2022, the New York DEC denied certification for the project. Eagle Creek filed a copy of New York DEC's denial of certification on November 14, 2022. Pursuant to 40 CFR 121.8, we are providing notice that New York DEC's denial satisfies the requirements of 40 CFR 121.7(e).

Dated: December 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–27121 Filed 12–13–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0417; FRL–10108–01–OCSPP]

Chlorpyrifos; Notice of Intent To Cancel Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) hereby announces its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the Agency's revocation of all tolerances for chlorpyrifos. This document identifies the products at issue, summarizes EPA's basis for this Notice of Intent to Cancel (NOIC), and explains how adversely affected persons may request a hearing and the consequences of requesting or failing to request such a hearing.

DATES: The affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before January 13, 2023, whichever occurs later. Other adversely affected parties must request a hearing on or before January 13, 2023. Please see unit VII. for specific instructions.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2022–0417, is available online at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.* For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Requests for hearing must be filed with the Hearing Clerk in EPA's Office of Administrative Law Judges (OALJ), in conformance with the requirements of 40 CFR part 164. The OALJ uses different addresses depending on the delivery method. Please see unit VII. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the revocation of all chlorpyrifos tolerances. Specifically, EPA intends to cancel each of the following pesticide products, which allow for use on food crops, listed in sequence by EPA registration number.

- EPA Reg. No. 93182–3 Chlorpyrifos Technical.
- EPA Reg. No. 93182–7 Pilot 4E Chlorpyrifos Agricultural Insecticide.
- EPA Reg. No. 93182–8 Pilot 15G Chlorpyrifos Agricultural Insecticide.

The following information is the address on record for Gharda, the registrant of the products listed in this unit and subject to this notice, and includes the company number which corresponds to the first part of the EPA registration number of the products:

- EPA Co. No. 93182—Gharda Chemicals International, Inc., 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238.

In addition, this document summarizes EPA's legal authority for the proposed cancellation (see unit II.); the revocation of tolerances for residues of chlorpyrifos on food commodities (see unit III.); the Agency's rationale for issuance of this NOIC (see unit IV.); the timing of the proposed cancellations, EPA's existing stocks determination, and the potential scope of any final cancellation order (see unit V.); the results of the Agency's coordination with the U.S. Department of Agriculture (USDA) and the FIFRA Science Advisory Panel (SAP) (see unit VI.); and how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (unit VII.).

B. What is the Agency's authority for this action?

The Agency's authority to cancel a pesticide that does not comply with the provisions of FIFRA is contained in FIFRA section 6(b), 7 U.S.C. 136d(b).

C. Who may be affected by this action?

This announcement will directly affect the pesticide registrant listed in

unit I.A., supplemental distributors, and others who may distribute, sell, or use the products listed in unit I.A. This announcement may also be of particular interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. EPA believes the stakeholders described above encompass those likely to be affected; however, more remote interests may also be affected, and the Agency has not attempted to describe all specific entities that may be affected by this action.

II. Legal Authority

With minor exceptions not at issue here, as provided in FIFRA section 3(a), a pesticide product may not be lawfully sold or distributed in the United States unless and until the product is registered by EPA. 7 U.S.C. 136a(a). A pesticide registration is a license allowing a pesticide product to be sold and distributed and includes a label with use instructions that delineates the specific uses for which the pesticide may be used, including precautions and other terms and conditions established by EPA when it grants the registration.

As a general matter, in order to obtain or maintain a registration for a pesticide under FIFRA, an applicant or registrant must demonstrate that the pesticide satisfies the statutory standard for registration. 7 U.S.C. 136a(c)(5). That standard requires, among other things, that the pesticide perform its intended function without causing ''unreasonable adverse effects on the environment.'' *Id.* The term ''unreasonable adverse effects on the environment'' is defined under FIFRA section 2(bb) as including two parts: (1) ''[A]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide'' and (2) ''[A] human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.'' 7 U.S.C. 136(bb). It is under the second part of the definition that the FIFRA registration standard incorporates the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, safety standard.

EPA establishes, modifies, or revokes tolerances for pesticide residues under FFDCA section 408. 21 U.S.C. 346a. A ''tolerance'' represents the maximum level for residues of a pesticide legally allowed in or on raw agricultural commodities and processed food. Under the FFDCA, ''any pesticide chemical residues in or on a food shall be deemed unsafe,'' unless a tolerance or exemption for such residues ''is in effect''. 21 U.S.C. 346a(a)(1). In other words, without a tolerance or an exemption from the requirement of a tolerance, pesticide residues in or on food are considered unsafe, as a matter of law. The consequence of having pesticide residues in or on food that are not covered by a tolerance, or an exemption is that the food containing such residues is rendered adulterated under the FFDCA. 21 U.S.C. 342(a)(2)(B). It is a violation of the FFDCA to introduce adulterated food into interstate commerce. 21 U.S.C. 331(a).

Because the FIFRA registration standard incorporates the FFDCA safety standard, a pesticide that results in residues in or on food that are unsafe, which includes residues not covered by a tolerance or tolerance exemption, does not meet the FIFRA registration standard. EPA will not approve any application to register a pesticide with food uses that may reasonably be expected to result in pesticide residues on food without appropriate tolerances or exemptions in place, *see* 40 CFR 152.112(g), and registrations bearing labeling for food use must be modified or cancelled, pursuant to FIFRA section 6(b).

The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration and continues as long as the registration is in effect. 40 CFR 164.80(b); *see also Industrial Union Dept.* v. *American Petroleum Institute,* 448 U.S. 607, 653 n.61 (1980); *Stearns Electric Paste* v. *EPA,* 461 F.2d 293 (7th Cir. 1972); *Environmental Defense Fund* v. *EPA,* 510 F.2d 1292, 1297 (D.C. Cir. 1975).

Under FIFRA section 6(b), the Agency may issue a notice of its intent to cancel a registration of a pesticide product whenever it appears either that ''a pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.'' 7 U.S.C. 136d(b). The cancellation proposed in the notice shall become final 30 days after publication of the notice, or the date the registrant receives the notice, whichever is later, unless the registrant makes the necessary corrections to the registrations, or a hearing is requested by a person adversely affected by the notice. If a hearing is requested by an adversely affected person, the final order concerning cancellation of the product is not issued until after an administrative hearing.

A cancellation hearing shall be conducted in accordance with the regulations establishing the procedures for hearings under FIFRA set forth at 40 CFR part 164. Under those regulations, the Agency has the burden of presenting an affirmative case for cancellation. 40 CFR 164.80(a). However, the ultimate burden of proof is on the proponent of the registration. 40 CFR 164.80(b); *Industrial Union Dept.,* 448 U.S. at 653, n. 61; *Stearns Electric Paste* v. *EPA,* 461 F.2d 293 (7th Cir. 1972). Once the Agency makes its *prima facie* case that a product's continued use fails to meet the FIFRA standard for registration, the responsibility to demonstrate that the product meets the FIFRA standard is upon the proponents of continued registration. 40 CFR 164.80(b); *Dow* v. *Ruckelshaus,* 477 F.2d 1317, 1324 (8th Cir. 1973).

III. Revocation of Chlorpyrifos Tolerances

Chlorpyrifos is a broad-spectrum, chlorinated organophosphate insecticide that is registered for a wide variety of food and non-food uses. In September 2007, Pesticide Action Network North America and Natural Resources Defense Council filed a petition with EPA requesting revocation of all chlorpyrifos tolerances alleging that, among other things, the pesticide caused adverse neurodevelopmental effects in children at exposure levels below the Agency's regulatory standard (*i.e.,* 10% acetylcholinesterase inhibition). See Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos, available at *https://www.regulations.gov,* using document identification number EPA–HQ–OPP–2007–1005–0005. Following several years of proposed responses and litigation, EPA issued a final response to the petition on March 29, 2017. *See* 82 FR 16581, April 5, 2017 (FRL–9960–77). That response denied the many claims of the petition, including by concluding that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. *See id.* at 16590. As permitted under the FFDCA, objections to EPA's denial were filed, and EPA responded to those objections on July 18, 2019. *See* 84 FR 35555, July 18, 2019 (FRL–9997–06). In its denial of those objections, rather than issuing a

determination concerning the safety of chlorpyrifos, EPA denied the objections in part on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the petitioners' burden. *See id.* at 35562. EPA's denial of the petition and denial of objections were subsequently challenged by several advocacy groups and states in the Ninth Circuit.

On April 29, 2021, the Ninth Circuit Court of Appeals ruled against EPA in litigation involving the question of whether the chlorpyrifos tolerances should be revoked. *See League of United Latin American Citizens et al.,* v. *Regan,* 996 F.3d 673 (9th Cir. 2021) (''*LULAC*''). In that case, the Court concluded that EPA violated the FFDCA by not making a safety determination to support the retention of the chlorpyrifos tolerances, as required under the FFDCA. Consequently, the Court ordered EPA to issue a final rule in which the Agency would either revoke the tolerances (if it could not make the requisite safety finding to leave tolerances in place) or modify the existing chlorpyrifos tolerances, provided that the Agency concurrently issued a safety determination supporting the modified tolerances. The Court imposed a tight deadline for EPA to issue the final rule and told EPA not to engage in further fact-finding or delay. Specifically, the court said: ''To be clear, however, this is not an open-ended remand or a remand for further factfinding. The EPA must act based upon the evidence and must immediately revoke or modify chlorpyrifos tolerances. For these reasons, the Court remands this matter to the EPA with instructions to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate.''

In implementing the Court's order within the mandated timeframe, EPA found that it could not make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA section 408(b)(2). 21 U.S.C. 346a(b)(2). Under the FFDCA, a tolerance may be left in place only if the Agency determines that the tolerances are safe, *i.e.,* that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' Id. Because EPA found that at the time it could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to chlorpyrifos residues, including all anticipated dietary (food and drinking water) exposures and all other exposures, EPA published the final rule revoking all tolerances for chlorpyrifos in the **Federal Register** on August 30, 2021. 86 FR 48315, August 30, 2021 (FRL–5993–04–OCSPP) (the Final Rule). As described in greater detail in the Final Rule, the Agency's analysis indicated that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from then-currently registered uses, exceeded safe levels. Id. at 48317. That analysis relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition level as an endpoint for risk assessment and included the FFDCA default tenfold (10X) margin of safety to account for uncertainties related to the potential for adverse neurodevelopmental effects to infants, children, and pregnant women. Id. The Final Rule revoked the chlorpyrifos tolerances but provided a transition period of six months, until February 28, 2022. *Id.* at 48334.

Pursuant to FFDCA section 408(g)(2), EPA provided an opportunity to file objections to the Final Rule and seek an evidentiary hearing on those objections. See also 21 U.S.C. 346a(g)(2); 40 CFR 178.32(b). In response to the Final Rule, several objections, hearing requests, and requests to stay the Final Rule were filed by parties representing a wide variety of growers and pesticide users. On February 28, 2022, EPA published its order denying all objections, hearing requests, and requests to stay the Final Rule in the **Federal Register** (87 FR 11222, February 28, 2022) (FRL–5993–05–OCSPP) (the Denial Order). EPA's publication of the Denial Order completed the Agency's administrative process for the Final Rule. Pursuant to the terms of the Final Rule, all chlorpyrifos tolerances expired on February 28, 2022. EPA notes that EPA's Final Rule revoking chlorpyrifos tolerances is a separate final agency action, and as such, comments challenging EPA's action in that Final Rule are outside the scope of this Notice. Gharda and several other grower groups have challenged that rule in the U.S. Court of Appeals for the Eighth Circuit, *see Red River Valley Sugarbeet Growers Ass'n et al.,* v. *Regan* (9th Cir. No. 22–1422).

Because at this time there are no tolerances or exemptions from the requirement of a tolerance for chlorpyrifos residues in or on food, there is no basis for allowing food uses to remain on chlorpyrifos registered products. See 21 U.S.C. 346a(a)(1). Therefore, between March 1 and March 9 of 2022, after EPA's publication of the Denial Order, EPA issued letters to all registrants of chlorpyrifos products with food uses confirming revocation of the tolerances and recommending that such registrants consider various cancellation and label amendment options. EPA requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food uses from product labels or to submit a voluntary cancellation for products where all uses are subject to the tolerance revocation by March 30, 2022. All chlorpyrifos registrants to whom that letter was sent have submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels, with the exception of Gharda, the registrant of products listed in this Notice. While Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, Gharda's products identified in unit I.A. are subject to this Notice.

IV. Basis for Issuance of Notice of Intent To Cancel

EPA has determined that the chlorpyrifos registrations listed in unit I.A. must be cancelled because they each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products, bearing labeling for use on food crops, (i) pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the FFDCA and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

As noted in unit II., tolerances establish the maximum amount of pesticide residues that are allowed in or on a food. In situations where no tolerance exists to cover residues of a particular pesticide in or on food, those residues are ''deemed unsafe,'' as a matter of law under the FFDCA. 21 U.S.C. 346a(a)(1). As a consequence, a pesticide resulting in residues in or on food for which there is no tolerance does not meet the FIFRA standard for registration. See 7 U.S.C. 136(bb). Moreover, any food containing ''unsafe'' pesticide chemical residues is ''deemed to be adulterated,'' and introduction of that food into interstate commerce is a violation of the FFDCA. 21 U.S.C. 342(a)(2)(B), 331(a).

A. The Pesticide Generally Causes Unreasonable Adverse Effects on the Environment Because It Is Unsafe as a Matter of Law

As discussed in unit II., in order to maintain a registration for a pesticide under FIFRA, a registrant has the burden to demonstrate that the pesticide satisfies the statutory standard for registration. 40 CFR 164.80(b); see also 7 U.S.C. 136a(c)(5). One element of that standard is that the pesticide performs its intended function without unreasonable adverse effects on the environment, which is defined under FIFRA section 2(bb) to include ''a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.'' 7 U.S.C. 136(bb). The standard referenced in the FIFRA definition is the FFDCA safety standard, *i.e.,* that tolerances, which cover the amount of pesticide residues in or on food, must be safe. See 21 U.S.C. 346a(b)(2).

Also noted in unit II., it is a matter of law that pesticide chemical residues in or on food are ''deemed unsafe,'' unless covered by a tolerance or exemption. 21 U.S.C. 346a(a)(1). Any residues from pesticides used on food where no tolerances exist for those residues are, therefore, unsafe. Unsafe residues are not consistent with the FFDCA safety standard. Thus, any pesticide resulting in such residues, causes, as a legal matter, unreasonable adverse effects on the environment. Such pesticide is subject to cancellation under FIFRA section 6(b).

Because all tolerances for chlorpyrifos have been revoked, chlorpyrifos residues in or on food are unsafe as a matter of law. Because the chlorpyrifos registrations listed in unit I.A. bear labeling for use on food, use of which would result in unsafe pesticide residues on food, these products pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2). 7 U.S.C. 136(bb)(2).

B. The Pesticide and Its Labeling Do Not Comply With FIFRA

Additionally, because the chlorpyrifos products in unit I.A. bear labeling for use on food, for which the registrant did not submit the necessary label amendments and/or cancellations to remove all food uses, and because all tolerances for chlorpyrifos have been revoked, these products are misbranded and thus not in compliance with FIFRA. It is a violation of FIFRA to sell and distribute pesticides that are misbranded. 7 U.S.C. 136j(a)(1)(E). FIFRA's definition of ''misbranded'' provides many ways in which a pesticide may be misbranded, including if its labeling ''bears any statement . . . that is false or misleading.'' 7 U.S.C. 136(q)(1)(A). Pesticide labeling bearing directions for use on food crops that results in adulterated food is misleading because it is illegal to distribute that food in commerce. A commercial farmer complying with approved use directions would apply the pesticide to crops but then, in the absence of necessary tolerances or an exemption, would be producing adulterated food, which cannot be delivered into interstate commerce without violating the FFDCA. Thus, the label misleads the consumer into believing a pesticide can be applied to food crops, but ultimately results in adulterated food or feed crops that cannot be sold. To avoid this conflict, EPA's regulations prevent EPA from issuing a registration for a pesticide that ''bears labeling with directions for use on food, animal feed, or food or feed crops, or may reasonable be expected to result, directly or indirectly, in pesticide residues (or results of any active or inert ingredient of the product, or of any metabolite or degradate thereof) in or on food or animal feed,'' unless tolerances or exemptions covering such residues have been issued. 40 CFR 152.112(g).

In summary, because the aforementioned products would result in pesticide residues in or on food that are, as a matter of law, unsafe, the products pose unreasonable adverse effects on the environment. Moreover, EPA has determined that because the aforementioned products are misbranded, continued sale and distribution would not comply with the provisions of FIFRA. Consequently, EPA has determined that these products must be cancelled.

V. Status of Products That Become Cancelled

A. Timing of Cancellation

The cancellation of registration for the specific products identified in unit I.A. of this document will be final and effective 30 days after the affected registrant receives notice of EPA's intent to cancel the pesticide registrations listed in unit I.A., or on January 13, 2023, unless within that time the registrant makes the necessary corrections (see unit V.C.) or a hearing is requested by an adversely affected person regarding such product. 7 U.S.C. 136d(b).

In the event a hearing is held concerning a particular product, the cancellation of the registration for that product will not become effective except pursuant to (i) an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b) or (ii) if the Administrative Law Judge's initial decision is appealed or subject to Administrator review pursuant to 40 CFR 164.101, a final order issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator. Final cancellation orders following a public hearing are subject to judicial review within 60 days of the entry of the order. 7 U.S.C. 136d(h).

B. Existing Stocks Issues

FIFRA section 6(a)(1) allows the Agency to permit the continued sale and use of existing stocks of pesticides whose use has been cancelled, to the extent the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). EPA has defined ''existing stocks'' as ''those stocks of a registered pesticide which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action.'' 56 FR 29362, June 26, 1991 (FRL–3846–4). This section addresses how the Agency intends to treat existing stocks when and if pesticide registrations are cancelled pursuant to this Notice.

The Agency does not believe that continued sale or use of existing stocks of any chlorpyrifos registrations identified in this Notice following cancellation would be consistent with FIFRA. The continued sale and distribution of products cancelled in a proceeding pursuant to this Notice would be the sale and distribution of misbranded products, which, if used in accordance with the labeling, would lead to the production of adulterated food and the use of products that would pose unreasonable adverse effects on human health due to residues in or on food that are inconsistent with the FFDCA safety standard. Accordingly, EPA has determined that the continued sale and distribution of existing stocks of pesticide products cancelled pursuant to this Notice should not be permitted, with the exception of movement of existing stocks for the sole purposes of lawful export consistent with FIFRA; disposal consistent with applicable state disposal requirements; or return to the registrant consistent with the terms of a return program agreement with EPA, if any. Moreover, EPA does not intend to allow existing stocks in the hands of end-users to continue to be used, unless they are being used for non-food uses. Any use

of chlorpyrifos on food would result in adulterated food, which is illegal to deliver into interstate commerce; therefore, use of existing stocks for use on food cannot be permitted.

It is settled law that existing stocks issues are not required to be a part of a cancellation proceeding, and that the treatment of existing stocks issues is only included as an issue in a cancellation proceeding when the Notice giving rise to the right to a hearing voluntarily identifies and includes existing stocks as an issue for examination. See *In the Matter of Cedar Chemical Co., et al.,* 2 E.A.D. 584, nn. 7, 9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator). The Administrator's decision in *Cedar Chemical* on whether existing stocks had to be included as an issue in the hearing was affirmed by the United States Court of Appeals for the Ninth Circuit in *Northwest Food Processors Association* v. *Reilly,* 886 F. 2d 1075, 1078 (9th Cir. 1989). In the case of this Notice, EPA has determined not to include existing stocks as an issue in any hearing arising from this Notice, since the lack of tolerances means that any continued sale, distribution, or use of the pesticide would be inconsistent with the purposes of FIFRA. Instead, the only issue for hearing under this Notice is whether the subject products should be cancelled.

C. Potential Scope of Final Action

FIFRA section 6(b) allows the registrant, within the 30 days following publication or receipt of EPA's notice, to ''make the necessary corrections, if possible''. 7 U.S.C. 136d(b). As noted in unit IV., the chlorpyrifos products listed in unit I.A. must be cancelled because they bear labeling for use on food although no tolerances exist to cover chlorpyrifos residues in or on food for those uses. Terminating food uses and removing those uses from labels would resolve the violations EPA has identified in this Notice. Therefore, EPA recognizes that the registrant has an opportunity to make corrections by requesting cancellation of these uses and amending labels.

FIFRA section 6(b) also states ''in taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the **Federal Register** an analysis of such impact.'' Id.

Accordingly, in any final action on this Notice, EPA may consider, as an alternative to cancellation of the whole registrations, cancelling only those uses that result in residues in or on food. As part of its registration review of chlorpyrifos, EPA considered the potential economic impacts on growers if chlorpyrifos use was eliminated for various registered food crops. *See* Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (November 18, 2020), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969;* Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031.* Although EPA may consider benefits for certain uses under FIFRA, economic impacts to growers is not a consideration for EPA in making a safety determination under the FFDCA. Because EPA determined that the tolerances did not meet the safety standard under the FFDCA, EPA revoked all chlorpyrifos tolerances. See 86 FR 48315. As a result, chlorpyrifos may not be used in or on food without resulting in adulterated food, which cannot be distributed in interstate commerce. Restricting the chlorpyrifos products listed in unit I.A. to only those uses that do not result in residues in or on food would have no economic impact, beyond the impact already resulting from the revocation of the chlorpyrifos tolerances, since these products already cannot be used on food due to the lack of tolerances.

VI. Mandated FIFRA Reviews

A. What is required?

When EPA intends to issue a NOIC, it must furnish a draft of that Notice and an analysis of the impact of the proposed action on the agricultural economy to the Secretary of the USDA for comment at least 60 days prior to sending such Notice to the registrant or making such Notice public. 7 U.S.C. 136d(b). When a public health use is affected, FIFRA section 6(b) also directs the Secretary of the Department of Health and Human Services (HHS) to provide available benefits and use information, or an analysis thereof. Within the same time period, the Agency must also submit the proposed cancellation action to the FIFRA Scientific Advisory Panel (SAP) for comment concerning the impact of the proposed action on health and the environment, unless the SAP agrees to waive its review. 7 U.S.C. 136w(d).

In the event that written comments are received from the USDA, HHS, or the SAP within 30 days of such referral, the Agency must publish those comments and the Agency's response to the comments.

B. What are the results of this review?

Because all tolerances for chlorpyrifos have already been revoked for the reasons set forth in the Final Rule and Denial Order, this proposed cancellation action itself is not anticipated to have any impacts on the agricultural economy. This NOIC is purely an administrative action to address three registrations that the registrant is unable or unwilling to cancel or modify to comply with the Agency's tolerance revocation. EPA provided a draft of this NOIC to the SAP requesting a waiver due to the lack of scientific issues for consideration by the SAP. The SAP waived its review of this NOIC on August 19, 2022.

This NOIC is not subject to review by HHS because there are no public health uses affected by this NOIC.

On August 11, 2022, EPA provided a draft of this NOIC to USDA for review and received a response from USDA on September 11, 2022. USDA expressed three major concerns in its comments: (1) that an economic analysis was not provided for review in conjunction with the draft NOIC; (2) USDA's opinion that historical precedent and procedures was not followed; and (3) USDA's opinion that EPA could have retained some tolerances consistent with the proposal in the Proposed Interim Registration Review Decision for Chlorpyrifos (2020 PID) instead of revoking all tolerances and should initiate action to reestablish tolerances consistent with the conclusions of the 2020 PID. USDA's comments are available at *https://www.regulations.gov* in the docket for this action, docket ID EPA–HQ–OPP–2022–0417.

The Agency has considered each of these comments prior to finalizing this Notice. Below is a summary of these comments and the Agency's detailed responses to these comments.

Comment: USDA notes that FIFRA requires EPA to consider the impact of the action proposed in the NOIC on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and to provide that analysis to the USDA. USDA expressed concern with statements in EPA's draft NOIC that the cancellation of the products would produce no negative effects beyond those that were already imposed when EPA revoked the chlorpyrifos tolerances. Since, as USDA notes in

their comments, the FFDCA does not provide for consideration of economic impacts in a determination of whether to retain tolerances, the USDA had concerns about the lack of consideration to the economy.

EPA Response: As noted in unit III, EPA revoked the chlorpyrifos tolerances in a final rule issued in August 2021, as a result of concluding that the chlorpyrifos tolerances were not safe. As USDA recognizes, the FFDCA does not authorize EPA to consider economic impacts to farmers when determining whether to retain tolerances. As noted in the Final Rule and the Denial Order, the FFDCA permits EPA to leave a tolerance in place only if it is safe; whether a tolerance is important to the agricultural economy is not a permissible consideration for EPA in determining whether to leave a tolerance in place.

When the tolerances were revoked, chlorpyrifos was no longer permitted to be used on food crops. Although not a consideration under the FFDCA, as part of its assessment of chlorpyrifos in registration review, EPA prepared a benefits assessment and a small business analysis of the economic benefits of chlorpyrifos for a variety of crops as well as the potential economic impact if chlorpyrifos were not available. *See* Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (November 18, 2020), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969;* Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031.*

Although the benefits assessment and small business analysis did indicate some economic impacts as a result of chlorpyrifos not being available for growers, those impacts have already occurred as a result of the revocation of the tolerances and would not be attributable to the cancellation of these products. Even if these products were not cancelled, the products could still not be used as a result of the tolerance revocation; thus, the same economic impact would result with or without this cancellation action. To the extent the products being cancelled are registered for non-food uses, these are not the only chlorpyrifos products registered for these non-food uses. Consequently, EPA concluded that the cancellation action being proposed in this NOIC itself does not actually result in any impact on agricultural commodities, retail food prices, or the agricultural economy.

Comment: USDA notes that it considers EPA's process for revoking tolerances as ''harmful precedent'' that has created confusion and concern among agricultural stakeholders and international trading partners. USDA asserts that the lack of a phase-out period has caused a widespread disposal problem for existing stocks of chlorpyrifos, and that the ''divergence from normal procedures caused confusion and concerns'' and may ''harm the economic viability of U.S. producers in the long-term'' by undercutting U.S. credibility in future trade negotiations.

EPA Response: As an initial matter, EPA notes that this comment does not appear to be directly relevant to the cancellation of the particular products identified in this NOIC, but rather a commentary on EPA's issuance and implementation of the final rule revoking tolerances. Prior to the issuance of the final rule, EPA coordinated with FDA and USDA to ensure they could develop any necessary enforcement guidance, such as how long legally treated food and feed commodities may be in the channels of trade, and FDA released a document entitled *Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities,* in order to provide guidance to stakeholders in the food industry. In addition, in the Final Rule itself and contrary to the USDA's assertion, EPA did provide a six-month transition period between the publication of the final revoking tolerances and the effective date of the revocation consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures. Although EPA recognizes that there has been confusion in the regulated community on what to do with registered chlorpyrifos products that can no longer be used on food, EPA is, and has been, working with registrants to provide for an appropriate transition. Specifically, the Agency continues to work with the registrants in the development of their return programs and update stakeholders and the Agency's website with the latest information regarding chlorpyrifos.

To the extent this comment expressed a concern about the process EPA used for terminating use of chlorpyrifos on food, EPA fully addressed this comment in its Denial Order. *See* 87 FR at 11247–49. Objectors to EPA's Final Rule alleged that EPA was required to negotiate with chlorpyrifos registrants and cancel food uses under FIFRA before revoking tolerances under the FFDCA. Consistent with EPA's position in the Denial Order, neither FIFRA nor the FFDCA direct that the Agency proceed with cancellation under FIFRA prior to revoking tolerances under the FFDCA. *Id.* Where EPA determines that tolerances are not safe, the FFDCA requires that tolerances be revoked, regardless of the economic impact of that revocation. In addition, in this particular instance, the Ninth Circuit prioritized the Agency taking action under the FFDCA over taking action under FIFRA, by ordering EPA to take action on the tolerances within 60 days of the issuance of the mandate in that case, *i.e.,* August 20, 2021, and to take action to cancel food uses ''in a timely fashion''. *LULAC,* 996 F.3d. at 703–04.

Nonetheless, even with the restricted timeframe imposed by the Ninth Circuit and the need to prioritize tolerance actions under the FFDCA over cancellations under FIFRA, EPA did attempt to coordinate the tolerance revocations with cancellation actions. While EPA was unable to complete the necessary steps for that process to impact the tolerance revocation rule for chlorpyrifos by the Court's deadline, EPA recognizes that coordinating tolerance revocations and FIFRA cancellations can be helpful since product cancellation orders can provide clarity around existing stocks and disposal procedures.

Comment: USDA's comments outline its opinion that the Agency could have pursued a pathway on the 11 high benefit uses outlined in the 2020 PID instead of revoking all tolerances. USDA also requests Agency-initiated action to reestablish tolerances consistent with the conclusions of the 2020 PID.

EPA Response: EPA notes that this comment appears to be more appropriately directed towards the Final Rule itself rather than the cancellation action that is the subject of this NOIC. Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of the 2021 final tolerance rule and may also request a hearing on those objections. USDA did not file any such objection, although several other parties did, asserting that EPA should have left tolerances in place associated with 11 uses as described in the 2020 PID rather than revoking all the tolerances. EPA denied that objection in its Denial Order. See 87 FR at 11244–47. The Denial Order fully explained the

rationale for not adopting the proposal presented in the 2020 PID. Briefly, in the December 2020 PID, EPA proposed that all chlorpyrifos uses contributing aggregate exposures be cancelled except for 11 specific uses in specific geographic areas. Those 11 uses were identified by registrants and EPA as having high benefits, although the Agency recognized that it was just one possible subset of uses that might be retainable. The Agency's proposed safety determination for those uses was contingent on other uses being cancelled and additional use restrictions being in effect. It is also important to note that the findings in the PID were simply proposals, and those proposals, and the underlying risk assessments on which those proposals were based, were subject to public comment and did not represent a final safety determination. Despite the potential for supporting a safety finding consistent with the PID, at the time that EPA was required to expeditiously issue a rule by the Ninth Circuit, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: no uses had been cancelled, no labels had been revised to geographically limit applications or limit maximum application rates, nor had any applications to initiate such actions been filed with the Agency. Therefore, at the time of the Final Rule, the option to leave certain tolerances in place was not available. Thus, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance, finding that it could not determine that there was a reasonable certainty of no harm from aggregate exposure. As a result, chlorpyrifos tolerances were revoked and expired as of February 28, 2022.

A challenge to the Final Rule is outside the scope of this NOIC. All the chlorpyrifos tolerances have been revoked, so the products identified in this document must be cancelled because they bear labeling for use on food. As noted above, the Agency views this NOIC as an administrative action, as once tolerances were revoked, chlorpyrifos products cannot bear labeling for use on food, since the products could no longer be used without rendering food and feed crops adulterated.

The request to reestablish tolerances associated with those 11 uses is also outside the scope of this NOIC. At this time, the Agency does not intend to initiate a rulemaking to re-establish those tolerances. Initiating tolerance rulemaking under section 408(e) of the FFDCA is a discretionary action, 21 U.S.C. 346a(e), and at this time, no petition has been submitted requesting specific tolerances to be established under section 408(d) of the FFDCA, 21 U.S.C. 346a(d). Even if EPA initiated such a rulemaking, or if a petition were submitted, EPA would need to follow the statutory process and make a determination that the tolerances were safe in order to establish them. It is important to note that the proposal in the 2020 PID was only a proposed safety finding based on a subset of uses; it was not a final determination of safety. Any final safety determination supporting the re-establishment of the tolerances would need to take into consideration aggregate exposures to chlorpyrifos.

VII. Requesting a Hearing

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Who can request a hearing?

A registrant or any other person who is adversely affected by a cancellation of registration as described in this Notice may request a hearing.

B. When must a hearing be requested?

A request for a hearing by a registrant must be submitted in writing within 30 days after the date of receipt of the NOIC, or within 30 days after publication of this announcement in the **Federal Register**, whichever occurs later. A request for a hearing by any other person adversely affected by the Agency's proposed action must be submitted within 30 days after the date of publication of this Notice in the **Federal Register**. See the **DATES** section of this document.

C. How must a hearing be requested?

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Among other requirements, these rules include the following requirements:

- Each hearing request must specifically identify by registration or accession number each individual pesticide product for which a hearing is requested, 40 CFR 164.22(a);
- Each hearing request must be accompanied by a document setting forth specific objections that respond to the Agency's reasons for proposing cancellation as set forth in this Notice, and stating the factual basis for each such objection, 40 CFR 164.22(a); and
- Each hearing request must be received by the OALJ within the applicable 30-day period, 40 CFR 164.5(a).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation for the products in question by operation of law.

D. Where does a person submit a hearing request?

Requests for hearing must be submitted to the OALJ. The OALJ strongly encourages electronic filing due to the coronavirus pandemic. *See* Order Urging Electronic Service and Filing, issued by Chief ALJ Biro (April 10, 2020), available at *https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.*

1. *Submitting the hearing request electronically.* To file a document electronically, a party shall use a web-based tool known as the OALJ E-Filing System by visiting the OALJ's website at *https://www.epa.gov/alj.* Documents filed electronically are deemed to constitute both the original and one copy of the document.

Any party choosing to file electronically must first register with the OALJ E-Filing System at *https://yosemite.epa.gov/oa/eab/EAB-ALJ_Upload.nsf.* There may be a delay of one to two business days between the time a party applies for registration and the time at which the party is able to upload documents into the system.

A document submitted to the OALJ E-Filing System is considered ''filed'' at the time and date of electronic reception, as recorded by the OALJ E-Filing System immediately upon reception. To be considered timely, documents submitted through the OALJ E-Filing System must be received by 11:59 p.m. Eastern Time on the date the document is due, unless another time is specified by the Judge. Within an hour of a document being electronically filed, the OALJ E-Filing System will generate an electronic receipt of the submission that will be sent by email to both the party submitting the document and the Headquarters Hearing Clerk. This emailed electronic receipt will be the filing party's only proof that the OALJ received the submitted document. The absence or presence of a document on the OALJ's E-Docket Database web page, available at *https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf,* or on the Agency's Administrative Enforcement Dockets web page, available at *https://yosemite.epa.gov/oa/rhc/epaadmin.nsf,* is not proof that the document was or was not received. If the filing party does not receive an electronic receipt within one hour after submitting the document through the OALJ E-Filing System, the

Headquarters Hearing Clerk may be able to confirm receipt of the document but not earlier than one hour after the document was submitted.

The OALJ E-Filing System will accept any type of digital file, but the file size is limited to 70 megabytes. Electronically filed textual documents must be in Portable Document Format (''PDF''). If a party's multimedia file exceeds 70 megabytes, the party may save the file on a compact disc and send it by U.S. mail to the Hearing Clerk mailing address identified in unit VII.D.2. of this Notice, or the party may contact the Headquarters Hearing Clerk at (202) 564–6281 for instructions on alternative electronic filing methods.

A motion and any associated brief may be filed together through the OALJ E-Filing System. However, any documents filed in support of a brief, motion, or other filing, such as copies of proposed exhibits submitted as part of party's prehearing exchange, should be filed separately as an attachment. Where a party wishes to file multiple documents in support of a brief, motion, or other filing, rather than filing a separate attachment for each such document, the documents should be compiled into a single electronic file and filed as a single attachment, to the extent technically practicable.

2. *Submitting the hearing request by non-electronic means.* Alternatively, if a party is unable to file a document utilizing the OALJ E-Filing System, *e.g.,* the party lacks access to a computer, the party may file the document by U.S. mail or facsimile, although the OALJ's ability to receive filings via those methods is limited. U.S. mail is currently being delivered to the OALJ at an offsite location on a weekly basis only, and documents sent by facsimile will also be received offsite. If a party must file documents by U.S. mail or facsimile, the party shall notify the Headquarters Hearing Clerk each time it files a document in such a manner by calling (202) 564–6281.

To file a document using U.S. mail, the document shall be sent to the following mailing address: Mary Angeles, Headquarters Hearing Clerk, Office of Administrative Law Judges (Mail Code 1900R), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Please note that mail deliveries to federal agencies are screened off-site, and this security procedure can delay delivery.

Facsimile may be used to file a document if it is fewer than 20 pages in length. To file a document using facsimile, the document shall be sent to OALJ's offsite location at (916) 550–9639.

A document submitted by U.S. mail or facsimile is considered ''filed'' when the Headquarters Hearing Clerk physically receives it, as reflected by the inked date stamp physically applied by the Headquarters Hearing Clerk to the paper copy of the document.

At this time, the OALJ is not able to accept filings or correspondence by courier or commercial delivery service, such as UPS, FedEx, and DHL. Likewise, the physical office of the OALJ is not currently accessible to the public, and the OALJ is not able to receive documents by personal delivery. For further information on filings with the OALJ, please see *https://www.epa.gov/alj.*

3. *Important reminders.* Regardless of the method of filing, all filed documents must be signed in accordance with 40 CFR part 164 and must contain the contact name, telephone number, mailing address, and email address of the filing party or its authorize representative. A copy of each document filed in this proceeding shall also be ''served'' by the filing party on the presiding judge and on all other parties.

E. The Hearing

If a hearing concerning any product affected by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings, 40 CFR part 164, and the procedures set forth in this unit. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

F. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. 40 CFR 164.7. To facilitate compliance with the *ex parte* rule, the following are designated as adjudicatory personnel for purposes of this proceeding: the Administrative Law Judges and their staff and the Environmental Appeals Board and its staff. None of the persons identified as adjudicatory personnel may discuss the merits of the proceeding with any person with an interest in the proceeding, or representative of such person, except in compliance with 40 CFR 164.7.

List of Subjects

Environmental protection, Pesticides and pests, Cancellation.

Dated: December 9, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–27130 Filed 12–13–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0732; FRL–9942–02–OCSPP]

Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final revision to the risk determination for the perchloroethylene (PCE) risk evaluation issued under the Toxic Substances Control Act (TSCA). The revision to the PCE risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that PCE, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. This revision supersedes the condition of use-specific no unreasonable risk determinations in the December 2020

EXHIBIT B

Gharda Chemicals International, Inc. Letter to US EPA
March 30, 2022

Gharda Chemicals International, Inc.

March 30, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Request for (1) Voluntary Cancellation of Certain Chlorpyrifos Food Use Registrations and (2) Sub-labels for Non-Food Uses

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the March 1, 2022 letter of the U.S. Environmental Protection Agency (EPA or Agency), in which EPA requested that Gharda voluntarily cancel registrations and/or uses impacted by EPA's decision to revoke all chlorpyrifos tolerances.

Consistent with its commitment to EPA in the weeks leading up to EPA's Final Rule revoking all chlorpyrifos tolerances, and pursuant to Section 6(f)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Gharda requests voluntary cancellation of the food use registrations identified in Table 1. These uses comprise all of Gharda's currently registered food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**).

Table 1: Gharda Chemicals International, Inc. Voluntarily Cancelled Food Uses

Product name	**EPA Registration No.**	**Voluntarily Cancelled Food Uses**
Chlorpyrifos Technical	93182-3	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **Asparagus** (**except** in MI), Banana, Blueberry, Caneberry, Cherimoya, **Citrus Fruits** (**except** in AL, FL, GA, NC, SC, TX), Corn, **Cotton** (**except** in AL, FL, GA, NC, SC,

		VA), Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, **Soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), Sunflowers, **Sugar Beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), Sugarcane, **Strawberries** (**except** in OR), Sweet Potatoes, Tree Fruit, (**apples** [**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV], pears, **cherries** [**except** tart cherries in MI], plums/prunes, **peaches** [**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV] and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY).
Pilot 4E Chlorpyrifos Agricultural Insecticide	93182-7	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **apple** (**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV), **asparagus** (**except** in MI), brassica (cole), leafy vegetables, radish, rutabaga, turnip, **citrus fruits and citrus orchard floors** (except in AL, FL, GA, NC, SC, TX), corn (field corn and sweet corn, including corn grown for seed) **cotton** (**except** in AL, FL, GA, NC, SC, VA), cranberries figs, grape, legume vegetables (succulent or dried, except soybean), onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), **soybean** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), **strawberry** (**except** in OR), **sugar beet** (**except** in IA, ID, IL, MI, MN, ND, OR,

		WA, WI), sunflower, sweet potato, almond, walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip) tree nuts (foliar sprays) tree nut orchard floors, **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY), **cherries** (**except** tart cherries in MI), and **peaches** (**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV).
Pilot 15G Chlorpyrifos Agricultural Insecticide	93182-8	**Citrus and citrus orchards** (**except** in AL, FL, GA, NC, SC, TX), broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions, radishes, rutabagas, sweet potatoes, corn, **asparagus** (**except** in MI), **alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), sorghum, **soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), peanuts, **sugar beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), turnips, and sunflowers.

Gharda understands that cancellation of the food uses outlined in Table 1 will result in cancellation of the same food uses for the supplemental distribution product identified below in Table 2.

Table 2: Supplemental Distribution Product

Distributor Product Number	Distributor Company Name	Distributor Product Name
93182-7-55467	Tenkoz, Inc.	Govern Insecticide

Gharda understands that a notice of receipt of this voluntary cancellation request will be published in the Federal Register, as required by Section 6(f) of FIFRA. Gharda further understands that the notice may allow up to a 180-day period after publication for public comment, during which time EPA may not approve or reject the request, and that the registrant may request that the comment period be waived. Gharda is not requesting waiver of the comment period. Gharda also understands that it is the Agency's policy to consider comments

received during the public comment period before making its final determination on such a request.

Gharda is not in a position to voluntarily cancel its registration for the Eleven Uses at this time, given the litigation pending in the U.S. Court of Appeals for the Eighth Circuit. Gharda stands prepared to engage in a dialogue with EPA and/or the Department of Justice concerning the Eleven Uses at the appropriate time.

Gharda nevertheless understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses. Accordingly, Gharda has suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda is also prepared to accept return of its branded product from its distributors and dealers back to its possession and control for relabeling, export, or storage. Gharda is committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit.

With the Agency's permission, Gharda is prepared to submit a request to EPA for sub-labels for its technical and end-use products that would include only non-food uses. This would limit continued domestic distribution, sale, and use of Gharda's relabeled chlorpyrifos products to non-food uses only, consistent with EPA's revocation order. This request is faithful to EPA's revocation order and also preserves Gharda's rights in the ongoing litigation, consistent with the Federal Food, Drug, and Cosmetic Act and FIFRA. Gharda is prepared to work with the Agency on a plan for relabeling consistent with this request.

I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency's convenience.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

CC: Patricia Biggio
Melissa Grable

EXHIBIT C

USDA Letter to Edward Messina, Esq., Director
September 11, 2022

United States Department of Agriculture
Office of the Chief Economist
Office of Pest Management Policy
1400 Independence Avenue, SW
Washington, D.C. 20250-3810

September 11, 2022

Edward Messina, Esq., Director
Office of Pesticide Programs Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: USDA Comments on the Draft Notice of Intent to Cancel Chlorpyrifos Registrations

Dear Mr. Messina:

Thank you for your August 11, 2022, letter and the opportunity to review and comment on EPA's draft notice of intent to cancel (NOIC) registrations of chlorpyrifos under Section 25(a)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). USDA acknowledges and recognizes that, in response to the April 29, 2021, order from the U.S. 9th Circuit Court of Appeals[1] EPA chose to revoke all tolerances[2] for residues of chlorpyrifos in food without canceling the associated products. We also recognize EPA's position that the February 28, 2022, revocation of tolerances for residues of chlorpyrifos in food makes any remaining registrations bearing labeled food uses of these products misbranded and out of compliance with FIFRA. As such, EPA considers this NOIC to be an administrative action. USDA disagrees, and has some overarching concerns with this action, as follows.

Under FIFRA, EPA is compelled to consider "the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." In addition, EPA is required to provide the Secretary of Agriculture with a 30-day comment period to review the notice (provided in your August 11, 2022, letter) and the Agency's analysis of the impact on the agricultural economy. As an analysis of impact, EPA states in its draft NOIC that this action produces no negative impacts to producers beyond those that were already imposed when EPA revoked chlorpyrifos tolerances. However, revocation under the Federal Food Drug and Cosmetic Act does not explicitly provide for analysis of the impact on the agricultural economy. As such, we have legal concerns around this action and would like to meet to discuss further.

In addition, USDA views this outcome as a harmful precedent. Processes exist for a reason and should be followed whenever possible. The regulatory certainty and transparency that result from predictable processes help to maintain public trust in the institutions responsible for regulating agricultural pesticides. This chlorpyrifos decision has left the significant agricultural impacts of the tolerance revocation unaddressed. Agricultural stakeholders are confused about the legality

[1] https://cdn.ca9.uscourts.gov/datastore/opinions/2021/04/29/19-71979.pdf
[2] https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0030

of use of labeled chlorpyrifos product in their possession, and both EPA and FDA have been forced to divert resources to improving clarity *post hoc*. The lack of a phase-out period caused a widespread disposal problem for existing stocks of chlorpyrifos products that can no longer be used. This divergence from normal procedures also caused confusion and concerns among international trading partners who look to the EPA as a model for consistent, risk-focused, and science-based pesticide regulatory processes that help to deliver a safe food supply. When U.S. stakeholders advocate for similar science-based policies and processes among international trading partners, examples of Agency actions that deviate from this model may undercut U.S. credibility in trade negotiations and other international regulatory venues. This can further harm the economic viability of U.S. producers in the long-term.

Lastly, EPA's 2020 proposed interim decision (PID) for chlorpyrifos[3] stated that a number of labeled food uses could be retained (with regional nuances) and still meet the Agency's safety finding under FFDCA and FQPA, even with the inclusion of a 10x safety factor. This list included alfalfa (including seed production), apples, asparagus, cherries (tart), citrus, cotton, peaches, soybeans, strawberries, sugar beets, and wheat. USDA also submitted comments[4] in response to this PID that includes an approach to exposure characterization that would allow the retention of other food uses that are important to growers. While EPA asserts that they had no choice but to revoke all tolerances because tolerances must be considered in aggregate under FQPA, other pathways could have been pursued to refine pesticide use patterns prior to tolerance revocations. A more practical, less disruptive pathway could have included negotiations with the registrants to narrow registration approvals and maintain safe uses, along with a transition plan for agriculture for uses for which the safety standard could not be met. This approach would have been consistent with past Agency practices: there are many examples of EPA taking such approaches and addressing risks while minimizing impacts to agriculture. Instead, the Agency chose to ignore its prior analysis and procedures and move forward with a wholesale and abrupt revocation of all tolerances based on the aggregate risk. In doing so, many agricultural stakeholders believe that the Agency put forth an outcome that created unnecessary chaos and confusion.

USDA recognizes the important and difficult work done by our EPA colleagues. We continue to support EPA as an international standard bearer in pesticide regulation. While we may sometimes disagree on specific regulatory outcomes, we continue to believe in the Agency's expertise and capabilities, and we strongly advocate for EPA as a credible and globally respected model for effective, science-based pesticide regulatory policy and decisions. We believe that the chlorpyrifos example is a deviation from this model. Rather than proceed with the NOIC under review, USDA would strongly support an Agency-initiated action to reestablish tolerances for and ultimately retain chlorpyrifos uses that meet the Agency's safety finding when considered as a subset of the aggregate (in accordance with the 2020 PID). We would be happy to provide input that could help inform EPA's analysis and risk/usage characterization.

On behalf America's agricultural producers seeking regulatory certainty, we also support EPA's typical decision-making process, the precedent for product cancellations and tolerance revocations established through the reregistration and registration review programs since the enactment of the Food Quality Protection Act in 1996, and the legal requirements for review by USDA. We are requesting that, in future actions, EPA follow historical precedent and legal

[3] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0964
[4] https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1101

procedures. We believe this will help to prevent unnecessary confusion among agricultural stakeholders and restore confidence in EPA's regulatory processes.

Please contact Clayton Myers at Clayton.Myers@usda.gov or me at Kimberly.Nesci@usda.gov if you would like to discuss our comments on this NOIC.

Sincerely,

Kimberly Nesci
Director, Office of Pest Management Policy

cc: Elissa Reaves, Ph.D., Director
Pesticide Re-evaluation Division, Office of Pesticide Programs
Environmental Protection Agency

EXHIBIT D

USDA Letter to The Honorable Vicky Hartzler
September 20, 2022

USDA United States Department of Agriculture

Office of the Secretary
Washington, DC 20250

September 20, 2022

THE HONORABLE VICKY HARTZLER
U.S. House of Representatives
2235 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman Hartzler:

Thank you for your letter of July 11, 2022, cosigned by your colleagues, in which you request the rescission of the Environmental Protection Agency's (EPA) August 18, 2021, final rule canceling all food uses of the organophosphate pesticide chlorpyrifos and in which you offer several questions for both EPA and the U.S. Department of Agriculture (USDA). I apologize for the delayed response.

USDA is committed to providing all U.S. farmers with a diverse "toolbox" for addressing pest management challenges. The composition of this toolbox will undoubtedly continue to expand and evolve over time. At present, the judicious use of pesticides continues to be an important tool for farmers—and one which is strictly regulated to ensure safety to applicators, consumers, and the environment. USDA vigorously supports continuous progress and improvements to food systems that support our health, environment, and economy.

I encourage you to look at USDA's Agriculture Innovation Agenda and the U.S. Agriculture Innovation Research Strategy, which describe some of the extraordinary achievements of U.S. agriculture and our forward-looking vision for continuing to increase agricultural productivity by 40% while cutting the environmental footprint of U.S. agriculture in half by 2050. This information is available at: https://www.usda.gov/aia.

USDA is strongly supportive of the EPA's pesticide regulatory and policymaking process, for both its scientific rigor and its commitment to integrity and transparency. Under U.S. law, the EPA evaluates not only the potential risks associated with pesticide use, but also balances those risks with the benefits derived from pesticide use in agriculture, as well as in public health, residential settings, and our parks, forests, and public lands. The EPA's deliberative scientific evaluation process ensures farmers' continued access to the safe tools and technologies that are necessary to providing Americans with an abundant and affordable food supply.

Regarding the recent regulatory actions on chlorpyrifos, we are coordinating closely with the EPA and agricultural stakeholders. While chlorpyrifos is a broad-spectrum organophosphate insecticide that has been a part of U.S. growers' toolbox for multiple decades, its use has declined in recent years, and alternative pest control methods are available in many crop production systems. We are actively working to identify additional tools to replace critical uses of chlorpyrifos that currently lack viable pest management alternatives, including those critical uses in Missouri.

The USDA also collaborates with states, universities, and growers to promote the development of integrated pest management (IPM) strategies that reduce the economic, environmental, and public health risks from pests and the methods used to control them in agricultural and natural resource environments. You can find more information about our efforts to support IPM at: https://www.usda.gov/oce/pest/integrated-pest-management.

In response to your specific questions, please see below:

Question 1. Did scientists at the USDA's Office of Pest Management Policy agree with EPA's decision to cancel all food tolerances of chlorpyrifos in 2021 under FFDCA?

> **Answer:** USDA-Pest Management Policy (OPMP) scientists believe EPA could retain certain chlorpyrifos uses that meet EPA's safety standard, based on the EPA's proposed interim decision (PID). USDA-OPMP scientists also presented arguments for why additional uses should be considered for retention. This is summarized in USDA-OPMP's comments submitted to EPA in response to the chlorpyrifos PID in March 2021: https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1101.

Question 2. What was USDA's level of involvement in this decision?

> **Answer:** USDA has no formal regulatory role over pesticide regulatory decisions, but instead, through OPMP, provides information to EPA for use and consideration in regulatory decision-making. In addition to our public comment submission, OPMP has been in regular contact with EPA to discuss the importance of chlorpyrifos.

Question 3. Was USDA briefed by DOJ and EPA regarding EPA's final rule canceling all food tolerances for chlorpyrifos, of which was the administration's response to the April 29, 2021, directive by the U.S. Court of Appeals for the Ninth Circuit?

> **Answer:** USDA was briefed by EPA but was not briefed by the Department of Justice.

Question 4. EPA recently requested voluntary cancellations under FIFRA from the registrants of chlorpyrifos. Voluntary cancellations occurred for all except the 11 uses that EPA deemed safe in its December 2020 PID for chlorpyrifos, including Missouri soybeans, alfalfa, and wheat. The registrant has requested EPA work with on sublabels for said 11 continued uses.

a. Are your agencies working to approve these 11 sublabels?

b. If so, what is the expected timeline for approval?

> **Answer:** USDA does not have a formal role in approving pesticide regulatory decisions. The decision to re-visit or potentially re-register labels with chlorpyrifos uses rests with EPA. We have and will, however, provide information to help inform EPA's decision,

including information on the benefits of chlorpyrifos to growers. We will work to make the case to follow the science and maintain safe use of chlorpyrifos for those 11 crops, and any others that might still be adjusted or refined to meet EPA's safety standard.

Question 5. Will you prioritize a way for chlorpyrifos use this growing season, given the chemistry has few viable and cost-effective alternatives?

Answer: As with any chemical uses determined to meet the safety standard, we will encourage EPA to allow for continued use.

Thank you for your letter, and I hope the information and responses I have provided are helpful. I would also like to welcome you to reach out directly to our Office of Pest Management Policy (kimberly.nesci@usda.gov or clayton.myers@usda.gov) which coordinates pest management and pesticide regulatory policy for the USDA. A similar response is being sent to your colleagues.

Sincerely,

THOMAS J. VILSACK
Secretary

U.S. Department of Justice

Environment and Natural Resources Division

Environmental Defense Section
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Washington, DC 20044

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December 23, 2022

VIA CM/ECF
Clerk of the Court Michael E. Gans
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton U.S. Courthouse
111 South 10th Street
St. Louis, MO 63102

Re: *RRVSG Assoc., et al. v. Michael Regan, et al.*; Nos. 22-1422, 22-1530
Response to Petitioners' Federal Rule of Appellate Procedure 28(j) letter

Dear Mr. Gans,

Petitioners' recent submission, Doc. ID 5227503, misstates the facts and the law.

First, Petitioners claim that the Cancellation Notice "reaffirms EPA's determination that the 11 Safe Uses are safe" mischaracterizes the Cancellation Notice. To the contrary, EPA stated in the Cancellation Notice that "the findings in the PID were simply proposals, and those proposals, and the underlying risk assessments on which those proposals were based, were subject to public comment and did not represent a final safety determination." Doc. ID 5227503 at 12.

Second, Petitioners claim that "all chlorpyrifos registrations have been withdrawn, except those for the Safe Uses held by Gharda that are the subject of the Notice." But as of the issuance of the Final Rule and Denial Order, EPA had received no voluntary requests to cancel chlorpyrifos registrations. Resps.' Br. at 18. While EPA has since received voluntary cancellation requests for all food uses from every registrant except Gharda, and some have been cancelled, the Agency is still processing requests.[1] Although Gharda seeks to leave in place the 11 uses proposed for retention in the Proposed Interim Decision ("PID"), its label amendments do not reflect the revised application rates underlying the PID's proposed safety finding. *See* AR 40 at 55-59, Pet'rs' App. at 420-24. Even if Gharda had submitted such labels, the PID did not make a final safety determination and assessed only one subset of uses. Resps.' Br. at 32-36, 40. Retention of any food uses would require EPA to make a safety determination. 21 U.S.C. § 346a(b)(2)(A)(i).

Third, USDA commented in response to EPA's Cancellation Notice but did not object to or otherwise comment on the Final Rule now under review. Since USDA's comments were submitted to EPA *after* EPA had issued both the Final Rule and Denial Order, they are not part of the administrative record. Regardless, USDA offered no independent scientific analysis supporting the safety of chlorpyrifos tolerances. *See* Doc. ID 5227503 at 10-12.

[1] *See* 87 Fed. Reg. 53471 (Aug. 31, 2022); 87 Fed. Reg. 76191 (Dec. 13, 2022).

Respectfully submitted,

TODD KIM
Assistant Attorney General
Environment and Natural Resources Division

s/ Laura J. Glickman
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CERTIFICATE OF SERVICE

I, Laura J. Glickman, hereby certify that on December 23, 2022, I electronically filed the foregoing Response to Petitioners' FRAP 28(j) letter with the Clerk of the Court of the United States Court of Appeals for the Eighth Circuit by using the CM/ECF System. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Laura J. Glickman

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January 18, 2023

VIA ELECTRONIC FILING

Michael E. Gans, Clerk of Court
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton United States Courthouse
111 South 10th Street
St. Louis, MO 63102

Re: Federal Rule of Appellate Procedure 28(j) Letter for *Red River Valley Sugarbeet Growers Association, et al. v. Michael Regan, et al.*
Nos. 22-1422(lead), 22-1530

Dear Mr. Gans:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, Petitioners write to alert the Court to two sets of "pertinent and significant authorities" occurring since the submission of briefs and oral argument.

First, on January 6, 2023, Petitioners asked EPA to stay or withdraw EPA's Notice of Intent to Cancel Gharda's chlorpyrifos registrations ("NOIC") pending review by this Court of the tolerances for the Safe Uses. *Letter from Petitioners to Michael S. Regan, Adm'r, EPA, Requesting Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos* (Jan. 6, 2023) (Ex. A). EPA denied Petitioners' request, ignoring this Court's exercise of jurisdiction with respect to the tolerances for the Safe Uses and using the revocation of those tolerances as the reason for moving forward with registration cancellation. *Letter from EPA to Petitioners Denying Request to Stay/Withdraw Notice of Intent to Cancel* (Jan. 11, 2023) (Ex. B). These documents are pertinent to Judge Stras's questions directed to the government's counsel at oral

argument and demonstrate that (1) EPA will continue to seek cancellation of the registrations (2) unless remand of the Final Rule is accompanied by vacatur of the Final Rule's revocation of the tolerances for the Safe Uses and (3) vacatur is needed in time for the 2023 growing season, which commences in March for many crops.

Second, Petitioners have submitted objections to EPA's NOIC. *Gharda Chemicals International, Inc.'s Request for Hearing and Statement of Objections and Request for Stay* (Jan. 13, 2023) ("Gharda's Objections") (Ex. C); *Request for Hearing and Statement of Objections by Red River Valley Sugarbeet Growers Ass'n, et al.* (Jan. 13, 2023) (Ex. D).[1] In response to the NOIC, Gharda's Objections include amended product labels that add application rates for each of the Safe Uses. Ex. C at Ex. 3. Gharda's addition of the application rates, developed by EPA in support of the PID, leaves no doubt that EPA has everything necessary to approve labels consistent with EPA's determination of Safe Uses.

Respectfully submitted,

s/ NASH E. LONG
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Attorneys for Petitioner Gharda Chemicals International, Inc.

[1] The voluminous exhibits submitted to EPA with Exs. C and D are available upon request.

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Attorneys for Petitioners Red River Valley Sugarbeet Growers Association, US Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, and Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America

CERTIFICATE OF SERVICE

I certify that on this 18th day of January, 2023, a copy of the foregoing Federal Rule of Appellate Procedure 28(j) Letter was served electronically through the Court's CM/ECF system on all registered counsel.

s/ Nash E. Long
Nash E. Long

EXHIBIT A

Petitioners' Letter to EPA on NOIC
January 6, 2023

January 6, 2023

The Honorable Michael S. Regan
Administrator, United States Environmental
Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos

Dear Administrator Regan:

We write on behalf of nineteen grower groups (representing thousands of farmers around the country who rely upon the pesticide product known as chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda Chemicals International, Inc. ("Gharda")) (collectively "Petitioners"). Over the last 30 years, the global agricultural system has managed to feed almost 2.5 billion more people whilst reducing per capita environmental impacts by 20%. America's farmers are committed to producing safe and affordable food for consumers in the U.S. and around the world. Around 98% of U.S. farms are family owned and on a daily basis these farming families work to ensure a sufficient, safe, and nutritious food supply exists. We respectfully request that EPA immediately stay or withdraw EPA's Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations dated December 14, 2022 ("NOIC"). This request is based on several reasons.

First, EPA's primary basis for its NOIC is that tolerances for all food uses of chlorpyrifos were revoked by way of EPA's Final Rule published August 30, 2021, and the chlorpyrifos registrations must be cancelled as a follow-up to the tolerance revocation. However, Petitioners have challenged EPA's Final Rule as to eleven high benefit food uses found safe by the Agency ("Safe Uses") in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.,* No. 22-1422 (8th Circuit) ("lawsuit"). There is no reason that EPA action with respect to chlorpyrifos registrations cannot await the Eighth Circuit's decision. As the Agency has said many times, once the tolerances expired, pesticide products containing chlorpyrifos could no longer be used on food crops. Registration cancellation does not alter or add to that result. The fact that EPA did not initiate the process until 15 months after the Final Rule lends support for the fact that cancellation will not impact the reality that it is already illegal to use pesticide products containing chlorpyrifos on food crops. Thus, EPA's NOIC is unnecessary at this time and premature in light of the lawsuit. It will only add considerably to the costs of Petitioners and other adversely affected parties who seek to have their rights addressed as to the Safe Uses.

Second, there is no urgency that the NOIC seeks to address. There is no reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce, necessitating registration cancellation at this time. As noted above, EPA's tolerance revocations made distribution or use illegal as a matter of law. Moreover, in correspondence

dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. The Agency threatened the immediate initiation of involuntary cancellation proceedings if Gharda did not do as the Agency had demanded. Gharda responded on March 30; *see* attached March 30, 2022, letter from Gharda to EPA. Gharda's response: (1) requested the voluntary cancellation of all of Gharda's food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda's commitment to the Agency well before the Final Rule); (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit." Nothing has changed since Gharda's commitment, and EPA has never responded to Gharda's letter.

Third, the timing of EPA's NOIC is highly questionable. Published the day before oral argument in the Eighth Circuit in the lawsuit and coupled with an inflammatory press release issued by EPA, the NOIC appears to be an effort to interfere with the jurisdiction of the Eighth Circuit with respect to the Safe Uses. The issuance of the NOIC also appears to be an attempt to signal urgency when, as noted above, none exists except for American growers' desperate need of the Safe Uses of chlorpyrifos for the 2023 growing season commencing in March. In sum, there is no need based on the law or the facts for EPA to issue the NOIC while the Eighth Circuit litigation is pending. Indeed, for the Agency to wait nine months after Gharda's commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, smacks of an effort to create urgency where EPA's conduct demonstrates none exists, thereby impeding fair consideration of the lawsuit by the Court. This is especially true given USDA's adamant opposition to the NOIC and tolerance revocation as to the Safe Uses.

Finally, issuance of the NOIC with a response deadline shortly after the holiday period seems punitive by any measure. As set forth above, there is simply no reason to force Petitioners and other adversely affected parties to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, the Petitioners respectfully request that EPA stay and/or withdraw the NOIC until after the Eighth Circuit's decision in the lawsuit. ***The Petitioners further request that EPA rule on this request as soon as possible in order to allow the Petitioners time to seek other relief, if necessary, consistent with this request.***

Sincerely,

South Dakota Soybean Association

By: _____
Jerry Schmitz
Executive Director

Red River Valley Sugarbeet Growers Association

By: _____
Brent Baldwin
Vice President

American Soybean Association

By: _____
Stephen Censky
Chief Executive Officer

Iowa Soybean Association

By: _____
Kirk Leed
Chief Executive Officer

Missouri Soybean Association

By: _____
Matthew Wright
President

Minnesota Soybean Growers Association

By: _____
Joseph Smentek
Executive Director

Nebraska Soybean Association

By: _____
Lori Luebbe
Executive Director

North Dakota Soybean Growers Association

By: _____
Kasey J. Bitz
President

American Farm Bureau Federation

By: _____
Samuel Kieffer
Vice President, Public Affairs

American Sugarbeet Growers Association

By: _____
Luther Markwart
Executive Vice President

U.S. Beet Sugar Association

By: _____
Cassie Bladow
President

Southern Minnesota Beet Sugar Cooperative

By: _____
Paul Fry
Chief Executive Officer

American Crystal Sugar Cooperative

By: _____
Thomas Astrup
President and Chief Executive Officer

Minn-Dak Farmers Cooperative

By: _____
Kurt Wickstrom
Chief Executive Officer

Florida Fruit and Vegetable Growers Association

By: _____
Mike Aerts
Vice President

Georgia Fruit and Vegetable Growers Association

By: _____
Chris Butts
Executive Vice President

Gharda Chemicals International, Inc.

By: _____
Ram Seethapathi
President

National Cotton Council of America

By: _____
Gary Adams
President and Chief Executive Officer

National Association of Wheat Growers

By: _____
Nicole Berg
President

Attachment

cc: Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: freedhoff.michal@epa.gov.

Edward Messina, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency: messina.edward@epa.gov.

Elissa Reaves, Pesticide Re-Evaluation Division, Office of Pesticide Programs, U.S. Environmental Protection Agency: reaves.elissa@epa.gov.

Dana Friedman, Branch Chief, Office of Pesticide Programs, Risk Management and Implementation Branch I (RMIB I), U.S Environmental Protection Agency: friedman.dana@epa.gov.

The Honorable Thomas J. Vilsack, Secretary, U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250

Gharda Chemicals International, Inc.

March 30, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Request for (1) Voluntary Cancellation of Certain Chlorpyrifos Food Use Registrations and (2) Sub-labels for Non-Food Uses

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the March 1, 2022 letter of the U.S. Environmental Protection Agency (EPA or Agency), in which EPA requested that Gharda voluntarily cancel registrations and/or uses impacted by EPA's decision to revoke all chlorpyrifos tolerances.

Consistent with its commitment to EPA in the weeks leading up to EPA's Final Rule revoking all chlorpyrifos tolerances, and pursuant to Section 6(f)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Gharda requests voluntary cancellation of the food use registrations identified in Table 1. These uses comprise all of Gharda's currently registered food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**).

Table 1: Gharda Chemicals International, Inc. Voluntarily Cancelled Food Uses

Product name	**EPA Registration No.**	**Voluntarily Cancelled Food Uses**
Chlorpyrifos Technical	93182-3	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **Asparagus** (**except** in MI), Banana, Blueberry, Caneberry, Cherimoya, **Citrus Fruits** (**except** in AL, FL, GA, NC, SC, TX), Corn, **Cotton** (**except** in AL, FL, GA, NC, SC,

		VA), Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, **Soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), Sunflowers, **Sugar Beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), Sugarcane, **Strawberries** (**except** in OR), Sweet Potatoes, Tree Fruit, (**apples** [**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV], pears, **cherries** [**except** tart cherries in MI], plums/prunes, **peaches** [**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV] and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY).
Pilot 4E Chlorpyrifos Agricultural Insecticide	93182-7	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **apple** (**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV), **asparagus** (**except** in MI), brassica (cole), leafy vegetables, radish, rutabaga, turnip, **citrus fruits and citrus orchard floors** (except in AL, FL, GA, NC, SC, TX), corn (field corn and sweet corn, including corn grown for seed) **cotton** (**except** in AL, FL, GA, NC, SC, VA), cranberries figs, grape, legume vegetables (succulent or dried, except soybean), onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), **soybean** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), **strawberry** (**except** in OR), **sugar beet** (**except** in IA, ID, IL, MI, MN, ND, OR,

		WA, WI), sunflower, sweet potato, almond, walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip) tree nuts (foliar sprays) tree nut orchard floors, **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY), **cherries** (**except** tart cherries in MI), and **peaches** (**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV).
Pilot 15G Chlorpyrifos Agricultural Insecticide	93182-8	**Citrus and citrus orchards** (**except** in AL, FL, GA, NC, SC, TX), broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions, radishes, rutabagas, sweet potatoes, corn, **asparagus** (**except** in MI), **alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), sorghum, **soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), peanuts, **sugar beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), turnips, and sunflowers.

Gharda understands that cancellation of the food uses outlined in Table 1 will result in cancellation of the same food uses for the supplemental distribution product identified below in Table 2.

Table 2: Supplemental Distribution Product

Distributor Product Number	Distributor Company Name	Distributor Product Name
93182-7-55467	Tenkoz, Inc.	Govern Insecticide

Gharda understands that a notice of receipt of this voluntary cancellation request will be published in the Federal Register, as required by Section 6(f) of FIFRA. Gharda further understands that the notice may allow up to a 180-day period after publication for public comment, during which time EPA may not approve or reject the request, and that the registrant may request that the comment period be waived. Gharda is not requesting waiver of the comment period. Gharda also understands that it is the Agency's policy to consider comments

received during the public comment period before making its final determination on such a request.

Gharda is not in a position to voluntarily cancel its registration for the Eleven Uses at this time, given the litigation pending in the U.S. Court of Appeals for the Eighth Circuit. Gharda stands prepared to engage in a dialogue with EPA and/or the Department of Justice concerning the Eleven Uses at the appropriate time.

Gharda nevertheless understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses. Accordingly, Gharda has suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda is also prepared to accept return of its branded product from its distributors and dealers back to its possession and control for relabeling, export, or storage. Gharda is committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit.

With the Agency's permission, Gharda is prepared to submit a request to EPA for sub-labels for its technical and end-use products that would include only non-food uses. This would limit continued domestic distribution, sale, and use of Gharda's relabeled chlorpyrifos products to non-food uses only, consistent with EPA's revocation order. This request is faithful to EPA's revocation order and also preserves Gharda's rights in the ongoing litigation, consistent with the Federal Food, Drug, and Cosmetic Act and FIFRA. Gharda is prepared to work with the Agency on a plan for relabeling consistent with this request.

I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency's convenience.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

CC: Patricia Biggio
Melissa Grable

EXHIBIT B

EPA Letter to Petitioners Denying Request to Stay/Withdraw
Notice of Intent to Cancel
January 11, 2023

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA EMAIL, RETURN RECEIPT REQUESTED

January 11, 2023

To: Carrie Meadows, U.S. Beet Sugar Association

On behalf of: Julie Gordon, Cherry Marketing Institute
Jerry Schmitz, South Dakota Soybean Association
Brent Baldwin, Red River Valley Sugar Beet Growers Association
Stephen Censky, American Soybean Association
Luther Markwart, American Sugarbeet Growers Association
Cassie Bladow, U.S. Beet Sugar Association
Kirk Leed, Iowa Soybean Association
Matthew Wright, Missouri Soybean Association
Paul Fry, Southern Minnesota Beet Sugar Cooperative
Joseph Smentek, Minnesota Soybean Growers Association
Thomas Astrup, American Crystal Sugar Cooperative
Lori Luebbe, Nebraska Soybean Association
Kurt Wickstrom, Minn-Dak Farmers Cooperative
Kasey J. Bitz, North Dakota Soybean Grower Association
Mike Aerts, Florida Fruit and Vegetable Growers Association
Samuel Kieffer, American Farm Bureau Federation
Chris Butts, Georgia Fruit and Vegetable Growers Association
Gary Adams, National Cotton Council of America
Ram Seethapathi, Gharda Chemicals International, Inc.
Nicole Berg, National Association of Wheat Growers

Per your letter dated January 6, 2023, you requested that EPA immediately stay or withdraw EPA's Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations dated December 14, 2022 (the "NOIC")[1] until the issuance of the Eighth Circuit's decision in *RRVSG Assoc., et al. v. Michael Regan, et al.*, No. 22-1422, 22-1530 (8th Cir.).

EPA's rationale for the issuing NOIC is discussed in detail in the NOIC itself. *See, e.g.*, unit IV of the NOIC.[2] To summarize, the chlorpyrifos registrations identified in the NOIC each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products (i) pose unreasonable adverse effects on the environment under Federal Insecticide,

[1] 87 Fed. Reg. 76,474 (Dec. 14, 2022) (FRL-10108-01-OCSPP).
[2] *Id*. at 76,476-77 (Dec. 14, 2022).

Fungicide, and Rodenticide Act (FIFRA) section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

Therefore, between March 1 and March 9 of 2022, after EPA's publication of its order denying all objections, hearing requests, and requests to stay the Final Rule in the Federal Register (87 Fed. Reg. 11,222, February 28, 2022) (FRL–5993–05–OCSPP), EPA issued letters to all registrants of chlorpyrifos products with food uses confirming revocation of the tolerances and recommending that such registrants consider various cancellation and label amendment options. EPA requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food uses from product labels or to submit a voluntary cancellation for products where all uses are subject to the tolerance revocation by March 30, 2022. All chlorpyrifos registrants to whom that letter was sent have submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels, with the exception of Gharda, the registrant of products listed in the NOIC. While Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, EPA issued the NOIC for the Gharda's products identified therein.

Under FIFRA section 6(b), the Agency may issue a notice of its intent to cancel a registration of a pesticide product whenever it appears either that ''a pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.'' 7 U.S.C. 136d(b). As noted in the NOIC, EPA concluded that those conditions for cancellation are met here. The registrations subject to the NOIC have not changed since the issuance of the NOIC, so EPA continues to believe that the conditions for cancellation are met. EPA therefore declines to withdraw or stay the NOIC consistent with your letter.

Per FIFRA section 6(b) and as noted in the NOIC, the cancellation proposed in the NOIC shall become final 30 days after publication of the NOIC, or the date the registrant receives the NOIC, whichever is later, unless the registrant makes the necessary corrections to the registrations, or a hearing is requested by a person adversely affected by the NOIC. The deadline for submitting corrections or a hearing request is Friday, January 13, 2023. Unless one of those submissions

occurs by that date, the cancellation proposed in the NOIC will become final as of Friday, January 13, 2023.[3]

Sincerely,

MICHAEL GOODIS

Digitally signed by
MICHAEL GOODIS
Date: 2023.01.11
14:16:18 -05'00'

Ed Messina
Director, Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
United States Environmental Protection Agency

Cc: Kimberly Nesci
Director, Office of Pest Management Policy
United States Department of Agriculture

[3] 87 Fed. Reg. 76,474 at 76,480-81 (Dec. 14, 2022).

EXHIBIT C

Gharda Chemicals International, Inc.'s
Request for Hearing and Statement of Objections
January 13, 2023

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

IN RE FIFRA SECTION 6(b) NOTICE OF INTENT TO CANCEL PESTICIDE REGISTRATIONS FOR CHLORPYRIFOS	))))	**DOCKET NO. EPA-HQ-OPP-2022-0417**

GHARDA CHEMICALS INTERNATIONAL, INC.'S REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS AND REQUEST FOR STAY

Gharda Chemicals International, Inc. ("Gharda") hereby requests a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the proposed cancellation of the following of its pesticide product registrations:

- EPA Reg. No. 93182-3 Chlorpyrifos Technical[1]
- EPA Reg. No. 93182-7 Pilot 4E Chlorpyrifos Agricultural Insecticide[2]
- EPA Reg. No. 93182-8 Pilot 15G[3]

These three registrations are referred to herein as the "chlorpyrifos registrations." A Notice of Intent to Cancel was issued by the U.S. Environmental Protection Agency ("EPA" or "the Agency") and published in the Federal Register on December 14, 2022. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022), Ex. 1. Copies of the approved labels for the chlorpyrifos registrations, and Gharda's most recent proposed amendments to the labels (**submitted January 13, 2023**) for the chlorpyrifos registrations, are attached here. *See* Exs. 2 & 3.

[1] Product information on EPA Reg. No. 93182-3 can be found here.
[2] Product information on EPA Reg. No. 93182-7 can be found here.
[3] Product information on EPA Reg. No. 93182-8 can be found here.

In the NOIC, EPA is proposing to cancel the registrations of Gharda's chlorpyrifos products noted above. EPA alleges that the chlorpyrifos registrations should be cancelled because the Agency had revoked tolerances for all food uses of chlorpyrifos by way of a Final Rule dated August 30, 2021.[4] In the NOIC, EPA also challenges the sufficiency of voluntary cancellations and label amendments Gharda submitted in March 2022 and June 2022, which brought its chlorpyrifos registrations and labels in line with the Final Rule as to all but a subset of uses that are the subject of ongoing litigation. Gharda and other affected parties urged EPA to immediately stay or withdraw the NOIC in correspondence dated January 6, 2023, but EPA denied this request.

The NOIC states that "the affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before January 13, 2023, whichever occurs later." 87 Fed. Reg. at 76,474, Ex. 1. Gharda notes that the address for Gharda identified in the NOIC is incorrect[5] and states that Gharda has not received a copy of the NOIC from EPA. **Accordingly, Gharda submits that the 30-day time period for requesting a hearing on the NOIC has not yet begun to run and respectfully requests that EPA cure its defective notice promptly.**

While Gharda reserves all rights as to the ripeness of any further proceedings on the NOIC until it receives proper notice, Gharda hereby objects to the cancellation of the

[4] *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"), Ex. 4.

[5] *Compare* 87 Fed. Reg. at 76,474, Ex. 1 (identifying Gharda's address of record as 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238) *with* https://www3.epa.gov/pesticides/chem_search/ppls/033658-00026-20121220.pdf (Gharda submission of amended labeling to EPA identifying Gharda address as 4032 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238).

chlorpyrifos registrations and provides this notice of its objections and request for a hearing under 40 C.F.R. section 164.20(b) and request for a stay of the NOIC.

INTRODUCTION

This matter concerns the insecticide chlorpyrifos, a crop protection tool growers have relied upon for decades. After working with registrants in 2019 to identify key U.S. crop uses for chlorpyrifos, EPA used up-to-date science to determine that the tolerances for a subset of uses, on eleven crops in select geographic regions, meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act ("FFDCA") (the "Safe Uses"). Despite that finding, which EPA announced in its Proposed Interim Decision ("PID")[6] in 2020 and reaffirmed in the Final Rule and several times since, EPA elected to revoke ***all*** food tolerances, including those the Agency found safe, at the expense of farmers across the country. EPA's Final Rule disregarded Gharda's written commitment *before* the Final Rule to modify its registration and product labels consistent with the Agency's safety finding as to the Safe Uses. Indeed, Gharda was standing by before the Final Rule to submit amended labels to EPA narrowing uses to the Safe Uses, at EPA's instruction, when EPA abruptly ceased discussions with Gharda. Gharda and others submitted objections to and requested a stay of the Final Rule (incorporated by reference here), which EPA denied.[7]

Nineteen grower groups (representing thousands of farmers around the country who rely on chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda) (collectively "Petitioners") challenged the Final Rule as to the Safe Uses because it is arbitrary

[6] Chlorpyrifos Proposed Interim Registration Review Decision, EPA-HQ-OPP-2008-0850 (Dec. 3, 2020) https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971, Ex. 5.
[7] Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022), Ex. 6.

and capricious and contrary to the FFDCA in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir.) (the "lawsuit"). In the lawsuit, Petitioners seek vacatur of the Final Rule as to the Safe Uses. The lawsuit has been fully briefed, and oral argument took place on December 15, 2022. The parties' principal briefs in the lawsuit are incorporated by reference here.[8]

As set forth below, the extreme and unprecedented action EPA has taken in issuing the NOIC is objectionable on numerous grounds. The NOIC is based on the Final Rule, which is arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses for all of the reasons set forth in Gharda's objections to the Final Rule and briefing to the Eighth Circuit; the NOIC is accordingly itself arbitrary and capricious, even more so based on the current record before the Agency, in which there can be no doubt that EPA has all available tools and information at its disposal showing that the chlorpyrifos registrations are consistent with the Agency's safety finding. EPA also improperly attempts to narrow the scope of the NOIC by contending that the propriety of EPA's Final Rule—the sole basis for the NOIC—cannot be a topic for the NOIC. What is more, EPA's NOIC blatantly disregards important FIFRA-mandated cancellation rights and processes. Indeed, EPA's NOIC fails to comply with requirements established by FIFRA regarding consideration of alternatives to registration cancellation and input from the U.S. Department of Agriculture ("USDA"). Further, EPA ignores Gharda's due process and property rights by, *inter alia*, failing to follow processes mandated by FIFRA for registration cancellation and failing to appropriately consider Gharda's

[8] Pet'rs' Opening Br. ("Pet'rs Br."), *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. May 24, 2022), ID No. 5160660; Resp't Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. July 26, 2022), ID No. 5180922; Pet'rs' Reply Br. ("Pet'rs Reply Br."), *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022), ID No. 5195044, Ex. 7.

efforts to make its registrations and product labels align with EPA's Final Rule. Finally, EPA in large part ignores the lawsuit, which could be decided any day and could make the NOIC moot. EPA waited 15 months after the Final Rule—until the day before oral argument in the lawsuit—to publish the NOIC. Based on EPA's own conduct, there is no urgent need or other basis for EPA to proceed with the NOIC before the Eight Circuit's decision. Accordingly, Gharda respectfully submits that the Administrative Law Judge should dismiss the NOIC. At a minimum, the NOIC should be delayed until after the Eighth Circuit's decision.

GHARDA'S OBJECTIONS

OBJECTION 1: The NOIC is improperly based on the Final Rule, which incorrectly revoked tolerances for the Safe Uses. Contrary to EPA's contention in the NOIC (87 Fed. Reg. at 76,476, Ex. 1), comments and arguments challenging EPA's actions in the Final Rule are very relevant to the NOIC and scope of the NOIC.

- The primary basis for the NOIC is that in its Final Rule, EPA revoked all food tolerances for chlorpyrifos and, therefore, uses set forth in Gharda's registrations for food uses cannot stand and must be cancelled. Similarly, the NOIC contends that Gharda's product registrations and amended labels are not consistent with the Final Rule because they include the Safe Uses.

- For all the reasons set forth in Gharda's objections to the Final Rule and the Petitioners' briefing in the lawsuit (incorporated by reference here), the Final Rule was arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses. *See* Pet'rs Br. at 23–26, 42–54 (ID No. 5160660); Pet'rs Reply Br. at 14-22 (ID No. 5195044), Ex. 7; Gharda Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos ("Gharda Objs."), EPA-HQ-OPP-2021-0523, at 9-11, 31-34 (Oct. 22, 2021), https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0028, Ex. 8. In the absence of a proper basis for revocation of tolerances for the Safe Uses, there is no basis for the NOIC, which seeks to cancel registered uses for the Safe Uses.

- The validity of the Final Rule as to the Safe Uses is currently under consideration by the Eighth Circuit. Oral arguments in the lawsuit occurred on December 15, 2022, and a decision is expected in the near future.

- If the Eighth Circuit vacates/remands the Final Rule as to the tolerances for the Safe Uses, the NOIC's purported basis for the cancellation action becomes moot.

OBJECTION 2: Action on the NOIC should be delayed until after the Eighth Circuit decides Petitioners' challenge to the Final Rule.

- Taking action on the NOIC is contrary to the exercise of jurisdiction by the Eighth Circuit regarding the tolerances for the Safe Uses. *See* Pet'rs Br. at 1-5 (ID No. 5160660), Ex. 7.

- If registration cancellation occurs and the Eighth Circuit subsequently rules in Petitioners' favor by either vacating or remanding the Final Rule as to the Safe Uses, EPA would likely argue that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition process. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. EPA should not be allowed, through the NOIC process, to evade a potential Eighth Circuit invalidation of the Final Rule, especially when the lawsuit has been fully briefed and argued, and the Eighth Circuit's decision is forthcoming at any time.

- In addition, (1) challenging registration cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives prior to a decision by the Eighth Circuit would be overly burdensome and unfair and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit.

- In short, it would be improper and prejudicial to use the NOIC to circumvent judicial review and to force Gharda to pursue costly and time-consuming alternatives in parallel to the pending court proceeding. These inappropriate outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit's decision.

OBJECTION 3: The NOIC erroneously signals an urgent need for registration cancellation. To the contrary, there is no urgency for the NOIC to address because there are currently no chlorpyrifos products used on food in the stream of commerce, as EPA knows, and therefore no reason that the NOIC cannot be delayed until after the Eighth Circuit's decision.

- The NOIC makes statements implying that chlorpyrifos is currently being sold, distributed and/or used for food uses. *See, e.g.,* 87 Fed. Reg. at 76,477 ("It is a violation of FIFRA to sell and distribute pesticides that are misbranded…because the aforementioned [chlorpyrifos] products would result in pesticide residues in or on

food…continued sale and distribution [of chlorpyrifos products] would not comply with the provisions of FIFRA."), Ex. 1. This is misleading.

- In correspondence dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. Gharda responded on March 30, 2022. *See* Ex. 9. Gharda's response: (1) requested the voluntary cancellation of all of Gharda's food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda's commitment to the Agency well before the Final Rule); (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit."

- EPA has never provided evidence contrary to Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit.

- There is no evidence of or reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce for use on food, necessitating registration cancellation at this time. EPA's tolerance revocations made distribution or use unlawful. As noted above, in correspondence dated March 30, 2022, Gharda recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses" and "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit."

- The NOIC alleges no facts inconsistent with Gharda's commitments or otherwise demonstrating that chlorpyrifos products are being distributed, sold, and/or used in a manner inconsistent with the Final Rule.

- Oral argument in the lawsuit took place on December 15, 2022. For the Agency to wait nine months after Gharda's commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, demonstrates an inappropriate attempt by the NOIC to create urgency where EPA's conduct demonstrates none exists. In sum, there is no urgent need based on the facts for the NOIC to proceed with actions as extreme as cancellations before the Eighth Circuit's decision.

OBJECTION 4: The NOIC violates FIFRA by ignoring several of the statutorily required steps that *must* precede registration cancellation, including the requirement to consider alternatives to cancellation, and by improperly attempting to narrow the scope of the Administrative Law Judge's review.

- FIFRA Section 6(b) provides that "*[i]n taking any final action under this subsection*, the Administrator *shall* consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and *shall* include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact." 7 U.S.C. § 136d(b) (emphasis added).

- FIFRA does not permit EPA to ignore these statutory requirements simply because a tolerance action precedes a cancellation action. EPA is required to review the full record before the Agency in issuing a decision on a NOIC. *See* 40 C.F.R. § 164.90(b).

- EPA contends in the NOIC that only the Final Rule and the facts existing at the time of the Final Rule are relevant to the NOIC. The NOIC thus ignores FIFRA's requirement that alternatives to registration cancellation *must* be considered *in taking any final action under FIFRA Section 6(b)* and improperly attempts to limit the scope of the Administrative Law Judge's review.

- EPA did not consider the PID and the Safe Uses identified by the PID as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider Gharda's repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements. *See* Decl. of Ram Seethapathi in Support of Gharda's Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos ("Seethapathi Decl."), EPA-HQ-OPP-2021-0523, ¶¶ 21–36 and Exhibits to Seethapathi Decl. A–H (Oct. 22, 2021), Ex. 8; *see also* Ex. 9.

- EPA has never provided evidence contrary to Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit.

- EPA did not consider Gharda's submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider Gharda's submission of amended labels, which eliminated all food uses for chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA's registration cancellation requirements.

- The Administrator of EPA did not publish in the Federal Register an analysis of the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA's registration cancellation requirements.

- FIFRA Section 6(b) requires EPA to respond to USDA's comments with respect to the NOIC.

- EPA gave no meaningful consideration to USDA's request that EPA re-establish tolerances for the Safe Uses based on EPA's own scientific findings and therefore violated FIFRA's cancellation requirements. *See* Letter from Kimberly Nesci, Dir., Office of Pest Mgmt. Pol'y, United States Dep't of Agriculture to Edward Messina, Dir., Office of Pesticide Programs ("USDA Comments Letter"), EPA, EPA-HQ-OPP-2022-0417 (Sept. 11, 2022) at 2, https://www.regulations.gov/document/EPA-HQ-OPP-2022-0417-0002.

- EPA gave no meaningful consideration to USDA's comments that, *inter alia*, EPA was not following "historical precedent and legal procedures" with respect to the Final Rule and NOIC and that the EPA's actions constituted "harmful precedent" and therefore violated FIFRA's registration cancellation requirements. *Id*. at 1–3.

- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA's comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 5: The NOIC violates Gharda's due process rights.

- Once a pesticide registration is granted, it becomes the registrant's property interest, *see, e.g., Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010), and cannot "be taken away without that procedural due process required by the Fourteenth Amendment," *Bell v. Burson*, 402 U.S. 535, 539 (1971). FIFRA protects these due process rights by establishing an elaborate scheme for EPA to follow before cancelling a pesticide registration. *See, e.g.*, 7 U.S.C. §§ 136d(b)(1), (2); 136d(d); 136a(g)(1)(v); *see also Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (FIFRA "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration.").

- Due process is denied when the statutorily mandated process for taking away a property right is not followed.

- EPA has failed to provide Gharda with due process by, *inter alia*: (1) instructing Gharda, before the Final Rule, to be prepared to submit a voluntary cancellation letter narrowing uses consistent with the PID and then abruptly terminating discussions; (2) not considering as an alternative to registration cancellation maintaining the Safe Uses as

registered uses in accordance with the PID and EPA's determination of Safe Uses; (3) not considering as an alternative to registration cancellation Gharda's repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses; (4) not considering as an alternative to registration cancellation Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit; (5) not considering as an alternative to registration cancellation Gharda's submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation; (6) not considering as an alternative to registration cancellation Gharda's submission of amended labels which eliminated all food uses for chlorpyrifos except the Safe Uses; (7) not considering the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (8) not publishing in the Federal Register an analysis of the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (9) failing to await the decision from the Eighth Circuit before issuing the NOIC when chlorpyrifos cannot be sold or used and there is otherwise no urgency for registration cancellation proceedings at this time; (10) overburdening Gharda and other adversely affected parties with the necessity to spend resources to defend the NOIC when an Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses would eliminate the need for the NOIC; (11) overburdening Gharda with the necessity to spend resources to challenge registration cancellation that may occur and be followed by a favorable Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses; and, (12) failing to consider or meaningfully consider USDA's comments in response to the NOIC, including, as set forth above, that EPA should re-establish tolerances for the Safe Uses and did not follow "historical precedent and legal procedures" regarding the Final Rule and NOIC.

- EPA's actions in issuing the NOIC compound the Agency's due process violations in issuing the Final Rule. EPA violated the due process rights of Gharda and others by revoking all tolerances in disregard of the Agency's own scientific findings as to the Safe Uses and Gharda's written commitment in advance of the Final Rule to modify its registration in accordance with the Agency's safety finding. *See* Gharda Objs. at 31–37, Ex. 8.

OBJECTION 6: Under the circumstances of this matter, EPA's demand in the NOIC that Gharda amend its registration labels to voluntarily cancel food uses for the Safe Uses is overly burdensome, unrealistic, punitive, and improperly seeks to interfere with the exercise of jurisdiction by the U.S. Court of Appeals for the Eighth Circuit.

- As noted above, on March 30, 2022, Gharda submitted a letter to EPA seeking cancellation of all food uses of chlorpyrifos in Gharda's registrations except the eleven

Safe Uses. Gharda explained in its letter that EPA's revocation of tolerances for the Safe Uses was currently under review by the Eighth Circuit. Ex. 9. Gharda also submitted amended labels to EPA omitting all food uses but the Safe Uses on June 10, 2022. Ex. 10.

- The NOIC states that "[w]hile Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, Gharda's products identified [in the NOIC] are subject to this Notice." 87 Fed. Reg. at 76,476, Ex. 1. The NOIC misleadingly omits that the only way Gharda's registrations do not align with the Final Rule is as to the Safe Uses currently under review by the Eighth Circuit.

- To the extent Gharda's prior commitments before the Final Rule and submissions to EPA after the Final Rule are somehow insufficient to satisfy EPA that label changes consistent with EPA's safety finding can be accomplished (a position Gharda views as contrary to the law and facts, *see* Pet'rs Br. at 23–28 (ID No. 5160660)), Gharda has submitted amended labels to EPA (included with this submission at Ex. 3) that once again limit food uses to the Safe Uses in the permitted geographic regions (that are the subject of the ongoing litigation) and also add application rate changes consistent with the PID safety finding. Gharda submits these changes to further demonstrate its commitment to conform its registrations to EPA's safety finding in the PID, despite that the changes proposed are based on information the Agency developed and has had in its possession for years. *See* Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-2008-0850-0941 at 33–34 (Sep. 22, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941, Ex. 11.

- The NOIC states that the cancellation proposed in the NOIC shall become final unless "the registrant makes the necessary corrections to the registrations" or a hearing is requested. 87 Fed. Reg. at 76,475, Ex. 1.

- Thus, EPA demands that Gharda voluntarily cancel all remaining food uses, the tolerances for which are currently under review by the Eighth Circuit. EPA's actions appear to be punitive, and an attempt to undermine and thwart Gharda's justified attempt to obtain judicial review of EPA's Final Rule as to the Safe Uses.

- If registration cancellation occurs before an Eighth Circuit decision invalidating the Final Rule, EPA would likely contend that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition processes. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule to the Agency as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. But (1) challenging cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives would

be overly burdensome and unfair, and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit. These outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit decision.

OBJECTION 7: The NOIC does not give due consideration to the USDA's views, contrary to FIFRA.

- FIFRA Section 6(b) requires EPA to respond to USDA's comments with respect to the NOIC. 7 U.S.C. § 136d.

- EPA gave no meaningful consideration to USDA's request that EPA re-establish tolerances for the Safe Uses in accordance with its scientific findings and therefore violated FIFRA's registration cancellation requirements. *See* USDA Comments Letter at 2.

- EPA gave no meaningful consideration to USDA's comments that, *inter alia*, EPA was not following "historical precedent and legal procedures" with respect to the Final Rule and NOIC and that the EPA's actions constituted "harmful precedent" and therefore violated FIFRA's registration cancellation requirements. *Id*. at 1–3.

- As noted by USDA, it is unprecedented for EPA to ignore FIFRA-mandated cancellation rights and processes in a situation where tolerance revocation occurs first.

- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA's comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 8: Issuance of the NOIC with a response deadline shortly after the holiday period is burdensome, unfair, and unnecessary.

- As set forth above, there is no urgency or any other good faith reason to force Gharda and other adversely affected parties to respond to the NOIC during the holiday period and to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, Gharda respectfully requests that the Administrative Law Judge stay action on the NOIC until after the Eighth Circuit's decision in the lawsuit.

REQUEST FOR STAY OF NOIC

Based on the foregoing, Gharda respectfully requests that the Administrative Law Judge delay any action with respect to the NOIC, including but not limited to the conduct of the hearing

requested herein, until after the Eight Circuit's decision in the lawsuit. A stay of the NOIC proceedings is warranted because proceeding with a potential registration cancellation now would prejudice the rights of Gharda and others to obtain judicial relief from the Final Rule underlying the NOIC in the ongoing litigation. Should a potential cancellation of the chlorpyrifos registrations precede a favorable ruling by the Eighth Circuit invalidating the Final Rule, EPA may nevertheless take the position that Gharda must initiate the FIFRA registration and tolerance petition processes for chlorpyrifos anew—destroying decades of investment, causing the needless expenditure of Agency and registrant resources, and further delaying access to a crop protection tool critical to U.S. growers. As discussed above, as there are no chlorpyrifos products approved for use on food currently in the stream of commerce, there are no public health concerns with simply delaying further action on the NOIC until the Eighth Circuit rules.[9]

CONCLUSION

For the reasons set forth above, EPA's unprecedented NOIC is contrary to FIFRA in many respects, violates the due process rights of Gharda, and is otherwise deficient. Moreover, there is no urgent need or other basis for the NOIC to proceed before the Eighth Circuit's decision in the lawsuit. Forcing Gharda to defend the NOIC before the Eighth Circuit's decision would be unfairly burdensome and unnecessary and is contrary to the Eighth Circuit's exercise of jurisdiction over the tolerances for the Safe Uses.

[9] In other administrative actions, EPA has applied the stay criteria set forth by the U.S. Food and Drug Administration at 21 CFR § 10.35(e)(1)–(4) ((1) petitioner will suffer irreparable injury; (2) petitioner's case is not frivolous and pursued in good faith; (3) sound public policy grounds support a stay; and (4) delay from a stay is not outweighed by public health or other public interests). For reasons outlined herein, Gharda has satisfied these criteria here.

Gharda respectfully requests a hearing on the NOIC and requests that the Administrative Law Judge find that the Administrator did not have a proper basis for issuing the NOIC and dismiss the NOIC. At a minimum, the Administrative Law Judge should delay action on the NOIC until after a decision from the Eighth Circuit in the lawsuit.

Respectfully submitted,

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Date: January 13, 2023

CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, true and correct copies of the foregoing Request for Hearing and Statement of Objections and Request for Stay, and all associated Exhibits, were filed electronically with the EPA OALJ E-Filing System for the OALJ's E-Docket Database, with a copy (without attachments) via electronic mail to the following:

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EXHIBIT D

Grower Petitioners' Request for Hearing and Statement of Objections
January 13, 2023

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations	Docket Nos. FIFRA-HQ-2023-0001; EPA-HQ-OPP-2022-0417

REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS

by

Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America

January 13, 2023

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MISCELLANEOUS

This Request for Hearing and Statement of Objections is submitted on behalf of the grower groups currently involved in litigation with the U.S. Environmental Protection Agency in the U.S. Court of Appeals for the Eighth Circuit[1] (Grower Petitioners) challenging EPA's Final Rule[2] revoking all tolerances for chlorpyrifos, including the 11 food uses EPA deemed to be safe (the Safe Uses).[3] The Grower Petitioners object to EPA's recent notice of intent to cancel (NOIC)[4] Gharda Chemicals International Inc.'s (Gharda's) products Chlorpyrifos Technical (EPA Reg. No. 93182-3),[5] Pilot 4E Chlorpyrifos Agricultural Insecticide (EPA Reg. No. 93182-7),[6] and Pilot 15G Chlorpyrifos Agricultural Insecticide (EPA Reg. No. 93182-8).[7] The Grower

[1] *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir. filed Feb. 28, 2022) (*Red River Valley Sugarbeet Growers Ass'n et al.*).

[2] "Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the Final Rule) (Exhibit 1).

[3] The Safe Uses of chlorpyrifos are the uses EPA unequivocally found to be safe in its Proposed Interim Registration Review Decision (PID) for Chlorpyrifos, Case Number 0100, December 2020 (Chlorpyrifos PID), EPA-HQ-OPP-2008-0850-0971 (Exhibit 2). These Safe Uses are the use of chlorpyrifos on alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat in specifically designated regions as set forth in EPA's PID. Petitioners have challenged EPA's revocation of the tolerances for the Safe Uses of chlorpyrifos.

[4] EPA Notice "Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations," 87 Fed. Reg. 76,474 (Dec. 14, 2022) (Exhibit 3).

[5] A copy of the label for EPA Reg. No. 93182-3 can be found here. (Exhibit 4).

[6] A copy of the label for EPA Reg. No. 93182-7 can be found here. (Exhibit 5).

[7] A copy of the label for EPA Reg. No. 93182-8 can be found here. (Exhibit 6).

Petitioners have urged EPA to immediately stay or withdraw the NOIC,[8] and EPA rejected this request.[9] The Grower Petitioners therefore request a hearing on the NOIC and these objections.

EPA's NOIC seeks a premature revocation of registrations for uses of an economically critical pesticide that EPA has unequivocally found to be safe. EPA announced this safety finding in the PID and has since that time reiterated to the public and to the Eighth Circuit that the Safe Uses present no risks of concern.[10] Each of the registrants of chlorpyrifos have cancelled (or requested cancellation) of all food uses for chlorpyrifos other than the Safe Uses. Thus, the only action EPA proposes to take in the NOIC is to cancel Gharda's registrations for the Safe Uses. EPA's NOIC will cause unnecessary and irreparable harm to the Grower Petitioners.

The Grower Petitioners include the following entities:

Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association

[8] Letter from South Dakota Soybean Association and 18 additional Grower Groups, to The Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 6, 2023) (Exhibit 7); Letter from Julie Gordon, President/Managing Director, Cherry Marketing Institute, to the Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 9, 2023) (Exhibit 8).

[9] Letter from Michael Goodis, Dir., Office of Pesticide Programs, EPA, to Grower Petitioners (Jan. 11, 2023) (Exhibit 9).

[10] Brief of Respondents 12-13, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. July 26, 2022) (EPA Br.) (Exhibit 10).

of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and the National Cotton Council of America.

The Grower Petitioners represent thousands of farmers around the country who need chlorpyrifos as a critical crop protection tool and who would be adversely affected by EPA's NOIC. The Grower Petitioners object to EPA's NOIC on multiple grounds, as described below.

I. EPA's Proposed Cancellation of Gharda's Registrations for the Safe Uses Is Contrary to Law Because it Would Interfere with the Jurisdiction of the U.S. Court of Appeals for the Eighth Circuit.

EPA's proposed cancellation of Gharda's registrations for the Safe Uses is contrary to law. EPA explains in its NOIC that its sole justification for cancelling the registrations of Gharda's products containing chlorpyrifos is the Agency's Final Rule revoking *all* tolerances for chlorpyrifos.[11] EPA explains that Gharda's chlorpyrifos products must be cancelled because they bear labeling for use on food crops, and, due to the lack of tolerances for residues of chlorpyrifos, these products pose unreasonable adverse effects on the environment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[12] In other words, EPA's position is that, because it has revoked all tolerances for chlorpyrifos, "chlorpyrifos residues in or on food are unsafe as a matter of law."[13]

However, the legality of the Final Rule is currently being decided by the Eighth Circuit. It is premature and contrary to law to cancel registrations for the Safe Uses ahead of the Eighth Circuit's decision. Commencing cancellation proceedings before the court has rendered a decision would unjustly interfere with the jurisdiction of the Eighth Circuit. The Eighth Circuit

[11] 87 Fed. Reg. at 76,474.

[12] *Id*. at 76,476.

[13] *Id*. at 76,477.

will decide if EPA's rule revoking chlorpyrifos tolerances is lawful and whether growers can resume using chlorpyrifos as outlined in EPA's Safe Uses. EPA's attempt to remove these products from the market now on the basis that the products are "unsafe as a matter of law" interferes with the Eighth Circuit's pending decision on this very issue.

II. EPA's Proposed Cancellation of Gharda's Registrations Is Contrary to Law Because it Is Based on an Unlawful Rule.

EPA's decision to cancel Gharda's registrations is contrary to law because it is based on an unlawful rule—EPA's Final Rule revoking all tolerances for chlorpyrifos.[14] The Grower Petitioners have demonstrated that EPA's Final Rule is unlawful on the following grounds.

First, EPA's Final Rule is arbitrary and capricious because it disregards its own scientific evidence.[15] EPA's Final Rule reaffirmed its own scientific conclusions about any neurodevelopmental effects of chlorpyrifos. As discussed in the Petitioners' opening brief, EPA

[14] The Grower Petitioners hereby incorporate by reference the entirety of the Petitioners' Opening Brief, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. May 24, 2022) (Pet'rs Br.) (Exhibit 11), and Reply Brief, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. Sept. 6, 2022) (Pet'rs Reply Br.) (Exhibit 12), submitted to the Eighth Circuit. These objections also incorporate by reference the objections filed by Grower Petitioners in response to EPA's Final Rule revoking chlorpyrifos tolerances. Letter from Cassie Bladow, President, U.S. Beet Sugar Association, and Luther Markwart, Executive Vice President, American Sugarbeet Growers Association, to EPA, Office of Administrative Law Judges, "Objections to Decision Revoking All Chlorpyrifos Tolerances" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0029 (U.S. Beet Sugar Ass'n & Am. Sugarbeet Growers Ass'n Objections) (Exhibit 13); Letter from Richard Gupton, Senior Vice President of Public Policy & Counsel, Agricultural Retailers Association, et al., to EPA, "Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 19, 2021), EPA-HQ-OPP-2021-0523-0007 (Exhibit 14); Letter from David Milligan, President, National Association of Wheat Growers (Oct. 28, 2021), EPA-HQ-OPP-2021-0523-0016 (Exhibit 15); Letter from Kevin Scott, President, American Soybean Association, "Formal Written Objections, Request for Evidentiary Hearing, and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0022 (Exhibit 16); Letter from Kyle Harris, Director, Grower Relations, Cherry Marketing Institute, "Formal Written Objections and Request for Evidentiary Hearing for Chlorpyrifos Tolerance Revocation" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0024 (Exhibit 17).

[15] Pet'rs Br. 38.

found the data to be insufficient to show that there are neurodevelopmental effects below current regulatory requirements, and it maintained its longstanding 10 percent red blood cell acetylcholinesterase (RBC AChE) inhibition regulatory standard and applied the Food Quality Protection Act (FQPA) Safety Factor of 10X.[16] EPA also updated its drinking water assessment in 2020 to be the most cutting-edge, sophisticated drinking water assessment yet, reflecting the most advanced methodologies for assessing drinking water exposures and risks. The assessment underwent extensive peer review. EPA analyzed risks from exposures from 11 high-benefit agricultural uses in certain regions where estimated drinking water concentrations of chlorpyrifos were below EPA's benchmark level of concern. The PID found that, based on the drinking water assessment, those uses were safe.[17] And yet, EPA's Final Rule refuses to apply its own findings from its risk assessments and does not even dispute its scientific findings. Rather, EPA's refusal is based on a new legal interpretation that EPA contends required it to conclude that none of the existing tolerances was safe.[18] EPA misstates the law, which nowhere justifies EPA's decision to ignore its safety finding for the Safe Uses. EPA's rejection of its own scientific evidence is arbitrary and capricious.

Second, EPA's Final Rule is arbitrary and capricious and contrary to law because it ignores the text of the law and the intent of Congress in FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Based on the FFDCA's plain language, EPA was required to assess safety by not only considering currently registered uses but also by looking to anticipated exposures (a forward-looking mandate). EPA must also make safety determinations for each

[16] *Id*. at 39.

[17] *Id*. at 40.

[18] *Id*. at 42.

tolerance on an individual basis.[19] EPA has authority to modify tolerances and thereby narrow uses if it finds based on scientific evidence that an existing tolerance is not safe. While EPA must look at aggregate exposures, the reference to aggregate exposure in the FFDCA means EPA must consider, in making individual tolerance determinations, all of the exposures a person is "anticipated" to encounter.[20] Therefore, EPA's position in the Final Rule that all tolerances must rise or fall together, and that it is required to assess only currently registered uses, misreads the statute.[21]

Third, EPA's Final Rule is contrary to law because EPA failed to harmonize its safety determination under the FFDCA with FIFRA. Instead, EPA took the unprecedented position that its actions under the two statutes are separate.[22] EPA could have (and has in the past with other pesticides) coordinated its actions under the FFDCA with FIFRA by modifying tolerances or registrations accordingly.[23] EPA did not need to have cancellation and label amendment requests from all registrants in hand before acting on its safety finding.[24] EPA never gave registrants or the public notice of any such requirement, and in fact told Gharda that EPA would notify Gharda if it needed anything more than the written commitment Gharda had given EPA to voluntarily give up all but the Safe Uses. EPA never provided such notice to Gharda or, upon information and belief, to any other registrant. EPA should have followed its science and banned any food uses other than the Safe Uses, anticipating that regulated parties would follow the law and give

[19] *Id*. at 43.

[20] Pet'rs Reply Br. 18.

[21] Pet'rs Br. 45.

[22] *Id*. at 48.

[23] *Id*. at 53.

[24] Pet'rs Reply Br. 19.

up uses made unlawful by a tolerance revocation.[25] EPA's failure to do so renders the Final Rule arbitrary, capricious, and contrary to law.

Fourth, EPA's Final Rule is arbitrary and capricious because it offers no reasoned explanation that addresses the relevant factors and evidence. EPA's reason for revoking all tolerances was the claim that it had no reason to believe that the registrations would be amended, and thus it was allegedly required to consider the safety of all currently registered uses collectively. This reasoning is contrary to the statute, contrary to EPA's prior practice, and contrary to logic.[26]

Fifth, EPA's post-hoc rationalization that the PID finding was only a proposal, and therefore EPA was not required to consider it in the Final Rule, is wrong. EPA cannot disregard the scientific evidence before it simply because it may be revised later.[27] It was required to make decisions on tolerances based on available data and information regardless of whether it has been through notice and comment rulemaking.[28] EPA certainly treated its PID scientific findings as final in discussions with Gharda on a voluntary narrowing of uses consistent with the PID.[29] EPA's decision in the Final Rule to ignore the PID findings was arbitrary, capricious, and contrary to law.

Sixth, EPA incorrectly claims that the PID was based on a FIFRA-based analysis separate from the safety standard applicable to tolerances under the FFDCA.[30] Congress requires

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[25] *Id*. at 20.

[26] Pet'rs Br. 55.

[27] *Id*. at 56.

[28] Pet'rs Reply Br. 8.

[29] Pet'rs Br. 60.

[30] Pet'rs Reply Br. 11-12.

the same safety standard for food use pesticides for both FIFRA and the FFDCA. The PID's safety finding was therefore directly applicable to EPA's decision concerning the safety of chlorpyrifos tolerances. Here again, EPA's post-hoc justification is arbitrary, capricious, and contrary to law.

Finally, EPA's argument that it lacked the necessary basis to act on its safety finding ignores the plain language of the statute and the undisputed facts. EPA had written commitments from Gharda to give up all uses other than the Safe Uses. EPA had a reasonable basis to expect modifications to chlorpyrifos registrations because the practical effect of tolerance revocation is a ban on the use of the pesticide.[31] EPA did in fact receive voluntary cancellation requests of chlorpyrifos registrations once it issued its notice requesting the same, after revocation of the tolerances went into effect. If EPA needed any additional information in order to support modifying tolerances by revoking all but those for the Safe Uses, it had the statutory duty to obtain it from the registrants and the tools to compel production of such information.[32] EPA's attempts to defend the Final Rule confirm that it was arbitrary, capricious and contrary to law.

For the reasons argued by Grower Petitioners to the Eighth Circuit, summarized above, the Final Rule is unlawful. Because EPA's NOIC relies on this unlawful rule, the NOIC is itself contrary to law.

III. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious Because it Is Contrary to the Evidence.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious because it is contrary to the evidence. First, EPA has not presented any evidence that chlorpyrifos products are being sold or distributed for food uses. There is no evidence of a safety risk because

[31] *Id*. at 23.

[32] 21 U.S.C. § 346a(f).

there is no continuing sale or distribution of chlorpyrifos for use on food. Gharda is the only technical registrant of chlorpyrifos seeking to maintain a registration for chlorpyrifos, and even there only with respect to the Safe Uses. Moreover, Gharda clearly committed to EPA in March 2022 that its chlorpyrifos products would not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit. EPA's justification for cancelling Gharda's products on the basis that these products are allegedly unsafe is unsupported, as evidenced by the fact that the products are not being sold or distributed.

Second, EPA's cancellation of Gharda's products is contrary to EPA's own evidence that chlorpyrifos is safe for certain food uses. EPA's chlorpyrifos risk assessments[33] show that the Safe Uses are safe and meet the FQPA standard for safety set forth in FFDCA and applicable to registration review under FIFRA. EPA concluded that the Safe Uses meet the FQPA's safety standard using the 10X margin of safety and announced that finding in the 2020 PID.[34] There is no scientific evidence in the record to support any conclusion that the Safe Uses do not meet the applicable safety standard under FIFRA. EPA continues to agree that the Safe Uses are indeed safe.[35]

Third, there is no evidence that the extreme step of registration cancellation is necessary to address EPA's purported concerns with certain food uses of chlorpyrifos. EPA has the information necessary to amend the chlorpyrifos registrations and labels in order to limit use of

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[33] *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review*, (Sept. 22, 2020), EPA-HQ-OPP-2008-0850-0944 (Exhibit 18); Memorandum from Rochelle F.H. Bohaty, Ph.D., Senior Chemist, et al., EPA, to Patricia Biggio, Chemical Review Manager, et al., EPA, "Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (Sept. 15, 2020), EPA-HQ-OPP-2008-0850-0941 (Exhibit 19).

[34] Chlorpyrifos PID.

[35] EPA Br. 12-13; 87 Fed. Reg. 11,222, 11,241 (Feb. 28, 2022) (Exhibit 20).

chlorpyrifos to be consistent with the EPA's identified Safe Uses. EPA can and should amend, rather than cancel, Gharda's registrations.[36] EPA's failure to do so violates FIFRA section 6(b),[37] requiring EPA to consider restricting pesticide use as an alternative to cancellation.

Fourth, EPA's conclusion that cancellation of the registrations "is not anticipated to have any impacts on the agricultural economy"[38] is contrary to the evidence. The tolerances for the Safe Uses must be reinstated, as the Grower Petitioners have explained to the Eighth Circuit. Cancellation of the registrations would deprive Grower Petitioners of a critical crop protection tool that will cause significant crop losses and significant harm to the agricultural economy.

IV. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious because it Fails to Consider Important Aspects of the Problem.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious because it fails to consider important aspects of the problem, including the extent to which EPA's decision would interfere with the Eighth Circuit's jurisdiction, the harm it would cause the Grower Petitioners, the lack of necessity for the cancellation, and the impact the cancellation would have on the economy.

A. EPA Fails to Consider the Extent to Which its Actions Would Interfere with the Jurisdiction of the Eighth Circuit.

EPA fails to consider the extent to which its cancellation of Gharda's registrations interferes with the jurisdiction of the Eighth Circuit. The Eighth Circuit is currently deciding the

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[36] We note that these comments are relevant to the NOIC and not only to EPA's Final Rule revoking all chlorpyrifos tolerances because EPA's NOIC seeks to remove the last remaining chlorpyrifos products from the market, depriving growers from having access to chlorpyrifos in the future if the Eighth Circuit decides EPA's revocation of the tolerances for the Safe Uses is unlawful. EPA fails to justify why an NOIC is appropriate when it has the authority to amend registrations to remove the specific uses it determined to be unsafe.

[37] 7 U.S.C. § 136d(b).

[38] 87 Fed. Reg. at 76,478.

legality of EPA's revocation of the tolerances for the Safe Uses. EPA's preemptive cancellation of Gharda's registrations will cause serious consequences for Grower Petitioners. A favorable decision from the Eighth Circuit would allow Grower Petitioners to use chlorpyrifos for the Safe Uses in the 2023 growing season. But cancellation of Gharda's registrations for these Safe Uses would prevent Grower Petitioners from resuming use of chlorpyrifos in the upcoming growing season. The Grower Petitioners would have to wait years while registrants undertake the process to obtain new registrations for chlorpyrifos, all the while suffering the crop loses and year-on-year increases in pest pressure, as detailed in their sworn declarations before the Eighth Circuit.

B. EPA Fails to Consider the Harm this Action Would Cause the Petitioners and Other Growers.

EPA has failed to consider the substantial harm that growers are already facing and will continue to face by EPA's attempt to keep chlorpyrifos off the market. EPA has found chlorpyrifos critical to the agricultural economy.[39] In many instances, there is no available substitute for the effective control of pests. Growers are in desperate need of chlorpyrifos for the 2023 growing season. The Grower Petitioners have demonstrated in their objections to EPA and in their attestations to the Eighth Circuit[40] the dire situation they are facing and will continue to suffer for the survival of their businesses and the crops they supply for U.S. consumers with the loss of chlorpyrifos.

EPA's assumption that its NOIC will not have an impact on the economy, because chlorpyrifos tolerances have been revoked, is a fallacy. If the Eighth Circuit rules in favor of the

[39] EPA, "Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)," (Nov. 18, 2020), EPA-HQ-OPP-2008-0850-0969 (Exhibit 21).

[40] Pet. for Review, Attachment 2, Exhibits A-W, Supporting Declarations of Grower Petitioners, *Red River Valley Sugarbeet Growers Ass'n et al.* (8th Cir. Feb. 28, 2022). We hereby incorporate by reference the entirety of Attachment 2, Exhibits A-W (Exhibit 22).

Grower Petitioners, and EPA has already cancelled all chlorpyrifos registrations, growers will have no chlorpyrifos products available to protect the crops at issue. Growers would have to wait for registrants to submit new registrations to EPA and obtain approvals from EPA prior to sale or distribution of the pesticide. As explained below, this hurdle would cause significant harm to growers and disruptions in the economy.

On average, 8.8 million acres of agricultural crops were treated with chlorpyrifos annually from 2014-2018, and EPA estimated the total annual economic benefit of chlorpyrifos to crop production to be $19-130 million.[41] In the state of North Dakota alone, the per acre benefits of chlorpyrifos could be as high as $500 in parts of the state, leading the EPA-estimated high-end benefits over $30 million overall nationwide.[42] Therefore, the loss of chlorpyrifos has significant negative economic impacts for the agriculture industry.

The Grower Petitioners already suffer and will continue to suffer immediate, unrecoverable, significant irreparable harm in the form of economic losses and reputational damage unless EPA withdraws or stays this NOIC as soon as possible. The loss of chlorpyrifos as a pest management tool will result in substantially increased costs, lost profits, a larger environmental impact from the more frequent use of less effective alternatives, and decreased crop yields. All of these harms are compounded by the fact that growers reasonably relied on EPA's PID to plan for crop management, and several states took a measured approach to phase out uses of chlorpyrifos rather than immediately banning chlorpyrifos without a phase-out

[41] *Id*., Exhibit J at 3.

[42] *Amicus Curiae* Br. of the State of North Dakota in Support of Petitioners 16, *Red River Valley Sugarbeet Growers Ass'n et al.* (8th Cir. June 1, 2022) (North Dakota *Amicus* Br.) (Exhibit 23).

period.[43] And growers and states face burdens of having to address the tons of "stranded" and unusable chlorpyrifos stocks remaining that will need to be disposed of.[44] EPA's NOIC ignores these economic impacts.

1. Irreparable Harm to Sugarbeet Growers

For the sugarbeet industry, the estimated high-end benefits for the use of chlorpyrifos is $32.2 million per year, and this is likely an underestimate.[45] Chlorpyrifos is the most effective control against the sugarbeet root maggot (SBRM) and flies, and in some cases is the *only* effective pesticide. The industry depends significantly on chlorpyrifos as a critical crop protection tool to meet the sugar demands of the U.S. economy.[46] EPA has acknowledged that the lack of alternatives to chlorpyrifos can lead to potential yield loss in sugarbeet crops. The continued loss of chlorpyrifos products would be devastating to sugarbeet growers because registered alternatives can only suppress but not control the SBRM or are only registered for use on adult flies and not larvae.

For one sugarbeet farm located in a "hot spot" with a high incidence of SBRM infestation, 65 percent of its annual revenue comes from sugarbeets, and 75 percent of its annual revenue comes from crops on which it applies chlorpyrifos.[47] The farm estimated that without chlorpyrifos unrecoverable losses could be up to $200 per acre.[48] For another farm, where 50 percent of its annual revenue comes from crops on which it applies chlorpyrifos, it estimated

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[43] *Id*.

[44] *Id*. at 26.

[45] U.S. Beet Sugar Ass'n & Am. Sugarbeet Growers Ass'n Objections.

[46] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit A at 4-5.

[47] *Id*., Exhibit B at 3.

[48] *Id*. at 8.

unrecoverable losses of about $60,000 per year of its sugarbeet crop alone.[49] Another cooperative estimated unrecoverable losses of up to $30,000,000 per year for its members.[50] One cooperative estimated unrecoverable losses of approximately $34,436,634 in 2022 for its grower members .[51] Growers in this region cannot source sugarbeets from elsewhere because they cannot be shipped thousands of miles or be grown in other areas to make up for the losses.[52] Another cooperative estimated unrecoverable losses of up to $17,500,000 per year of its members.[53]

The State of North Dakota found that there would be a reduction of 1,565 pounds of sugar per acre produced and $201 per acre in revenue losses, resulting in $20,904,000 in losses in North Dakota SBRM areas and $18,395,642 in additional total production costs for a total of $39,299,642 in losses.[54] And these losses will compound with every year of using less effective alternatives. Without chlorpyrifos, SBRM can decrease crop yields by as much as 45 percent.[55]

Sugarbeet growers also face concerns about their healthy crops being impacted by being stored with crops from other farms that are damaged by destructive pests. Costs to sugarbeet growers are exacerbated by inflation, which has increased the cost of operating a farming business (fertilizer costs, fuel costs, chemical costs, and equipment costs) by over 30 percent.[56]

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[49] *Id*., Exhibit E at 7.

[50] *Id*., Exhibit F at 9.

[51] *Id*., Exhibit G at 11.

[52] *Id*. at 15.

[53] *Id*., Exhibit I at 10.

[54] North Dakota *Amicus* Br. 18-19.

[55] *Id*. at 22.

[56] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit B at 8.

In North Dakota, the sugarbeet industry is also suffering from impacts from extreme weather, early freezes, drought, and, in 2022, the latest spring on record caused by persistent cool and wet weather.[57]

For these farms and many others, chlorpyrifos is the only tool that has been consistently effective at controlling SBRM. Alternatives require multiple applications and are less effective, resulting in increased costs and a larger environmental impact. The problem cannot be ameliorated through methods like crop rotation because it is not an effective substitute for chlorpyrifos for SBRM control. SBRM larvae overwinter in fields and emerge the next year.[58] Without chlorpyrifos use in the future, this will likely lead to greater harm every year as the population of destructive SBRM grows with each growing season.[59]

Sugarbeet growers are also concerned that the loss of chlorpyrifos in the future will result in less protection for sugarbeets from symphylans, as chlorpyrifos is the only fully registered rescue option available in early spring to control symphylans.[60] One cooperative estimated that, if chlorpyrifos is not available, 25-33 percent of the sugarbeet seed production acreage will likely be affected, with up to a 50 percent loss of seed production.[61] Further, the loss of chlorpyrifos will negatively impact sugarbeet growers not only economically but also through reputational harm, creating uncertainty regarding the safety of food products in commerce.[62]

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[57] North Dakota *Amicus* Br. 25.

[58] *Id.* at 24.

[59] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit B at 6.

[60] *Id*., Exhibit C at 4.

[61] *Id*., Exhibit G at 14.

[62] *Id*., Exhibit C at 7.

2. Irreparable Harm to Soybean Growers

As the soybean industry has demonstrated, growers have relied on chlorpyrifos to control numerous insect pests, with the most critical uses being for the control of soybean aphids and two-spotted spider mites (TSM). These pests are notoriously difficult to control and can result in up to 60 percent yield loss.[63]

Some of these pests can vector plant pathogenic viruses which can result in double-digit yield loses and, in rare instances, reduce yields greater than 90 percent.[64] There are only a limited number of options to control aphids and TSM, and removal of any options such as chlorpyrifos will result in rapid build-up of insecticide resistance to the remaining options.[65] For growers who lose access to chlorpyrifos, there is no one-to-one replacement, meaning that growers will have to spray at least two active ingredients to control these pests, increasing their purchase and application costs. Soybean farmers estimate over $1.26 million in annual cost increases to protect their crops if they are forced to continue to use alternatives.[66]

3. Irreparable Harm to Fruit Growers

For cherry growers, chlorpyrifos has been one of the most effective tools and, according to one Grower Petitioner, is used on almost all of its cherry tree acres.[67] And there is no equivalent replacement for chlorpyrifos. Chlorpyrifos is unique in that it is the only effective chemistry to protect the cherry industry from trunk borers. Chlorpyrifos is active on adult, egg, and larval stages of most trunk boring pests. EPA has even acknowledged that borers are a

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[63] *Id*., Exhibit K at 4.

[64] *Id*., Exhibit M at 4.

[65] *Id*.

[66] *Id*., Exhibit K at 6.

[67] *Id*., Exhibit T at 3.

growing problem for which effective alternatives to chlorpyrifos are not available.[68] Tree loss from trunk borers can cost a grower $300 per tree in lost revenue.[69] Chlorpyrifos has also been important for peach growers to protect against lesser peach tree borers, as well as apple growers to protect against scale, stink bugs, aphids, and borers in apple production.[70]

Citrus growers in Florida also depend on chlorpyrifos. They currently face a dire situation with the growing problem citrus greening caused by the Asian citrus psyllid. The importance of chlorpyrifos in the management of citrus greening cannot be overemphasized. Already, the U.S. Department of Agriculture (USDA) reported in 2019 that citrus production overall in Florida has decreased by more than 74 percent since the introduction of the Asian citrus psyllid and the subsequent citrus greening infections.[71] Asian citrus psyllids, rust mites, spider mites, broad mites, scales, and Diaprepes root weevils all cause economic damage to citrus in Florida. All of these pests are targeted directly and managed effectively by chlorpyrifos. Other alternatives are less effective, have increased costs, and result in lower crop yields.

4. Irreparable Harm to Wheat and Cotton Growers

Chlorpyrifos has been used on winter and spring wheat and allows growers the flexibility needed to address pest pressures.[72] It has also been used to protect cotton crops from whitefly and late season cotton aphid infestations. If not controlled, the entire cotton chain is impacted from sugar excretions on the cotton from the pests. The resulting "sticky cotton" slows down the

[68] *Id*. at 4.

[69] *Id*. at 5-6.

[70] *Id*., Exhibit V at 4.

[71] *Id*., Exhibit U at 3.

[72] *Id*., Exhibit S at 3.

ginning process by up to 25 percent and will lower the grade and value of cotton. Over time, wheat and cotton growers will experience yield losses and increased costs.

As outlined above, grower groups will suffer immediate, irreparable harm in the form of significant yield losses, lost profits, and, consequently, lost jobs if they can no longer use chlorpyrifos to protect their crops. Chlorpyrifos is urgently needed because it has broad-spectrum effectiveness, has a relatively short persistence (making it less harmful to beneficial insects), and can be used in multiple delivery systems—all key attributes of an integrated pest management program.[73] The loss of chlorpyrifos will only expedite insect resistance to the few remaining alternatives and result in greater crop damage. These growers will also be forced to apply less effective alternatives in greater volumes, reducing their ability to be good environmental stewards.

C. EPA Fails to Consider That There Is No Purpose Served by Cancelling Gharda's Registrations.

EPA fails to consider that its proposed cancellation of Gharda's products does not serve the cited purpose. In fact, there is no legitimate purpose for cancelling Gharda's registrations. Chlorpyrifos cannot be used on food crops while the Eighth Circuit considers the validity of the Final Rule revoking all tolerances for chlorpyrifos. And, as stated previously, Gharda has committed to ensure chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit. EPA has not presented any evidence that chlorpyrifos products are being sold or distributed in violation of its revocation order. All EPA's NOIC accomplishes is prematurely revoking pesticide registrations for economically critical pesticide products on the basis of an unlawful Final Rule that the Grower Petitioners have asked

[73] *Id*., Exhibit J at 4.

to be vacated. EPA's NOIC would create more barriers and delays for growers who will need access to chlorpyrifos products in the future.

D. EPA Fails to Consider the Impact on the Economy.

EPA fails to consider, as required by FIFRA section 6(b) for registration cancellations, "restricting [chlorpyrifos's] use or uses as an alternative to cancellation" and fails to "take[] into account the impact" of cancellation of chlorpyrifos registrations "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."[74] As demonstrated by the Grower Petitioners, the economic impact of the total removal of all chlorpyrifos registrations for all food uses is devastating for the crops that, based on EPA's own evidence and safety finding for the Safe Uses, should not be restricted. While significant economic impacts are already being felt by growers, the harms will continue and be exacerbated with the cancellation of Gharda's products, the sole remaining approved chlorpyrifos products for the Safe Uses. Rather than have growers go out of business and consumers be deprived of critical food supply, EPA can simply amend chlorpyrifos registrations to restrict the non-safe food uses and allow the safe food uses to continue to be approved.

V. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious and an Abuse of Discretion Because it Offers No Reasoned Analysis for the Agency's Change in Course.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious and an abuse of discretion because it fails to provide a reasoned analysis for its sudden shift in position. EPA fails to explain why it is deviating from historical precedent and procedures. The USDA Office of Pest Management Policy (OPMP) believes EPA can retain certain chlorpyrifos uses

[74] 7 U.S.C. § 136d(b).

that meet EPA's safety standard based on its PID—the Safe Uses.[75] EPA provides no analysis for why its drastic actions to cancel all registrations is appropriate when specific uses it has determined to be safe can be preserved. EPA also inappropriately brushes aside the comments and concerns from USDA.[76]

VI. EPA's Refusal to Stay this Proceeding, Seeking Cancellation of Gharda's Registrations, Is Arbitrary, Capricious and Contrary to Law.

Petitioners in the Eighth Circuit, by letter dated January 6, 2023, asked EPA to withdraw or stay this proceeding in light of the pending Eighth Circuit litigation. Unfortunately, EPA rejected that request. As discussed, EPA's cancellation of Gharda's registrations would interfere with the jurisdiction of the Eighth Circuit and would force Grower Petitioners and other parties to needlessly expend additional resources fighting the cancellation while the Eighth Circuit litigation continues. Any cancellation of Gharda's registrations based upon the fact that tolerances have been revoked by EPA's Final Rule would become void upon an Eighth Circuit's ruling invalidating the Final Rule.

Because no use of chlorpyrifos can occur while the Final Rule is in effect, there is no legitimate purpose served by proceeding with cancellation of Gharda's registrations. EPA does not have reason to believe that chlorpyrifos is being sold or distributed in violation of the Final Rule. EPA waited to issue this NOIC for over nine months after Gharda's written commitment to ensuring its chlorpyrifos products do not enter the U.S. food supply. EPA's decision to issue the NOIC appears to be an attempt to interfere with the jurisdiction of the Eighth Circuit and the

[75] Letter from The Honorable Thomas J. Vilsack, Secretary, USDA, to The Honorable Rep. Vicky Hartzler (Sept. 20, 2022) (Exhibit 24).

[76] 87 Fed. Reg. at 76,478-79.

relief it might award Petitioners for EPA's unlawful Final Rule, rather than an action based on a legitimate concern about the unlawful sale and distribution of chlorpyrifos products for food use.

If the Eighth Circuit decides in favor of the Grower Petitioners, and growers can thereafter resume use of chlorpyrifos on the crops identified in the Safe Uses, cancelling Gharda's registrations will have unnecessarily created significant difficulties for growers in their ability to fight pests. It could take years before registrants of products containing chlorpyrifos apply for and obtain approval from EPA for new products or new food uses. In the meantime, growers will continue to suffer crop losses and/or increased costs of production.

The Grower Petitioners will suffer irreparable harm from EPA's cancellation of chlorpyrifos registrations for the Safe Uses. For the reasons set forth above, sound public policy supports a stay of the NOIC, and a stay would not harm public health or any public interest. The Grower Petitioners' objections to the NOIC are made in good faith and not frivolous. EPA should therefore stay the NOIC.[77]

VII. Grower Petitioners Request a Hearing on EPA's Proposed Cancellation of Gharda's Registrations.

For the reasons outlined above, Grower Petitioners object to EPA's NOIC and request a hearing on EPA's cancellation of Gharda's registrations. The Grower Petitioners are adversely affected by EPA's NOIC and EPA's refusal to withdraw or stay that action. EPA should not proceed with cancelling Gharda's chlorpyrifos product registrations until the litigation pending before the Eighth Circuit is resolved. Neither should EPA cancel Gharda's chlorpyrifos registrations until EPA first complies with the requirements of FIFRA. For the reasons set forth

[77] *Cf.*, 21 C.F.R. § 10.35(e)(1)-(4).

above, cancellation of Gharda's registrations is unlawful, arbitrary, capricious, and an abuse of discretion.

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Respectfully submitted,

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January 20, 2023

VIA CM/ECF
Clerk of the Court Michael E. Gans
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton U.S. Courthouse
111 South 10th Street
St. Louis, MO 63102

Re: *RRVSG Assoc., et al. v. Michael Regan, et al.*; Nos. 22-1422, 22-1530
Response to Petitioners' Federal Rule of Appellate Procedure 28(j) letter, Doc. ID 5237033

Dear Mr. Gans,

Petitioners provide no support for their claim that EPA's initiation of involuntary cancellation proceedings under FIFRA "ignor[es] this Court's exercise of jurisdiction" of their Petition for Review under the FFDCA. This Court denied Petitioners' stay motion, Doc. ID 5136844; therefore, EPA may move forward with involuntary cancellation proceedings. EPA's action is also consistent with the Ninth Circuit's direction to modify or cancel FIFRA registrations "in a timely fashion." *See League of United Latin Am. Citizens v. Regan,* 996 F.3d 673, 704 (9th Cir. 2021) (*"LULAC II"*). In any event, this Court is likely to rule on the instant Petition before involuntary cancellation proceedings are complete. *See* Resps.' Br. at 8. The Court should decline Petitioners' request to insert itself into an ongoing administrative proceeding that post-dates the agency action challenged here. Instead, the appropriate avenue for Petitioners to contest registration cancellations is the process set forth under FIFRA. *See* Resps.' Br. at 8.

The Court should dismiss the Petition because EPA's action was consistent with the law and the facts. Insofar as Petitioners claim that the initiation of involuntary cancellation proceedings supports partially vacating EPA's Final Rule, those proceedings are not before this Court and their outcome is not guaranteed. Moreover, contrary to Petitioners' claim, almost a year and a half after the issuance

of the Final Rule, Gharda has submitted amended labels for only one of its two end-use chlorpyrifos products. Thus, Petitioners' claim that there is "no doubt that EPA has everything necessary to approve labels consistent with EPA's determination of Safe Uses" is incorrect. Further, vacating as to the 11 uses would reinstate tolerances for which EPA has not made a final safety finding. *See* Resps.' Br. at 32-36. This would be inconsistent with *LULAC II* and the FFDCA. *See LULAC II,* 996 F.3d at 703 (requiring EPA to make "the requisite safety findings" to retain any uses); 21 U.S.C. § 346a(b)(2)(A)(i).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Laura J. Glickman, hereby certify that on January 20, 2022, I electronically filed the foregoing Response to Petitioners' FRAP 28(j) letter with the Clerk of the Court of the United States Court of Appeals for the Eighth Circuit by using the CM/ECF System. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Laura J. Glickman

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ENVIRONMENTAL APPEALS BOARD

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc., and Red River Valley Sugarbeet Growers Association, et al.,	)	**ALJ Docket No. FIFRA-HQ-2023-0001**
Petitioners.	)	

PETITIONERS' MOTION FOR APPEAL OF ORDER DENYING STAY TO ENVIRONMENTAL APPEALS BOARD

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Gharda Chemicals International, Inc. ("Gharda") and Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, and Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America ("Growers" and together with Gharda, "Petitioners") submit the following motion for appeal to the Environmental Appeals Board ("Motion for Appeal"). Petitioners respectfully request that the Environmental Appeals Board ("EAB") review the Administrative Law Judge's ("ALJ") March 31, 2023, order denying a stay of these proceedings ("Order Denying Stay"), pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and 40 C.F.R. § 164.100.

I. Standard for EAB Review

Pursuant to 40 C.F.R. § 164.100 and 40 C.F.R. § 22.29, when an interlocutory order or ruling is not certified by the ALJ, it shall be reviewed by the EAB upon request of a party and "in exceptional circumstances, that delaying review would be deleterious to vital public or private interests." 40 C.F.R. § 164.100. The EAB has explained that "exceptional circumstances" warranting interlocutory review include a resulting waste of resources, cases that raise fundamental issues of first impression, and where delaying resolution of the matter would be contrary to public interest. *In the Matter of Request to Reduce Pre-Harvest Interval for EBDC Fungicides on Potatoes,* 2008 EPA ALJ LEXIS 32, 29 (2008); *In the Matter of*

Chautauqua Hardware Corp., 3 E.A.D. 616 (EAB 1991); *In the Matter of Thermex Energy Corp*., 4 E.A.D. 68 (EAB 1992). The EAB's review of the Order Denying Stay shall be decided on the basis of the submissions made to the ALJ, 40 C.F.R. § 164.100, and Petitioners hereby incorporate by reference the arguments Petitioners made in the underlying proceeding. *See* Ex. 1 (Pet'rs' Req. for Certification of Order Den. Stay for Appeal to EAB); Ex. 2 (Resp't's Resp. to Req. for Certification of Order Den. Stay for Appeal to EAB); Ex. 3 (Pet'rs' Reply in Supp. of Req. for Certification of Order Den. Stay for Appeal to EAB); Ex. 4 (Order Den. Req. for Certification); Ex. 5 (Gharda Pet'r's Req. for Hr'g and Statement of Objs. and Req. for Stay); Ex. 6 (Grower Pet'rs' Req. for Hr'g and Statement of Objs.); Ex. 7 (Resp't's Resp. to Req. for Stay of Notice of Intent to Cancel Pesticide Registrations); Ex. 8 (Order Denying Stay).

II. The Circumstances of this Matter Constitute "Exceptional Circumstances" for EAB Review

For the reasons further detailed in Petitioners' Request for Certification and Reply in Support of Request for Certification—(i) the Order Denying Stay wrongly determined that the requested stay was for an "indefinite duration" and that there is no "pressing need" for a stay; (ii) not allowing Petitioners a reply brief to clarify the requested stay deprived Petitioners of their due process rights; and (iii) delaying review of the Order Denying Stay until after Petitioners have expended significant time and resources to arrive at a final judgment would be "inadequate or ineffective" and deleterious to public interests— "exceptional circumstances" exist warranting EAB's review of the Order Denying Stay. *See* Exs. 1, 3.

The Order Denying Stay denied Petitioners' request for a stay of the Notice of Intent to Cancel ("NOIC") proceeding. Petitioners had requested that the NOIC proceeding be stayed

pending a decision as to the legality of the Final Rule[1] underlying the NOIC proceeding in a lawsuit in the Eighth Circuit.[2] In denying the requested stay, the ALJ incorrectly determined that Petitioners' requested stay was for an "indefinite duration." But this is not the case when the Eighth Circuit lawsuit has been fully briefed and argued and the court's decision is forthcoming at any time. The ALJ also incorrectly determined that there is no "pressing need" for a stay, despite available information to the contrary. Specifically, the ALJ failed to consider the Declaration of Stephanie H. Stephens ("Stephens Declaration")[3] which clarified the time and expense involved if Petitioner Gharda's registrations are cancelled, the Eighth Circuit then remands or vacates the Final Rule, and Petitioner Gharda is forced to begin the registration process anew. The Stephens Declaration underscores the obvious point, made in Gharda's Objections (Ex. 5 at 6, 10), that it would be extremely costly and otherwise unfair to require Gharda to petition for a new registration if cancellation were to precede an Eighth Circuit remand or vacatur of the Final Rule.

Additionally, the ALJ's failure to allow Petitioners to reply to EPA's response to Gharda's Request for Stay prejudiced Petitioners in violation of their due process rights. Petitioners were not given an opportunity to elaborate on the harm identified in the Stephens Declaration, or to clarify that the requested stay was not for an indefinite duration. If Petitioners

[1] *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule").
[2] Petitioners have challenged the Final Rule underlying the NOIC as arbitrary and capricious, in the lawsuit captioned *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir.).
[3] This declaration was available in the materials related to the Eighth Circuit litigation cited in Petitioner Gharda's Objections and Request for Hearing in the NOIC proceeding. *See* Ex. 5 Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay, n. 8, Ex. 7 (citing Pet'rs Reply Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 2, 2022) (ID No. 5194647) (citing Pet. App. 1795, Stephens Declaration)).

had been permitted to submit a reply, they would have recommended a stay with appropriate guardrails for periodic review and reassessment.

Further, postponing review of the Order Denying Stay until after the Petitioners have expended significant time and resources to arrive at a judgment by the ALJ will be deleterious to vital public or private interests. *See In the Matter of Chautauqua Hardware Corp.,* 3 E.A.D. 616 (EAB 1991) ("exceptional circumstances" warranting EAB review exist where there will be a waste of resources). There is no dispute that postponing review of the Order Denying Stay until after Petitioners have expended significant time and resources to fully litigate the NOIC proceeding would be deleterious to the interests of Petitioners, and the public interests of efficiency in matters involving government agencies and expenditures. Moreover, "[a]s the Agency does not contest, post-judgment review of the Stay Order would be ineffective: Any benefits of a stay are necessarily lost by the time a case has proceeded to its conclusion." Ex. 4, Order Den. Req. for Certification at 2. Even the ALJ agrees that post-judgment review would be ineffective, *see id.*; thus, resulting in an enormous waste of resources to get to a judgment, which should not happen because a stay has been inappropriately denied. These exceptional circumstances warrant EAB review of the Order Denying Stay now in order to adequately afford relief to Petitioners.

III. Conclusion

For those reasons, and the reasons identified in the briefing before the ALJ with respect to the Request for Certification, Petitioners respectfully request that the EAB review and vacate the Order Denying Stay.

This 1st day of June, 2023,

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2023, true and correct copies of the foregoing was filed electronically with the EAB E-Filing System for the EAB's E-Docket Database, with a copy via electronic mail to the following:

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EXHIBIT 1

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc., and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners.	)	

PETITIONERS' REQUEST FOR CERTIFICATION OF ORDER DENYING STAY FOR APPEAL TO ENVIRONMENTAL APPEALS BOARD

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Gharda Chemicals International, Inc. ("Gharda") and Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, and Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America ("Growers" and together with Gharda, "Petitioners") respectfully request that the Administrative Law Judge ("ALJ") certify the ALJ's March 31, 2023, order denying a stay of these proceedings ("Order Denying Stay"), pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and 40 C.F.R. § 164.100, for appeal to the Environmental Appeals Board ("EAB").

I. Introduction

In its implementation of the Final Rule[1], EPA ignored its own science, leading to an arbitrary and capricious outcome. The Eighth Circuit is considering and will soon decide that contention. The U.S. Environmental Protection Agency ("EPA") is now using this Notice of Intent to Cancel ("NOIC") proceeding in a way never before conducted or contemplated and directly contrary to Petitioners' fundamental rights that Congress provided to registrants and other stakeholders under FIFRA. *See* Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay at 6, 9 (Jan. 13, 2023). Under these circumstances, a stay should be permitted for a reasonable period of time to permit the Eighth Circuit to issue a decision which may fully pre-

[1] *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule").

empt an outcome that would otherwise abridge Petitioners' rights. The Order Denying Stay, however, improperly denied Gharda's stay request by determining that the request was for a stay of "indefinite" duration which requires a "pressing need" that was not shown. The Order Denying Stay amounts to an important question of law, and delay of review by the EAB of the ALJ's determination on the requested stay until after the ALJ issues final judgment would be both inadequate and ineffective because the Petitioners would be forced to expend considerable time and resources to defend an NOIC proceeding that could be rendered moot by the Eighth Circuit's decision. The Order Denying Stay wrongly based the determination that the request for a stay did not demonstrate a "pressing need" on speculation, no evidentiary support, and a failure to consider the record at the Tribunal's disposal, and abused ALJ discretion in denying Petitioners the opportunity to reply to EPA's Response to the NOIC Stay Request, requiring immediate review by the EAB.

II. Background and Procedural History

Petitioners have challenged the Final Rule underlying the NOIC as arbitrary and capricious, in the lawsuit captioned *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir.) (the "Lawsuit"), because the Final Rule revoked all tolerances for chlorpyrifos, even though EPA found that tolerances for a subset of 11 uses (the "Safe Uses") meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The Lawsuit has been fully briefed, and oral argument took place on December 15, 2022. A decision by the Eighth Circuit could be issued at any moment and could include vacatur of the Final Rule.

On December 14, 2022, the day before oral argument in the Lawsuit, the EPA issued the NOIC, proposing to cancel Petitioner Gharda's registrations for chlorpyrifos products.

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022). Petitioners urged EPA to stay or withdraw the NOIC in correspondence dated January 6, 2023, but EPA denied this request. On January 13, 2023, Petitioners submitted objections to the NOIC, and Gharda also submitted a request for a stay of the NOIC. On February 8, 2023, the ALJ ordered EPA to respond to Gharda's stay request and *expressly disallowed Gharda the opportunity to reply*; EPA responded to Gharda's stay request on February 22, 2023. On March 31, 2023, the ALJ issued the Order Denying Stay.

III. The Order Denying Stay

The Order Denying Stay states that "Gharda requests a stay for an indefinite duration because the time at which the Eighth Circuit will issue a decision in *RRVSGA* [Lawsuit] is unknown. A stay is therefore warranted only if there is a pressing need for one." Order Denying Stay at 4. The Order Denying Stay further finds that "Gharda has not demonstrated a 'pressing need' for a stay of indefinite nature" because the NOIC proceeding does not "present[] any risk to the Eighth Circuit's jurisdiction" and the ALJ is "unconvinced by Gharda's arguments that, absent a stay, it may face unreasonable reregistration expenses or a protracted registration process." Order Denying Stay at 6. The ALJ therefore denied the request for stay because of the "absence of a pressing need for an indefinite stay of this matter." Order Denying Stay at 7.

IV. Standard for Request for Certification

The ALJ may certify an order for appeal to the EAB when:

> (a) The order or ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and (b) either (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or (2) review after the final judgment is issued will be inadequate or ineffective.

40 C.F.R. § 164.100.

V. The Order Denying Stay Involves an Important Question of Law

The first criteria in determining whether an order should be certified for interlocutory appeal under 40 C.F.R. § 164.100 is whether the order involves "an important question of law or policy about which there is substantial ground for difference of opinion." 40 C.F.R. § 164.100. The Order Denying Stay presents an important question of law because it improperly made a determination that Gharda did not show a "pressing need" for a stay when the weight of the record is to the contrary, and because the Order Denying Stay wrongly characterized Gharda's requested stay as being for an "indefinite" duration. These errors were compounded by the denial of a reply brief. As a result, and without EAB review now, the Petitioners will be forced to incur considerable time and expense to defend the NOIC proceeding.

a. The Order Denying Stay Incorrectly Finds There is No "Pressing Need" for a Stay

Contrary to the Order Denying Stay, Petitioners have shown a "pressing need" for a stay pending the Eighth Circuit determination on the Lawsuit. The Order Denying Stay reasons that Gharda will *not* be left at "square one" if it must "reregister" any of its products after registration cancellation that precedes an Eighth Circuit decision vacating the Final Rule as to the Safe Uses. However, the record before the ALJ demonstrates that Gharda will in fact be left at "square one" such that a "pressing need" exists to grant the requested stay.

The Order Denying Stay wrongly states that "Gharda *implies* that in the event of cancellation, it will be left at square one if it must reregister any products….This cannot be so. If Gharda prevails before the Eighth Circuit and then seeks wholesale reinstatement of its registrations, it will have as support the registrations' immediate precedents and all associated evidence and findings. Nor will Gharda need to reinvent the wheel if it must newly seek *updated* registrations." Order Denying Stay at 7 (emphasis added). The Order Denying Stay does not

cite any support for this conclusion that Gharda would not be "left at square one" as it relates to registering its products, and no such support exists in the record.

Gharda's claim that it will have to retreat to "square one" is not "implied"—it is fully supported by the uncontested views of a 30-year expert on EPA pesticide registration issues who participated in negotiations with EPA on behalf of Gharda regarding its chlorpyrifos registrations. *See* Ex. 1, Decl. of Stephanie H. Stephens ¶ 6 ("If Gharda were to submit applications for registration of new food uses and associated tolerances after EPA revoked all tolerances and cancelled all food uses, it would take approximately 38 months from the time of submission of the applications until *possible* EPA approval. EPA's fees for reestablishing U.S. food uses and associated tolerances would be approximately $875,000." (emphasis added)). This is not a "viable remedy" and makes it clear that, at great cost and delay, Gharda would have to start the FIFRA registration process anew in the event its registrations were cancelled in advance of an Eighth Circuit decision—*i.e., back to "square one*"—and with no certainty of success. *Id.* ¶ 7.

The Declaration of Stephanie H. Stephens was available to this Tribunal to review in making the determination on the request for stay because it was included in the materials related to the Eighth Circuit Lawsuit cited in Gharda's Objections and Request for Hearing. *See* Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay, n. 8, Ex. 7 (citing Pet'rs Reply Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022) (ID No. 5195044)). The Stephens Declaration is attached hereto as Exhibit 1. The Order Denying Stay demonstrates that this Tribunal reviewed at least some of the materials in the Eighth Circuit Lawsuit, as evidenced by the ALJ's citation to the Department of Justice's opposition to the stay request in the Lawsuit. *See* Order Denying Stay at 7 (citing Agency Resp.

Ex. 4 at 15 "Agency brief in opposition to stay request in *RRVSGA,* discussing Agency negotiations with Gharda regarding cancellation of chlorpyrifos registrations."). But there is no indication whatsoever that the ALJ weighed the significance of the Stephens Declaration.

Even EPA admitted that in the event of registration cancellations, "Petitioner Gharda or any registrant would need to follow the applicable process(es) for registration under FIFRA and the regulations promulgated thereunder." EPA Resp. to Req. for Stay of NOIC Pesticide Registrations at 10 (Feb. 22, 2023). This process described by EPA is exactly the back to "square one", non-viable remedy that Ms. Stephens references in her declaration. *See* Ex. 1 ¶ 6. EPA has not challenged Ms. Stephens' Declaration, either in the Eighth Circuit Lawsuit or in response to Gharda's request to stay these proceedings. Indeed, EPA has offered no commitment whatsoever that it would reinstate any chlorpyrifos registrations immediately as to the Safe Uses if the registrations are cancelled and the Eighth Circuit subsequently vacates the Final Rule as to the Safe Uses.

The fact of the matter is that Gharda *would be* back to "square one" in the event its registrations were cancelled and the Eighth Circuit vacated the Final Rule as to the Safe Uses—no clearer case for "pressing need" could be made. There is no guarantee at all that EPA would swiftly—or ever—reinstate the registrations in the event of these circumstances, and EPA certainly does not commit to doing so in any of its filings submitted to this Tribunal or to the Eighth Circuit.

The Order Denying Stay also concludes, without any basis in the record, that "[c]ancellation would not erase" the background work to develop registrations that "would fit Petitioners' wants and the Agency's public-health mandate." Order Denying Stay at 7. As showcased in the record, the discussions between Gharda and EPA that preceded the Final Rule

evidence that EPA's actions have been more akin to a bait-and-switch, rather than an approach that "fit[s] Petitioners' wants." *See* Decl. of Ram Seethapathi in Support of Gharda's Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos, EPA-HQ-OPP-2021-0523, ¶¶ 23, 26, 34, 36–37 (Nov. 10, 2021) ("in an effort to work cooperatively with EPA and believing it had little choice but to accept voluntary cancellation terms, Gharda committed to voluntarily cancel" certain crop uses; "EPA strongly implied during these discussions that the [Safe Uses] would remain in place as long as Gharda voluntarily cancelled all 1X uses"; EPA later advised Gharda that the voluntary cancellation of uses "were not sufficient for EPA's 'leadership'"; Gharda then "heard nothing further from EPA for weeks" and after significant discussions with EPA regarding the terms of voluntary cancellation of uses, "Gharda discovered a posting on EPA's website announcing the August 2021 revocation of all tolerances for chlorpyrifos" and the next day the Final Rule was announced).

Further, and just as importantly, Grower Petitioners and their members have a "pressing need" for chlorpyrifos in the current and future growing seasons to avoid unrecoverable losses and pest pressures. In many instances, chlorpyrifos is the only pesticide that can effectively control pests that afflict the Grower Petitioners' crops. *See* Petitioners' Opening Brief at 30-31, *Red River Valley Sugarbeet Growers Ass'n et al.*, Nos. 22-1422, 22-1530 (8th Cir. May 24, 2022), ID No. 5160660 ("Petitioners' Opening Brief") (citing Grower Declarations).[2] Without effective pest control, the insects will multiply and crop losses will grow. For the fruit trees that will be lost due to the unavailability of chlorpyrifos, it can take up to 10 years to get a replacement tree into production. Petition for Review, *Red River Valley Sugarbeet Growers*

[2] The Grower Declarations are found at Attachment 2 to the Petition for Review, *Red River Valley Sugarbeet Growers Ass'n,* No. 22-1422, Exhibits A – W, ID No. 5131400.

Ass'n, No. 22-1422, Att. 2 (8th Cir. Feb. 28, 2022), ID No. 5131400, Ex. J (Crittenden Decl.) ¶¶ 14-15; *id.*, Ex. T (Harris Decl.) ¶¶ 10-13. EPA itself recognized the important role that chlorpyrifos plays in protecting the Grower Petitioners' crops, describing these uses as "high benefit" and "critical." Petitioners' Opening Brief at 40. Together, the Grower Petitioners' crops contribute approximately $59 billion to the national economy every year. *Id.* at 31. The demonstrated safety of the Safe Uses of chlorpyrifos and the importance of these uses to Grower Petitioners and the agricultural economy has led the United States Department of Agriculture to oppose the cancellation of Gharda's registrations. *See* Petitioners' Rule 28(j) Submission, *Red River Valley Sugarbeet Growers Ass'n et al*., Nos. 22-1422, 22-1530 (8th Cir. Dec. 14, 2022), ID No. 5227503, Ex. A at 76,2478, Ex. C at 3, and Ex. D. Therefore, Petitioners have shown a "pressing need" for the requested stay.

b. Gharda's Request is Not a Request of Indefinite Duration

The Order Denying Stay concludes that "Gharda requests a stay of indefinite duration because the time at which the Eighth Circuit will issue a decision in *RRVSGA* is unknown." Order Denying Stay at 4. However, this conclusion ignores the current posture of the Eighth Circuit Lawsuit. The case in the Eighth Circuit has been fully briefed, and oral argument took place on December 15, 2022. Petitioners have impressed upon the Eighth Circuit Court the need for a decision to be made before the 2023 growing season, to avoid irreparable harm if the Safe Uses are not permitted to be used. *See* Petitioners' Rule 28(j) Submission, *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Jan. 18, 2023), ID No. 5237033.

Notably, the cases cited in the Order Denying Stay align with Gharda's request for a stay until the Eighth Circuit rules—a request of a reasonable duration. *See, e.g., Diomed, Inc. v. Total Vein Solutions, LLC*, 498 F.Supp.2d 385, 387 (D. Mass. 2007) (explaining that "a stay will most

likely be granted in situations likely to conserve judicial and party time, resources, and energy" and only denying the requested stay where the requesting party had already been "stalling" discovery for over a year); *In re Borla Performance Indus., Inc.*, EPA Docket No. CAA-09-2020-0044, 2022 EPA ALJ LEXIS 2 (ALJ, Mar. 15, 2022) (Order on Respondent's Motion to Stay the Proceedings) (where a stay was requested pending the outcome of related D.C. Circuit litigation, but briefing had not yet concluded in the D.C. Circuit litigation, and the issue being decided by the D.C. Circuit was "not at all dispositive" of the issues before the ALJ). Here, a decision in the Lawsuit is likely imminent and therefore a stay pending that decision is not "indefinite." Moreover, if the Eighth Circuit vacates the Final Rule as to the Safe Uses, that action should be dispositive as to the NOIC, saving the time and resources of this Tribunal. Finally, a stay could have been granted that would be subject to periodic review and reassessment, particularly given the pressing need as outlined above, *supra* § V(a), and would therefore not be "indefinite" as the Order Denying Stay determined.

VI. Review of the Order Denying Stay by the EAB After a Final Judgment is Issued by the ALJ Would be Inadequate or Ineffective

After the first prong of 40 C.F.R. § 164.00 is met, one of the following must also be met: "either (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or (2) review after the final judgment is issued will be inadequate or ineffective." 40 C.F.R. § 164.100. Here, review by the EAB after a final judgment is issued by the ALJ would be inadequate or ineffective, because Petitioners would have already been forced to pursue a costly and time-consuming defense to the NOIC. Further, EAB review of the stay request becomes moot if review is not afforded until after the ALJ issues a final judgment on the NOIC because the EAB cannot offer any remedy as to the stay request at that point.

VII. The Order Denying Stay Violates Petitioners' Due Process

The Order Denying Stay violates Petitioners' Constitutional due process rights because it was entered without affording Petitioners an opportunity to reply to EPA's response to the request for stay. Due process "requires that a person be given adequate notice and an opportunity to be heard in any proceeding where he or she may be deprived of life, liberty or property." *In the Matter of J.V. Peters & Co.*, 7 E.A.D. 77, 95 (E.P.A. April 14, 1997) (citing *Mullane v. Central Hanover Bank*, 339 U.S. 306, 313-14 (1950)). In its response, EPA mischaracterizes the request as seeking a stay for an "indefinite" duration, and wrongly contends that there is no "pressing need" for a stay—both of these arguments were considered by the ALJ and incorporated into the Order Denying Stay without Petitioners having an opportunity to reply to those arguments and clarify the duration of the requested stay. EPA Resp. to Req. for Stay of NOIC Pesticide Registrations at 8–9; Order Denying Stay at 4.

On February 8, 2023, the ALJ issued an Order to Respondent to Respond ("Order to Respond"), which required EPA to respond to Gharda's request for a stay. The Order to Respond expressly states that "[n]o replies will be permitted." Order to Respond at 2. If Gharda had been permitted to reply to EPA's Response, it would have outlined why the requirement to demonstrate a "pressing need" for a stay was not applicable here and explained that Gharda's request was not for a stay of an "indefinite" duration. While the ALJ has discretion under 40 C.F.R. § 164.60(b) as to whether a reply brief is permitted, the ALJ did not appropriately exercise such discretion in denying Gharda the opportunity to submit a reply brief to clarify EPA's, and therefore the ALJ's, misunderstanding of Gharda's request. The NOIC proceedings seek a deprivation of Gharda's property, and Gharda was not afforded an opportunity to be heard

on EPA's arguments regarding the requested stay. Under these circumstances, Petitioners' rights to due process were violated.

VIII. Conclusion

For those reasons, Petitioners respectfully request that this Tribunal certify the Order Denying Stay for appeal to the EAB.

This 10th day of April, 2023,

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CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2023, true and correct copies of the foregoing Request for Certification was filed electronically with the EPA OALJ E-Filing System for the OALJ's E-Docket Database, with a copy via electronic mail to the following:

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EXHIBIT 2

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners	)	

RESPONSE TO REQUEST FOR CERTIFICATION OF ORDER DENYING STAY FOR APPEAL TO ENVIRONMENTAL APPEALS BOARD

As directed by this Tribunal in its April 12, 2023 Order Setting Briefing Schedule on Petitioners' Request for Certification, Respondent the U.S. Environmental Protection Agency ("EPA," "Agency," or "Respondent") respectfully submits this Response to Petitioners' April 10, 2023 Request for Certification of Order Denying Stay for Appeal to Environmental Appeals Board.

On December 14, 2022, EPA published in the Federal Register a Notice of Intent to Cancel ("NOIC") the registrations of three pesticide products pursuant to section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136d(b). Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022). In its January 13, 2023 Request for Hearing and Statement of Objections and Request for Stay ("Gharda's Objections"), Petitioner Gharda Chemicals International, Inc. ("Gharda") requested that this Tribunal stay any action with respect to the NOIC, including but not limited to

the conduct of a hearing, pending resolution of the Petitioners' challenge to the Agency's rule revoking chlorpyrifos tolerances. Gharda's Objections at 12-13 (referring to *Red River Valley Sugarbeet Growers Ass'n v. Regan*, Nos. 22-1422, 22-1530 (8th Cir. argued Dec. 15, 2022) [hereinafter *RRVSGA*] (challenging Chlorpyrifos: Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the "Final Rule")). EPA opposed that request to stay this proceeding in its Response to Request for Stay of Notice of Intent to Cancel Pesticide Registrations filed February 22, 2023 ("EPA Response to Stay Request").

On March 31, 2023, this Tribunal denied Petitioner Gharda's stay request ("Order Denying Stay"), correctly finding that Petitioner Gharda failed to demonstrate a "pressing need" for a stay of indefinite duration.[1] Petitioner Gharda, along with a collection of grower groups[2] (collectively "Petitioners"), now seek to further delay these proceedings by requesting that this Tribunal certify the Order Denying Stay for appeal to the Environmental Appeals Board ("EAB"). *See* Petitioners' Request for Certification of Order Denying Stay for Appeal to Environmental Appeals Board (Apr. 10, 2023) ("Certification Request").

For the reasons set forth in more detail herein, Respondent respectfully requests that this Tribunal deny the Certification Request.

STANDARD OF REVIEW

As set forth in the Rules of Practice governing hearings under FIFRA arising from notices of intent to cancel pesticide registrations, 40 C.F.R. part 164,

[1] *See* Order on Petitioner Gharda Chemicals International, Inc.'s Motion to Stay at 6-7.
[2] Several grower groups ("Grower Petitioners") also filed with this Tribunal a Request for Hearing and Statement of Objections on the NOIC dated January 13, 2023.

> [t]he Administrative Law Judge may certify an order or ruling for appeal to the Environmental Appeals Board when: (a) The order or ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and (b) either (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or (2) review after the final judgment is issued will be inadequate or ineffective. The Administrative Law Judge shall certify orders or rulings for appeal only upon the request of a party.

40 C.F.R. § 164.100.

OBJECTIONS TO CERTIFICATION REQUEST

As discussed in more detail in the EPA Response to Stay Request, Respondent believes that a stay of these proceedings is unnecessary, inconsistent with the directives of the Eighth and Ninth Circuit Courts of Appeals, and inappropriate since Petitioner Gharda failed to demonstrate a "pressing need" for a stay of these proceedings pending the issuance of a decision by the Eighth Circuit in *RRVSGA*. Similarly, Petitioners fail to demonstrate in the Certification Request that there is "an important question of law or policy about which there is substantial ground for difference of opinion," 40 C.F.R. § 164.100, such that certification to the EAB and further delay of these proceedings would be appropriate. Although Petitioners assert that this Tribunal's conclusion that Petitioner Gharda failed to demonstrate a "pressing need" for its request for an "indefinite" stay presents such a question, Petitioners' arguments focus solely on whether there is an important question of law, and do not include any analysis of whether there is "substantial ground for difference of opinion" about such a question, as contemplated by 40 C.F.R. § 164.100.[3] Furthermore, the Order Denying Stay was merely this Tribunal's application of the relevant standard of review for consideration of an indefinite stay. The applicable case law does

[3] *See*, *e.g.*, Certification Request at 3 ("The Order Denying Stay amounts to an *important question of law*, and delay of review by the EAB…") and 5 ("The Order Denying Stay presents an *important question of law* because it improperly made a determination that Gharda did not show a 'pressing need' for a stay when the weight of the record is to the contrary, and because the Order Denying Stay wrongly characterized Gharda's requested stay as being for an 'indefinite" duration.'") (emphases added).

not permit granting "a stay of indefinite duration in the absence of a pressing need," *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936), and this Tribunal properly exercised its discretion when it determined that Petitioner Gharda failed to identify a pressing need for a stay.

First, Petitioners cannot escape that Petitioner Gharda's stay request is for a functionally indefinite duration, and that the Order Denying Stay was correct to therefore "balanc[e] interests favoring a stay against interests frustrated by a stay." Order Denying Stay at 4 (internal citations omitted). Second, Petitioners entirely omit any analysis of the interest balancing required by that standard of review. Petitioners focus exclusively on Petitioner Gharda's speculative need to re-register its products in the event of a particular decision from the Eighth Circuit and on Petitioners' potential economic losses, and fail to address the many countervailing interests raised by the Agency in the EPA Response to Stay Request and discussed by this Tribunal in the Order Denying Stay. Finally, Petitioners claim that this Tribunal's decision to disallow a reply to the EPA Response to Stay Request violates their Due Process rights, despite admitting that the ALJ has discretion to do so pursuant to 40 C.F.R. § 164.60(b). Certification Request at 11. The Grower Petitioners chose not to move this Tribunal for a stay,[4] and Petitioners now claim that their inability to "clarify" and "outline" Petitioner Gharda's arguments – which cited to the incorrect criteria for a stay and failed to enumerate how those criteria were satisfied – is a violation of Petitioners' right to due process. Petitioners had the full "opportunity to be heard 'at a meaningful time and in a meaningful manner'" as to the need for a stay of these proceedings, *In Re: J.V. Peters and Company, a Partnership, David B. Shillman, and Dorothy L. Brueggemeyer*, 7 E.A.D. 77, 95 (EAB 1997) (internal citations omitted), and this Tribunal

[4] *See* Order Denying Stay at 1, fn.2.

properly exercised its discretion under 40 C.F.R. § 164.60(b) to disallow a reply to the EPA Response to Stay Request.

I. This Tribunal Correctly Identifies Petitioners' Request as for a Stay of Indefinite Duration.

Petitioners argue that a decision in *RRVSGA* is "likely imminent," and therefore, a stay pending that decision is not "indefinite." Certification Request at 10. Petitioners do not cite to any authority for their assertion that a stay may not be considered "indefinite" simply because its duration is tied to the issuance of decision in a separate proceeding at some unspecified time in the future. On the contrary, as discussed below, courts have rejected stays of such vague duration.

As explained by Respondent in the EPA Response to Stay Request and affirmed by this Tribunal in the Order Denying Stay, it is unclear when the Eighth Circuit might issue its decision or what that decision might be. *See* EPA Response to Stay Request at 8 and Order Denying Stay at 4. It is also unclear what the next steps might be after the Eighth Circuit issues its order and whether Petitioners would make similar arguments to further delay these proceedings pending their appeal of what might well be an unfavorable decision. As a result, this Tribunal was correct to conclude that Petitioner Gharda's request was for a stay of indefinite duration and therefore to "balanc[e] interests favoring a stay against interests frustrated by a stay." Order Denying Stay at 4 (internal citations omitted).

Contrary to Petitioners' assertions, the cases cited by this Tribunal in the Order Denying Stay underscore that Petitioners seek a stay of indefinite duration, and that therefore a pressing need must exist. Petitioners misread *Diomed, Inc. v. Total Vein Sols., LLC* to suggest that the court in that matter only denied a stay where the requesting party had already been "stalling" discovery for over a year. Certification Request at 9-10 (internal citations omitted). While the

court indeed noted that plaintiff had complained about the defendant's "stalling," the court's analysis hinged on the sufficiency of the defendant's rationale for further delay rather than on the passage of some specific amount of time. *See Diomed, Inc. v. Total Vein Sols., LLC*, 498 F. Supp. 2d 385, 387 (D. Mass. 2007) ("Quite simply, [Defendant] has not articulated a sufficient reason to delay the adjudication of this action any further."). That court's emphasis on the movant's justification for a stay is similar to the "pressing need" standard properly employed by this Tribunal and, as discussed further below in Section II, that Petitioners have repeatedly failed to properly assess. Also, in *In the Matter of: Borla Performance Indus., Inc., Respondent*, this Tribunal found that the "contours of the stay" sought in that matter were too imprecise where it was unclear how long the Court of Appeals for the D.C. Circuit would need to consider briefs, consider issues raised at oral argument, and issue a decision. *In the Matter of: Borla Performance Indus., Inc., Respondent*, EPA Docket No. CAA-09-2020-0044, 2022 WL 887454, at *3 (ALJ, Mar. 15, 2022). As a result, this Tribunal found that such a stay would only be granted where there is a pressing need for one. *Id*. While briefing and oral argument have concluded in *RRVSGA*, it is similarly unclear how long the Eighth Circuit will need to consider the issues raised in oral argument and issue its decision. Nor is it apparent what that court's decision might be or how much time might be required to accommodate any necessary next steps resulting from that decision.

Petitioners note in support of their claim that an Eighth Circuit decision is "likely imminent" that they have impressed upon the Eighth Circuit the need for a decision prior to the 2023 growing season. Certification Request at 9 (*citing* Federal Rule of Appellate Procedure 28(j) Letter for *Red River Valley Sugarbeet Growers Association, et al. v. Michael Regan, et al.*, Nos. 22-1422 (lead), 22-1530, *RRVSGA* (8th Cir. Jan 18, 2023), Entry ID 5237033). Petitioners

fail to make clear, however, that Petitioners' Rule 28(j) submission making that request of the Eighth Circuit stated that the 2023 growing season commenced in March for many crops.[5] Since the Eighth Circuit has yet to issue its decision in *RRVSGA*, there is no reason to believe that a decision is imminent based on the Petitioners' request for a decision prior to the 2023 growing season.

Petitioners conclude by noting that "a stay could have been granted that would be subject to periodic review and reassessment." Certification Request at 10. This suggestion was not included in Petitioner Gharda's original stay request, and Petitioners provide no explanation for why this Tribunal should have *sua sponte* devised and imposed a reviewable stay of this nature based on the bare request included in Gharda's Objections. Furthermore, at this time, Petitioners propose no particular schedule or provide any details for their late-suggested review and reassessment. In any event, while appearing to suggest a stay of more limited duration, this suggestion would still ultimately result in a stay of indefinite duration because it would be inextricably tied to the issuance of an Eighth Circuit decision in *RRVSGA*,[6] and it remains unclear when the Eighth Circuit might issue its decision or what the next steps might be after the Eighth Circuit issues its order.

In light of the foregoing, Petitioners have failed to establish that there is substantial ground for difference of opinion as to the indefinite nature of Petitioners' stay request.

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[5] Federal Rule of Appellate Procedure 28(j) Letter for *Red River Valley Sugarbeet Growers Association, et al. v. Michael Regan, et al.* at 2, Nos. 22-1422 (lead), 22-1530, *RRVSGA* (8th Cir. Jan 18, 2023), Entry ID 5237033.

[6] *See Ortega Trujillo v. Conover & Co. Commc'ns*, 221 F.3d 1262, 1264 n.3 (11th Cir. 2000) (finding that an order for the parties to submit status reports on separate litigation "does not make the scope of a stay less indefinite."); *see also Landis*, 299 U.S. at 257 ("[A]n order which is to continue by its terms for an immoderate stretch of time is not to be upheld as moderate because conceivably the court that made it may be persuaded at a later time to undo what it has done.").

II. Petitioners' Arguments that a "Pressing Need" for a Stay Exists are Fatally Deficient.

As discussed in the Order Denying Stay, when determining whether to stay proceedings indefinitely, this Tribunal will identify a "pressing need" by "balancing interests favoring a stay against interests frustrated by a stay," with an overarching consideration of this Tribunal's obligation to "exercise jurisdiction timely in cases properly before it." Order Denying Stay at 4 (internal citations omitted). Petitioners completely disregard this balancing requirement, choosing instead to flatly assert that a pressing need for an indefinite stay exists because Petitioner Gharda *might* at some future point need to re-register the products subject to the NOIC and in light of certain economic hardships claimed by Petitioners once the products in question are cancelled. *See* Certification Request at 5-9.

As previously noted by Respondent, if the registrations subject to the NOIC are cancelled, and if tolerances for residues of chlorpyrifos are restored in the future, then Petitioner Gharda, like any other registrant seeking a pesticide registration, would need to follow the applicable process(es) for registration under FIFRA and the regulations promulgated thereunder, and would need to demonstrate that such uses meet the FIFRA standard.[7] While following those processes would necessarily be more burdensome to Petitioner Gharda than if none of the uses had ever been cancelled,[8] Petitioners' interest in avoiding the possibility that Petitioner Gharda

[7] *See, e.g.*, EPA Response to Stay Request at 10.

[8] Petitioners make much of the fact that Respondent has not challenged the time and expense figures included in the Declaration of Stephanie H. Stephens and cited in the Certification Request. *See* Certification Request at 6-7. Petitioners do not explain why Petitioner Gharda deemed these arguments unworthy of inclusion in Petitioner Gharda's initial stay request and instead opted to simply note at the conclusion of a procedural history of the *RRVSGA* litigation that the "parties' principal briefs in [*RRVSGA*] are incorporated by reference here." Gharda Objections at 4. In any event, Respondent is unable to verify the figures provided by Ms. Stephens based on information currently available to Respondent. For example, Ms. Stephens claims that "it would take approximately 38 months from the time of submission" of applications for new food uses and tolerances until approval, Certification Request at 6, while the longest decision review timeline in the Pesticide Registration Improvement Act fee tables is 36 months. *See* PRIA Fee Category Table - Registration Division (RD) - New Active Ingredients,

might have to follow the same statutory and regulatory processes for registering uses as any other similarly situated registrant is significantly outweighed by the Agency's need to comply with the Ninth Circuit's unequivocal directive to cancel uses in a timely fashion, its responsibility to properly administer the law, and its interest in clarifying the disposition of chlorpyrifos products, all of which EPA discussed in detail in the EPA Response to Stay Request.[9]

Notably, Petitioners do not even mention the Ninth Circuit's order to Respondent to modify or cancel pesticide registrations consistent with its tolerance decision "in a timely fashion," *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 704 (9th Cir. 2021) [hereinafter *LULAC II*], much less argue that their speculative concerns about product registration warrant frustrating the intent of that court's unambiguous order. Nor do Petitioners address Respondent's points that allowing these products to remain out of compliance with FIFRA for an indefinite period is inconsistent with public policy, or that cancellation of the products in question would provide clarity for disposition of these products and allow for movement of these products for disposal. *See* EPA Response to Stay Request at 11-12.

Petitioners assign equal significance to their interest in avoiding "unrecoverable losses and pest pressures" due to the Grower Petitioners' inability to use chlorpyrifos on their crops. Certification Request at 8. However, as Respondent EPA explained in the EPA Response to

available at https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-rd-new-active-ingredients. Ultimately, there are a number of variables associated with a potential registration scenario, such that the potential cost(s), applicable process(es), and timing are entirely speculative. For example, these costs and processes might vary depending on whether an applicant would seek to add a use to an existing registration or register a new product, whether the use remains registered on any other product, whether any new data might be necessary to assess the risks and benefits of a pesticide when the application is submitted, or whether any uses have previously been subject to cancellation. *See, e.g.,* 7 U.S.C. 136w-8; 40 C.F.R. part 152, subparts C and F. Respondent therefore does not have sufficient information to definitively calculate the time and expense Petitioner Gharda's speculative future application(s) might entail.

[9] *See* EPA Response to Stay Request at 8-12.

Stay Request, any such harms would be properly attributable to the Final Rule, not the NOIC which is the subject of these proceedings. EPA Response to Stay Request at 10-11. The NOIC and the cancellation of chlorpyrifos food uses is simply an administrative process to implement the Final Rule, and as this Tribunal noted, "there may be…no overlap between the Eighth Circuit's review of issues related to the Final Rule and this Tribunal's review of the NOIC." Order Denying Stay at 6. And even assuming *arguendo* that this Tribunal should take this interest into consideration, Petitioners again decline to balance this interest against those that would be frustrated by a stay and that have been clearly identified by Respondent in the EPA Response to Stay Request, as discussed above.

Ultimately, Petitioners' failure to properly apply the balancing test required by the applicable case law or to acknowledge the competing interests identified by the Respondent and affirmed by this Tribunal shows that there is no substantial ground for difference of opinion as to whether Petitioners have demonstrated a pressing need for a stay.

III. Petitioners Have Not Established a Due Process Violation.

Petitioners conclude by arguing that this Tribunal's decision to disallow a reply to the EPA Response to Stay Request violates their due process rights. *See* Certification Request at 11-12. Petitioners acknowledge, however, that this Tribunal has discretion to do so pursuant to 40 C.F.R. § 164.60(b). *Id*. at 11. Petitioners assert that if they were given a chance to reply, they could have "outlined" why the requirement to demonstrate a pressing need for a stay is not applicable, and "explained" their argument that their request was not for an "indefinite duration." *Id*.

As Petitioners note, due process "requires that a person be given adequate notice and an opportunity to be heard in any proceeding where he or she may be deprived of life, liberty or

property." *Id*. (citations omitted). The EAB has also noted that "[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *In Re: J.V. Peters and Company*, 7 E.A.D. at 95 (*quoting Mathews v. Eldridge*, 424 U.S. 319, 333 (1976)). Furthermore, "due process is flexible and calls for such procedural protections as the particular situation demands." *In Re: J.V. Peters and Company*, 7 E.A.D. at 97 n.31 (*citing Morrissey v. Brewer*, 408 U.S. 471, 481 (1972)).

In light of those principles, Respondent EPA asserts that Petitioners were in fact afforded the opportunity to be heard at a meaningful time and in a meaningful manner via their requests for hearings and statements of objections in this matter, and that the circumstances of this proceeding and the Order Denying Stay did not call for further submissions from Petitioners regarding a stay. The Grower Petitioners chose not to ask this Tribunal to stay these proceedings in their hearing requests and objections.[10] Petitioner Gharda included a request for a stay, but asserted that an incorrect standard should govern. *See* EPA Response to Stay Request at 3-4, Order Denying Stay at 4. Furthermore, Petitioner Gharda declined to enumerate how exactly it satisfied its proposed criteria, simply stating that "[f]or reasons outlined herein, Gharda has satisfied these criteria here." Gharda's Objections at 13. Petitioners argue that they could have "outlined" and "explained" their arguments in a reply to the EPA Response to Stay Request but provide no explanation for why they did not outline and explain their arguments for a stay in their initial requests for hearings and statements of objections. Now, after Respondent EPA identified the correct standard and attempted to graft Petitioner Gharda's arguments for a stay onto that framework for purposes of rebuttal, Petitioners essentially argue that this Tribunal should have allowed Petitioners a "do-over" on their original stay request.

[10] *See* Order Denying Stay at 1, 2.

This Tribunal has discretion to disallow replies per 40 C.F.R. § 164.60(b), as Petitioners acknowledge,[11] and this Tribunal appropriately considered the circumstances of this proceeding when it exercised that discretion to disallow a reply to the EPA Response to Stay. In addition to considering Petitioner Gharda's and Respondent's arguments for and against a stay, respectively,[12] this Tribunal reviewed the lengthy procedural history of *LULAC II* and *RRVSGA* and Respondent's ongoing efforts to address existing registrations of chlorpyrifos for food use to bring them in line with the Final Rule.[13] Petitioners had full opportunity to submit arguments in favor of a stay, and the arguments that Petitioners chose to submit were considered by this Tribunal and balanced against those put forth by Respondent in light of applicable legal requirements, including those giving this Tribunal discretion to disallow replies. There is ultimately no substantial ground for difference of opinion as to whether this Tribunal's resulting decision to disallow a reply to the EPA Response to Stay Request violates Petitioners' due process rights.

CONCLUSION

As discussed in more detail above, Respondent believes that Petitioners have failed to establish that the Order Denying Stay involves an important question of law or policy about which there is substantial ground for difference of opinion, as specified by 40 C.F.R. § 164.100. Petitioner Gharda's stay request is for an indefinite duration, and it was therefore proper for the Order Denying Stay to "balanc[e] interests favoring a stay against interests frustrated by a stay." Furthermore, Petitioners do not engage in the balancing required by that standard in their arguments that there is a "pressing need" for such a stay, and do not attempt to address the

[11] Certification Request at 11.
[12] Order Denying Stay at 5-6.
[13] *Id*. at 2-4.

interests that would be frustrated by a stay and that have already been clearly identified by Respondent. *See, e.g.*, EPA Response to Stay Request at 11-12. Finally, Petitioners' due process arguments are unavailing; this Tribunal's decision to disallow a reply to the EPA Response to Stay Request was well within the discretion afforded to it by 40 C.F.R. § 164.60(b), and Petitioners were afforded the opportunity to be heard at a meaningful time and in a meaningful manner in their requests for hearings and statements of objections in this matter. Ultimately, it is clear that Petitioners' goal is to further delay these proceedings based entirely on Petitioners' speculation of what an Eighth Circuit decision in *RRVSGA* might entail. As noted in the EPA Response to Stay Request,[14] Respondent has asserted that a delay in these proceedings is unnecessary and inappropriate, and as a result, Respondent respectfully requests that this Tribunal deny Petitioners' request to certify the Order Denying Stay for appeal to the EAB.

Respectfully submitted,

Dated: April 20, 2023

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[14] *See*, *e.g.*, EPA Response to Stay Request at 4.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing RESPONSE TO REQUEST FOR CERTIFICATION OF ORDER DENYING STAY FOR APPEAL TO ENVIRONMENTAL APPEALS BOARD, dated April 20, 2023, was filed electronically with the U.S. Environmental Protection Agency, Office of Administrative Law Judges E-filing system.

I also certify that a true and correct copy of the foregoing RESPONSE TO REQUEST FOR CERTIFICATION OF ORDER DENYING STAY FOR APPEAL TO ENVIRONMENTAL APPEALS BOARD was served on Petitioners via electronic mail to:

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EXHIBIT 3

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc., and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners.	)	

PETITIONERS' REPLY IN SUPPORT OF REQUEST FOR CERTIFICATION OF ORDER DENYING STAY FOR APPEAL TO ENVIRONMENTAL APPEALS BOARD

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Gharda Chemicals International, Inc. ("Gharda") and Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, and Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America ("Growers" and together with Gharda, "Petitioners") submit the following reply in support of their Request for Certification of the Order Denying Stay for Appeal to the Environmental Appeals Board ("Request for Certification"). Petitioners respectfully request that the Administrative Law Judge ("ALJ") certify the ALJ's March 31, 2023 order denying a stay of these proceedings ("Order Denying Stay"), pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and 40 C.F.R. § 164.100, for appeal to the Environmental Appeals Board ("EAB").

The Petitioners made their certification request not, as EPA contends, "to further delay these proceedings," EPA Resp. to Req. for Certification ("Response") at 2, but because (i) the Order Denying Stay incorrectly determined that the requested stay was for an "indefinite duration" and that there is no "pressing need" for a stay when the available information is to the contrary; (ii) not allowing Petitioners a reply brief to clarify "indefinite duration" and "pressing need" in the exceptional circumstances involved in this matter erroneously deprived Petitioners of their due process rights; and (iii) postponing review of the Order Denying Stay until after the Petitioners have expended significant time and resources to arrive at a final judgment will be

"inadequate or ineffective." 40 C.F.R. § 164.100. EPA's Response does not change these outcomes.

I. The Order Denying Stay Incorrectly Determined That the Requested Stay Was For an "Indefinite Duration" and That There Is No "Pressing Need" for a Stay—Constituting a Question of Law with Substantial Ground for Difference of Opinion

EPA does not challenge that an important question of law is presented by the determination in the Order Denying Stay that the requested stay was one of "indefinite duration" and not finding a "pressing need" to support such a stay. *See also In the Matter of: Request to Reduce Pre-Harvest Interval for EBDC Fungicide,* 2008 WL 4545096 (E.P.A. Oct. 6, 2008) (finding that "important questions of law and/or policy" exist where the issue "has been addressed in very few rulings in other cases" and has not been addressed in these particular circumstances)[1]. In fact, EPA's Response only disputes that there is substantial ground for difference of opinion.

In addition, EPA claims that Petitioners failed the balancing test used by this Tribunal to determine whether to grant the requested stay, but the use of such balancing test was wrong on two separate fronts. The Order Denying Stay first incorrectly determined that the requested stay

[1] The NOIC proceeding presents numerous issues of a novel, intertwined nature that do not appear to have been addressed in prior ALJ/EAB matters. Indeed, EPA's Response demonstrates the entanglement between the Ninth Circuit decision, the impending Eighth Circuit decision in the Lawsuit, and proposed-intervenors' request to intervene and argue science issues that are not at issue in these proceedings. *See* Pet'rs. Opp. to Mot. to Intervene. The Eighth Circuit Lawsuit has already been fully briefed, and oral argument took place on December 15, 2022—a decision by the Eighth Circuit could include vacatur of the Final Rule, the sole basis for the NOIC. Despite that the Eighth Circuit will soon decide the legality of the Final Rule, EPA has forged ahead and proposed to cancel Gharda's registrations in the NOIC based solely on the effect of the Final Rule. A stay of the NOIC proceedings would avoid such entanglement of the issues.

was for an "indefinite duration."[2] Second, even if the "pressing need" standard applied, which it only would for a stay of "indefinite duration", the Order Denying Stay failed to adequately weigh the evidence supporting a "pressing need" for a stay, rendering use of the balancing test inappropriate.

a. EPA Does Not Seriously Contest the Pressing Need Demonstrated by the Stephens Declaration

While the ALJ found that Gharda would not be "back to square one" in the event that the registrations are cancelled and the Eighth Circuit[3] later vacated the Final Rule[4], the evidence—not considered by the Order Denying Stay—is clear that Gharda would incur significant cost and harm if its registrations are cancelled and would in fact be "back at square one" if it needs to re-register its chlorpyrifos products following an Eighth Circuit vacatur. *See* Req. for Certification at Ex. 1, Decl. of Stephanie H. Stephens ¶ 6 (Apr. 10, 2023) ("If Gharda were to submit applications for registration of new food uses and associated tolerances after EPA revoked all tolerances and cancelled all food uses, it would take approximately 38 months from the time of submission of the applications until possible EPA approval. EPA's fees for reestablishing U.S. food uses and associated tolerances would be approximately $875,000."). EPA avoids Petitioners' arguments as to the harm that would be caused if the registrations are cancelled and the Final Rule is later vacated; instead, EPA relegates its attack on the Stephens' Declaration to a

[2] Because the requested stay was not for an "indefinite duration," a different standard applies. *See* Order Denying Stay at 4 ("When deciding motions to stay proceedings, this Tribunal's judges have considered" factors including, *inter alia*, whether a stay will "eliminate any unnecessary expense and effort."). Petitioners have met this standard. *See* Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay at 12–13.

[3] The Eighth Circuit is currently reviewing the legality of the Final Rule in the lawsuit captioned *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir.) (the "Lawsuit").

[4] *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule").

nineteen-line footnote that (1) does nothing to undermine the strength and veracity of this 30-year pesticide registration expert's views, and (2) makes no commitment whatsoever to reinstate Gharda's registrations immediately, ***if at all,*** if they are cancelled before an Eighth Circuit vacatur of the Final Rule. Indeed, EPA underscores the validity of the Stephens Declaration by asserting that "there are a number of variables associated with a potential registration scenario," EPA Resp. at 9 n.8, that could impact just how, whether, and when Gharda could ever get those registrations back. This again proves that Gharda would be "back to square one" in terms of the cost, time, and resources it would take to re-register its products.

EPA's Response cites to the PRIA Fee Category Table-Registration Division (RD)—New Active Ingredients (EPA Resp. at 8–9 n.8) for the proposition that Ms. Stephens' expert view on the length of time between submission of new chlorpyrifos registration applications and possible EPA approval (38 months) may be overstated by a few months. But EPA fails to note that it has renegotiated more than 60% of conventional pesticide PRIA deadlines, meaning that Ms. Stephens' Declaration may actually *underestimate* the waiting time that Petitioners would have to endure. Ex. 1, EPA, *PRIA Quarterly Stakeholder Meeting Presentation* at 18 (Apr. 13, 2023). Again, noticeably absent from EPA's Response is any commitment that Gharda's registrations would be immediately reinstated in the event of an Eighth Circuit vacatur that followed registration cancellation.

Further, while EPA may purport to raise its own competing interests against a stay of the NOIC proceedings, Petitioners' need for a stay clearly outweighs those interests. EPA argues that "allowing [chlorpyrifos] products to remain out of compliance with FIFRA for an indefinite period is inconsistent with public policy." EPA Resp. at 9. However, it is undisputed that there are currently no chlorpyrifos products used on food in the stream of commerce. Gharda's Req.

for Hr'g and Statement of Objs. and Req. for Stay at 6–7 (Jan. 13, 2023). EPA also argues that EPA's need to comply with the Ninth Circuit's directive to cancel uses in a "timely fashion" outweighs the Petitioners' need for a stay. EPA Resp. at 9. However, EPA's purported interests are significantly outweighed by Petitioners' need for a stay—Grower Petitioners[5] and their members have a pressing need to use chlorpyrifos products in the current and future growing seasons to avoid unrecoverable losses and pest pressures, and Gharda would be back to "square one" in the event its registrations are cancelled and the Eighth Circuit vacates the Final Rule as to the Safe Uses. EPA's Response also ignores Petitioners' argument that review of the Order Denying Stay now by the EAB is needed to avoid needless expense that will otherwise occur if review does not take place until after this matter is fully litigated before the ALJ.

b. Ground for Difference of Opinion Exists as to the Length of Petitioners' Requested Stay

EPA's Response demonstrates that ground for difference of opinion exists as to whether Petitioners' requested stay was for an "indefinite duration", which would determine whether the standard applied in the Order Denying Stay was appropriate. Petitioners believe that the requested stay is not 'indefinite' because it would be tied to the Eighth Circuit's decision, which is imminent. EPA argues that the requested stay is 'indefinite' because "it is unclear when the Eighth Circuit might issue its decision or what that decision might be." EPA Resp. at 5.[6] EPA's

[5] EPA mistakenly claims that Growers did not object to the failure to stay the cancellation proceeding, but Growers plainly raised this in their objections to the NOIC. *See* Growers' Req. for Hr'g and Statement of Objs. to NOIC at 20-21 (Jan. 13, 2023).

[6] EPA also argues that Petitioners' "failure to properly apply the balancing test required" or to "acknowledge the competing interests identified" by EPA shows that there is no substantial ground for difference of opinion. EPA Resp. at 10. To the contrary, the substantial ground for difference of opinion is actually *demonstrated* by EPA's arguments related to the appropriate standard to be applied in the Order Denying Stay. In any event, the failure of the Order Denying Stay to properly weigh the harm demonstrated by the Stephens' Declaration compounds the error of using the "pressing need" balancing test in the first place.

Response proves the difference of opinion that exists between Petitioners and EPA as to the length of Petitioners' requested stay. Because Petitioners have demonstrated both that the Order Denying Stay involves an important question of law, *see* Petitioners' Req. for Certification and *supra* § I, and that ground for difference of opinion exists as to the requested stay's duration, the ALJ should certify the Order Denying Stay for appeal to the EAB.

II. This Tribunal's Failure to Allow Petitioners to Reply Prejudiced Petitioners

This Tribunal failed to allow Petitioners to reply to EPA's response to Gharda's Request for Stay. Petitioners have been prejudiced by not having the opportunity to reply, and EPA's opposition to the request for certification demonstrates this further. Petitioners were not given an opportunity to elaborate on the harm identified in the Stephens Declaration, or the rationale that the requested stay was not for an indefinite duration, which they would have done if allowed to submit a reply.

EPA notes states that this Tribunal "reviewed the lengthy procedural history" of the Ninth Circuit case and Eighth Circuit Lawsuit, but fails to mention that the Order Denying Stay was silent on weighing the Stephens Declaration. EPA Resp. at 12. This is the exact issue that Petitioners would have addressed with the Tribunal, but they were not given the opportunity to do so.

EPA's opposition says that Petitioners should have included, in their original request for stay, any recommendations for the ALJ to fashion a stay that would be subject to periodic review and reassessment. EPA argues that the ALJ should not *sua sponte* devise and impose such a stay. Again, this is precisely why Petitioners needed an opportunity to reply—to address EPA's opposition to the requested stay, to clarify the reasons supporting a stay, and to recommend a stay with appropriate guardrails for periodic review and reassessment.

EPA further argues that, because Petitioners acknowledge the ALJ has discretion to allow a reply brief, Petitioners are barred from arguing that not being given the opportunity to reply constitutes a deprivation of Petitioners' due process rights. Petitioners are not foreclosed from identifying that this Tribunal abused its discretion by not allowing a reply brief. EPA's cancellation proceeding is not a simple, pro forma administrative process. This is a matter inextricably linked with the critical issues of administrative law that will be decided by the outcome of the Lawsuit in the Eighth Circuit. Moreover, as set forth in Gharda's Request for Hearing and Statement of Objections, EPA is attempting to use the NOIC in an unprecedented manner that ignores certain fundamental rights that Congress guaranteed to registrants and other stakeholders under FIFRA § 6. Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay at 12. Allowing a reply under such circumstances was critical. Petitioners were not afforded an opportunity to be heard on EPA's arguments regarding the requested stay, and therefore Petitioners' rights to due process were violated.

III. Review of the Order Denying Stay After a Final Judgment Will be "Inadequate or Ineffective"

EPA ignores, and cannot dispute, that postponing review of the Order Denying Stay until after the Petitioners have expended significant time and resources to arrive at a final judgment from this Tribunal will be "inadequate or ineffective." 40 C.F.R. § 164.100. If this matter is fully litigated in this Tribunal, it would require significant expense and resources. It would be prejudicial to allow EPA to use the NOIC proceedings to circumvent timely EAB review and force Petitioners to undergo the time consuming and costly processes attendant to the cancellation proceedings and, only then, have EAB review of the Order Denying Stay. It is simply undisputed that if the Tribunal issues an adverse determination on the NOIC, it would be "inadequate and ineffective" for the EAB to *then* review the Order Denying Stay because the

time and resources would have already been incurred to litigate the proceeding for which the stay was sought. Therefore, the EAB must review the Order Denying Stay now, to be effective and to adequately afford relief to Petitioners under these exceptional circumstances.

IV. Conclusion

For those reasons, and the reasons identified in the Request for Certification, Petitioners respectfully request that this Tribunal certify the Order Denying Stay for appeal to the Environmental Appeals Board.

This 27th day of April, 2023,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2023, true and correct copies of the foregoing Petitioners' Reply In Support Of Request for Certification was filed electronically with the EPA OALJ E-Filing System for the OALJ's E-Docket Database, with a copy via electronic mail to the following:

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EXHIBIT 4

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners.	)	

ORDER DENYING PETITIONERS' REQUEST FOR CERTIFICATION TO THE ENVIRONMENTAL APPEALS BOARD

I. Background

This matter relates to the U.S. Environmental Protection Agency's ("Agency's") Notice of Intent to Cancel Pesticide Registrations for chlorpyrifos. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76474-02 (Dec. 14, 2022) ("NOIC"). On January 13, 2023, Petitioner Gharda Chemicals International, Inc. ("Gharda") and a group of grower organizations styled the "Grower Petitioners" each filed objections to the NOIC and requested a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the registrations' cancellation. Gharda's Request for Hearing & Statement of Objections & Request for Stay (Jan. 13, 2023) ("Gharda Hearing Request"); Grower Petitioners' Request for Hearing & Statement of Objections (Jan. 13, 2023).

In connection with its Hearing Request, Gharda moved to stay this proceeding pending the outcome of related litigation before the U.S. Court of Appeals for the Eighth Circuit, namely *Red River Valley Sugarbeet Growers Ass'n v. Regan* ("*RRVSGA*"), Nos. 22-1422, 22-1530 (8th Cir.). Gharda Hr'g Req. 12–13. I denied Gharda's stay motion on March 31, 2023, finding that Gharda had failed to demonstrate a pressing need sufficient to justify its requested indefinite stay of this proceeding. Order on Petitioner Gharda Chemicals International, Inc.'s Motion to Stay (Mar. 31, 2023) ("Stay Order").

On April 10, 2023, Petitioners filed a request for certification to the Environmental Appeals Board, through which they sought leave to file an interlocutory appeal of the Stay Order. Petitioners' Request for Certification of Order Denying Stay for Appeal to Environmental Appeals Board (Apr. 10, 2023) ("Certification Request"). The Agency opposes the Certification Request. Respondent's Response to Request for Certification of Order Denying Stay for Appeal to Environmental Appeals Board (Apr. 20, 2023) ("Response"). For the reasons that follow, Petitioners' Certification Request is **DENIED**.

II. Standard for Certifying Orders for Interlocutory Appeal

The Rules of Practice that govern this proceeding allow for interlocutory review "only if the Administrative Law Judge [("ALJ")] certifies such orders or rulings for appeal, or . . . when the Environmental Appeals Board [("EAB")] determines, upon request of a party and in exceptional circumstances, that delaying review would be deleterious to vital public or private interests." 40 C.F.R. § 164.100. The ALJ may certify an order or ruling for appeal to the EAB only upon request from a party and only when:

> (a) The order or ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and (b) either (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or (2) review after the final judgment is issued will be inadequate or ineffective.

Id.

III. Party Arguments

Petitioners argue that certification is warranted pursuant to § 164.100 because:

> (i) the Order Denying Stay incorrectly determined that the requested stay was for an "indefinite duration" and that there is no "pressing need" for a stay when the available information is to the contrary; (ii) not allowing Petitioners a reply brief to clarify "indefinite duration" and "pressing need" in the exceptional circumstances involved in this matter erroneously deprived Petitioners of their due process rights; and (iii) postponing review of the Order Denying Stay until after the Petitioners have expended significant time and resources to arrive at a final judgment will be "inadequate or ineffective."

Petitioners' Reply in Support of Request for Certification 2–3 (Apr. 28, 2023) ("Reply").

The Agency counters that (i) no substantial grounds for difference of opinion exist as to whether Gharda's requested stay was indefinite in duration; (ii) because Petitioners fail to present the other side of the balancing test that applies to proposed stays of indefinite duration, they have failed to demonstrate substantial grounds for difference of opinion as to the results of that analysis; and (iii) Petitioners' due process argument fails because Petitioners' opening filings provided them a full and meaningful opportunity to be heard on the issue of the stay and because the Rules of Practice permit ALJs to forgo replies. Resp. 4–5, 7, 10.

IV. Analysis

As the Agency does not contest, post-judgment review of the Stay Order would be ineffective: Any benefits of a stay are necessarily lost by the time a case has proceeded to its conclusion. The sole issue before me, therefore, is whether Petitioners have shown that the Stay

Order "involves an important question of law or policy about which there is substantial ground for difference of opinion." I find that they have not.

Petitioners advance three possible "important questions" to justify certification: (1) whether the requested stay was indefinite in duration; (2) whether the evidence and argument presented in connection with Gharda's stay request demonstrated a "pressing need" for a stay; and (3) whether the undersigned's decision to forgo a reply as to Gharda's stay request violated Gharda's due process rights.[1] I address each issue in turn.

Indefinite duration. I agree with the Agency that whether Gharda's requested stay was of "indefinite duration" is not an important question of law or policy about which there is a substantial ground for difference of opinion. To begin, I disagree that this issue may be considered a "question of law or policy" at all, as opposed to a simple application of law to fact. *Cf. Ahrenholz v. Board of Trustees*, 219 F.3d 674, 676 (7th Cir. 2000) ("[T]he term 'question of law' does not mean the application of settled law to fact."). Petitioners disagree not with the legal standard that applies if their requested stay is indefinite in duration, but with whether that standard applies given the facts presented here. Nor does the question of what standard applies implicate any specific "policy" identified by Petitioners or identifiable by this Tribunal.

Regardless, I agree with the Agency that Petitioners have presented no *substantial* ground for difference of opinion on this issue. Petitioners posit that the requested stay *is* finite because it will end once the Eighth Circuit issues its decision, which is "imminent." Certification Req. 10; Reply 6. However, Petitioners fail to substantiate this claim of imminence. Petitioners' sole support for their assumed timeline is that they have advised the Eighth Circuit that they require a decision before the start of the 2023 growing season. Certification Req. 9. As the Agency observes, those pleas plainly have not spurred the *RRVSGA* panel to action as, according to the Petitioners themselves, the relevant 2023 growing season began over a month before this writing. Resp. 6–7 (citing Federal Rule of Appellate Procedure 28(j) Letter 2, *RRVSGA*, Nos. 22-1422, 22-1530 (8th Cir. Jan 18, 2023)). Petitioners' strong desire to receive a decision imminently is not evidence that the decision will soon materialize. The fact is that Petitioners simply do not know when the *RRVSGA* decision will issue. The proposed stay is therefore, by definition, indefinite. *See Indefinite*, Oxford English Dictionary (last accessed May 22, 2023), https://www-oed.com ("Of undetermined extent, amount, or number; unlimited."); *see also Borough of Naugatuck*, 1998 WL 743898, at *2 (ALJ Sept. 8, 1998) (Order Denying Certification for Interlocutory Appeal) (finding no substantial grounds for a difference of opinion as to interpretation of permit terms, because petitioner's interpretation "would require concluding that 'not at any time' means 'weekly or monthly average' and "[t]here are not substantial grounds for giving these words a meaning contrary to their plain import").

Pressing Need. Petitioners also fail to demonstrate that any of the alleged errors in the Stay Order's balancing of the factors mitigating for and against a stay constitute an "important question of law or policy about which there is substantial ground for difference of opinion." Petitioners first assert that the Stay Order errs in its failure to account for the Declaration of

[1] The Certification Request incorrectly assigns this alleged injury to all Petitioners. However, Grower Petitioners submitted no stay request in this action. *See generally* Grower Hr'g Req.

Stephanie H. Stephens ("Stephens Declaration"), Certification Req. Ex. 1. More specifically, Petitioners assert that:

> The Declaration of Stephanie H. Stephens was available to this Tribunal to review in making the determination on the request for stay because it was included in the materials related to the Eighth Circuit Lawsuit cited in Gharda's Objections and Request for Hearing. *See* Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay, n. 8, Ex. 7 (citing Pet'rs Reply Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022) (ID No. 5195044)).

Certification Req. 6. Petitioners' argument is baseless. Petitioners seem to suggest that the Stephens Declaration was cited in Gharda's Hearing Request and that it was included among the approximately 950 pages of exhibits Gharda submitted therewith.[2] Any such claim would be incorrect,[3] and the undersigned cannot have erred in failing to consider material with which she was never presented.[4] *See* Resp. 8 n.8 (correctly observing that Gharda faced no impediment to citing the Stephens Declaration as part of its stay request). Petitioners' assertion that I should have considered the Stephens Declaration because I considered one of the Agency's *RRVSGA* filings is facile: The Agency included the referenced filing as an exhibit to its response to Gharda's stay request. *See* Stay Order 7 (citing Respondent's Resp. to Request for Stay of Notice of Intent to Cancel Pesticide Registrations ("Agency Stay Response"), Ex. 4 at 15).

Petitioners next assert that the Stay Order erroneously concluded that "'[c]ancellation would not erase' the background work to develop registrations that 'would fit Petitioners' wants and the Agency's public-health mandate,'" because the parties hereto actually have a poor working relationship in which Petitioners' wants have been ignored. Certification Req. 7–8.

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[2] Petitioners' wording of this argument is abstruse. It is possible Petitioners instead meant to contend that it was incumbent upon the Tribunal to seek out the Stephens Declaration on the *RRVSGA* docket because Petitioners cited to a separate document that appears on that docket or because Petitioners cited to that docket generally. If so, Petitioners are incorrect. The EAB has confirmed that administrative tribunals, like their judicial counterparts, have no duty to scour the record for un-cited support for a movant's position. *Rochester Pub. Utils.*, 11 E.A.D. 593, 599 (EAB Aug. 3, 2004) (Order Denying Review) ("It is not our duty in an adversarial proceeding to comb the record and make a party's argument for it."). It is beyond peradventure that this holds true for materials a party has both failed to cite and omitted from the record entirely.

[3] For abundant clarity: The Stephens Declaration appears nowhere among any of Petitioners' or the Agency's exhibits in support of their briefing on Gharda's stay request. In addition, contrary to the Certification Request's assertions, Certification Req. 6, Petitioners did not submit the Stephens Declaration to the Eighth Circuit with the *RRVSGA* merits reply brief that Gharda cited in its Hearing Request. As the Stephens Declaration itself confirms, it was instead filed as an attachment to the sealed Declaration of Ram Seethapathi that Petitioners filed in support of the Reply in Support of Petitioners' Motion for a Partial Stay Pending Review in that case. Stephens Decl. ¶ 2 ("I am making this declaration on behalf of Petitioner Gharda Chemicals International, Inc. (Gharda) in support of Petitioners' Reply in Support of Petitioners' Motion for A Partial Stay Pending Review."); *see* Motion to Seal a Document, *RRVSGA*, No. 22-1422 (Mar. 3, 2022) (ECF No. 5132908) (appending Stephens Declaration as Exhibit 5 to to-be-sealed Declaration of Ram Seethapathi).

[4] I address Petitioners' argument that they should have been permitted an opportunity to present this evidence in reply below.

Petitioners' argument is beside the point. The Stay Order's optimistic observation about Petitioners' wants was tangential to the material, undisputed point that the parties have engaged in substantial background work to arrive at lawful modified registrations for chlorpyrifos. While the parties' relationship may have suffered greatly in the process, Petitioners fail to present any evidence to refute the Stay Order's finding (derived in part from Gharda's own submissions) that the parties have, indeed, engaged in protracted negotiations related to modified chlorpyrifos registrations. Stay Order 6–7 (citing Gharda Hr'g Req. 6, 11). Petitioners also present no evidence or argument that the work that has previously been done on that score will somehow evaporate upon cancellation. Accordingly, Petitioners fail to demonstrate that this issue presents substantial grounds for disagreement in any relevant respect.

Finally, Petitioners claim that the "Grower Petitioners and their members have a 'pressing need' for chlorpyrifos in the current and future growing seasons to avoid unrecoverable losses and pest pressures," and that this interest justifies a stay. Certification Req. 8. Petitioners identify no legal error associated with, nor any policy implicated by, the Stay Order's contrary determination that any present such harm to Grower Petitioners is the result of the Final Rule, not cancellation. To the extent Petitioners mean to argue that the Stay Order erred in balancing the interests in favor of and mitigating against a stay, that cannot be considered a "question of law or policy."

Due Process. As to Petitioners' due process argument, Petitioners again do not articulate a "substantial" disagreement regarding whether they were entitled to a reply. Where a party has had a meaningful opportunity to lay out its position, courts have found no due process right to a reply. *See, e.g.*, *Nat'l Lab. Rels. Bd. v. Eclipse Lumber Co.*, 199 F.2d 684, 686 (9th Cir. 1952) ("The Company claims that it is a denial of due process not to give a mandatory right to file a reply brief. We know of no such requirement."). The Rules of Practice accordingly forgo replies as a matter of course. 40 C.F.R. § 164.60(b) (providing that "*any party may serve and file an answer to [a] motion*," but that "the movant shall, *if requested* by the Administrator, his designee, or the Administrative Law Judge, *serve and file reply papers*"). Gharda had an opportunity to lay out its position in its initial stay request; when it did so, its arguments and support were limited. Gharda Hr'g Req. 6, 12–13. The Agency's Response did not rely on information or evidence unknown to Petitioners, and Petitioners thereafter made no effort to request oral argument, reply, or reconsideration.

Nevertheless, to leave no doubt as to any due process concerns, in issuing this order the undersigned has *sua sponte* reconsidered the Stay Order, taking into account Petitioners' arguments in their Certification Request and supporting Reply. Nothing therein materially changes the Stay Order's conclusions. As noted above, Petitioners' attempts to cast the Eighth Circuit's decision timeline as a finite period fail. The pertinent question, therefore, is whether Petitioners have shown a "pressing need" for a stay, as "identified by balancing interests favoring a stay against interests frustrated by a stay," keeping in mind "'the court's paramount obligation to exercise jurisdiction timely in cases properly before it.'" *Borla Performance Indus., Inc.*, 2022 WL 887454, at *3 (ALJ, Mar. 15, 2022) (Order on Respondent's Motion to Stay the Proceedings) (quoting *Cherokee Nation of Okla. v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997)).

The Stephens Declaration's cost projections, Petitioners' principal new support for their interest in a stay, do not alter my conclusion that Petitioners' anticipated harms are unlikely to materialize if this action is permitted to proceed. Petitioners offer no additional evidence as to the likelihood that the costs they anticipate—those of "reestablishing U.S. food uses and associated tolerances," Stephens Decl. ¶¶ 5, 6— will come due, which would be possible only if the Eighth Circuit failed to rule before cancellation became final. Nor do Petitioners address the comparative costs they would face from seeking the modifications to their registration that they have, themselves, indicated are necessary. *See* Stay Order 6–7 (citing Gharda Hr'g Req. 11). Indeed, the Stephens Declaration raises additional questions regarding Petitioners' anticipated costs. For example, the stated costs and timelines all relate to "registration of food uses *and associated tolerances*," and do not disaggregate the costs of registration. Stephens Decl. ¶¶ 5–6. The Stephens Declaration accordingly does not answer the question of what Petitioners' reregistration costs would be if the Eighth Circuit were to vacate the Final Rule after cancellation, thereby *restoring* the tolerances. And, although it offered no analysis supporting its decision to do so, it remains notable that the Eighth Circuit declined to stay the Final Rule pending litigation of *RRVSGA* even though (i) the Agency made clear to the court that it intended to begin cancellation proceedings based on the Final Rule; and (ii) Petitioners presented the court with the Stephens Declaration as evidence supporting a stay. *See* Agency Stay Resp. Ex. 3 (Eighth Circuit order denying stay in *RRVSGA*); Agency Resp. Ex. 4 at 8 (Agency response to *RRVSGA* petitioners' stay request, noting that "EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not submitted."); *supra* note 3.

As to Petitioners' assertion that, if permitted a Reply, they would have proposed a stay with a defined term, I observe that to date Petitioners have failed to do so, and I reiterate that, given the Ninth Circuit imperative that serves as this case's backdrop, I consider it inappropriate to supply my own roadblocks to this action's progress. *See* Stay Order 2–3, 7 (discussing *League of United Latin Am. Citizens v. Regan* (*LULAC II*), 996 F.3d 673 (9th Cir. 2021)); *see also LULAC II*, 996 F.3d at 678 (ordering the Agency to justify or revoke chlorpyrifos tolerances within 60 days and "to correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion"). For this and all the foregoing reasons, Petitioners' Certification Request is **DENIED**.

SO ORDERED.

Christine Donelian Coughlin
Administrative Law Judge

Dated: May 22, 2023
Washington, D.C.

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products, Docket No. FIFRA-HQ-2023-0001
Gharda Chemicals International, Inc., and Red River Valley Sugarbeet Growers Association, et al., Petitioners

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order Denying Petitioners' Request for Certification to the Environmental Appeals Board**, dated May 22, 2023, and issued by Administrative Law Judge Christine Donelian Coughlin, was sent this day to the following parties in the manner indicated below.

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Attorney-Advisor

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Dated: May 22, 2023
Washington, D.C.

EXHIBIT 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

IN RE FIFRA SECTION 6(b) NOTICE OF INTENT TO CANCEL PESTICIDE REGISTRATIONS FOR CHLORPYRIFOS	))))	**DOCKET NO. EPA-HQ-OPP-2022-0417**

GHARDA CHEMICALS INTERNATIONAL, INC.'S REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS AND REQUEST FOR STAY

Gharda Chemicals International, Inc. ("Gharda") hereby requests a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the proposed cancellation of the following of its pesticide product registrations:

- EPA Reg. No. 93182-3 Chlorpyrifos Technical[1]
- EPA Reg. No. 93182-7 Pilot 4E Chlorpyrifos Agricultural Insecticide[2]
- EPA Reg. No. 93182-8 Pilot 15G[3]

These three registrations are referred to herein as the "chlorpyrifos registrations." A Notice of Intent to Cancel was issued by the U.S. Environmental Protection Agency ("EPA" or "the Agency") and published in the Federal Register on December 14, 2022. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022), Ex. 1. Copies of the approved labels for the chlorpyrifos registrations, and Gharda's most recent proposed amendments to the labels (**submitted January 13, 2023**) for the chlorpyrifos registrations, are attached here. *See* Exs. 2 & 3.

[1] Product information on EPA Reg. No. 93182-3 can be found here.
[2] Product information on EPA Reg. No. 93182-7 can be found here.
[3] Product information on EPA Reg. No. 93182-8 can be found here.

In the NOIC, EPA is proposing to cancel the registrations of Gharda's chlorpyrifos products noted above. EPA alleges that the chlorpyrifos registrations should be cancelled because the Agency had revoked tolerances for all food uses of chlorpyrifos by way of a Final Rule dated August 30, 2021.[4] In the NOIC, EPA also challenges the sufficiency of voluntary cancellations and label amendments Gharda submitted in March 2022 and June 2022, which brought its chlorpyrifos registrations and labels in line with the Final Rule as to all but a subset of uses that are the subject of ongoing litigation. Gharda and other affected parties urged EPA to immediately stay or withdraw the NOIC in correspondence dated January 6, 2023, but EPA denied this request.

The NOIC states that "the affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before January 13, 2023, whichever occurs later." 87 Fed. Reg. at 76,474, Ex. 1. Gharda notes that the address for Gharda identified in the NOIC is incorrect[5] and states that Gharda has not received a copy of the NOIC from EPA. **Accordingly, Gharda submits that the 30-day time period for requesting a hearing on the NOIC has not yet begun to run and respectfully requests that EPA cure its defective notice promptly.**

While Gharda reserves all rights as to the ripeness of any further proceedings on the NOIC until it receives proper notice, Gharda hereby objects to the cancellation of the

[4] *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"), Ex. 4.

[5] *Compare* 87 Fed. Reg. at 76,474, Ex. 1 (identifying Gharda's address of record as 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238) *with* https://www3.epa.gov/pesticides/chem_search/ppls/033658-00026-20121220.pdf (Gharda submission of amended labeling to EPA identifying Gharda address as 4032 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238).

chlorpyrifos registrations and provides this notice of its objections and request for a hearing under 40 C.F.R. section 164.20(b) and request for a stay of the NOIC.

INTRODUCTION

This matter concerns the insecticide chlorpyrifos, a crop protection tool growers have relied upon for decades. After working with registrants in 2019 to identify key U.S. crop uses for chlorpyrifos, EPA used up-to-date science to determine that the tolerances for a subset of uses, on eleven crops in select geographic regions, meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act ("FFDCA") (the "Safe Uses"). Despite that finding, which EPA announced in its Proposed Interim Decision ("PID")[6] in 2020 and reaffirmed in the Final Rule and several times since, EPA elected to revoke ***all*** food tolerances, including those the Agency found safe, at the expense of farmers across the country. EPA's Final Rule disregarded Gharda's written commitment *before* the Final Rule to modify its registration and product labels consistent with the Agency's safety finding as to the Safe Uses. Indeed, Gharda was standing by before the Final Rule to submit amended labels to EPA narrowing uses to the Safe Uses, at EPA's instruction, when EPA abruptly ceased discussions with Gharda. Gharda and others submitted objections to and requested a stay of the Final Rule (incorporated by reference here), which EPA denied.[7]

Nineteen grower groups (representing thousands of farmers around the country who rely on chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda) (collectively "Petitioners") challenged the Final Rule as to the Safe Uses because it is arbitrary

[6] Chlorpyrifos Proposed Interim Registration Review Decision, EPA-HQ-OPP-2008-0850 (Dec. 3, 2020) https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971, Ex. 5.
[7] Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022), Ex. 6.

and capricious and contrary to the FFDCA in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir.) (the "lawsuit"). In the lawsuit, Petitioners seek vacatur of the Final Rule as to the Safe Uses. The lawsuit has been fully briefed, and oral argument took place on December 15, 2022. The parties' principal briefs in the lawsuit are incorporated by reference here.[8]

As set forth below, the extreme and unprecedented action EPA has taken in issuing the NOIC is objectionable on numerous grounds. The NOIC is based on the Final Rule, which is arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses for all of the reasons set forth in Gharda's objections to the Final Rule and briefing to the Eighth Circuit; the NOIC is accordingly itself arbitrary and capricious, even more so based on the current record before the Agency, in which there can be no doubt that EPA has all available tools and information at its disposal showing that the chlorpyrifos registrations are consistent with the Agency's safety finding. EPA also improperly attempts to narrow the scope of the NOIC by contending that the propriety of EPA's Final Rule—the sole basis for the NOIC—cannot be a topic for the NOIC. What is more, EPA's NOIC blatantly disregards important FIFRA-mandated cancellation rights and processes. Indeed, EPA's NOIC fails to comply with requirements established by FIFRA regarding consideration of alternatives to registration cancellation and input from the U.S. Department of Agriculture ("USDA"). Further, EPA ignores Gharda's due process and property rights by, *inter alia*, failing to follow processes mandated by FIFRA for registration cancellation and failing to appropriately consider Gharda's

[8] Pet'rs' Opening Br. ("Pet'rs Br."), *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. May 24, 2022), ID No. 5160660; Resp't Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. July 26, 2022), ID No. 5180922; Pet'rs' Reply Br. ("Pet'rs Reply Br."), *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022), ID No. 5195044, Ex. 7.

efforts to make its registrations and product labels align with EPA's Final Rule. Finally, EPA in large part ignores the lawsuit, which could be decided any day and could make the NOIC moot. EPA waited 15 months after the Final Rule—until the day before oral argument in the lawsuit—to publish the NOIC. Based on EPA's own conduct, there is no urgent need or other basis for EPA to proceed with the NOIC before the Eight Circuit's decision. Accordingly, Gharda respectfully submits that the Administrative Law Judge should dismiss the NOIC. At a minimum, the NOIC should be delayed until after the Eighth Circuit's decision.

GHARDA'S OBJECTIONS

OBJECTION 1: The NOIC is improperly based on the Final Rule, which incorrectly revoked tolerances for the Safe Uses. Contrary to EPA's contention in the NOIC (87 Fed. Reg. at 76,476, Ex. 1), comments and arguments challenging EPA's actions in the Final Rule are very relevant to the NOIC and scope of the NOIC.

- The primary basis for the NOIC is that in its Final Rule, EPA revoked all food tolerances for chlorpyrifos and, therefore, uses set forth in Gharda's registrations for food uses cannot stand and must be cancelled. Similarly, the NOIC contends that Gharda's product registrations and amended labels are not consistent with the Final Rule because they include the Safe Uses.

- For all the reasons set forth in Gharda's objections to the Final Rule and the Petitioners' briefing in the lawsuit (incorporated by reference here), the Final Rule was arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses. *See* Pet'rs Br. at 23–26, 42–54 (ID No. 5160660); Pet'rs Reply Br. at 14-22 (ID No. 5195044), Ex. 7; Gharda Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos ("Gharda Objs."), EPA-HQ-OPP-2021-0523, at 9-11, 31-34 (Oct. 22, 2021), https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0028, Ex. 8. In the absence of a proper basis for revocation of tolerances for the Safe Uses, there is no basis for the NOIC, which seeks to cancel registered uses for the Safe Uses.

- The validity of the Final Rule as to the Safe Uses is currently under consideration by the Eighth Circuit. Oral arguments in the lawsuit occurred on December 15, 2022, and a decision is expected in the near future.

- If the Eighth Circuit vacates/remands the Final Rule as to the tolerances for the Safe Uses, the NOIC's purported basis for the cancellation action becomes moot.

OBJECTION 2: Action on the NOIC should be delayed until after the Eighth Circuit decides Petitioners' challenge to the Final Rule.

- Taking action on the NOIC is contrary to the exercise of jurisdiction by the Eighth Circuit regarding the tolerances for the Safe Uses. *See* Pet'rs Br. at 1-5 (ID No. 5160660), Ex. 7.

- If registration cancellation occurs and the Eighth Circuit subsequently rules in Petitioners' favor by either vacating or remanding the Final Rule as to the Safe Uses, EPA would likely argue that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition process. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. EPA should not be allowed, through the NOIC process, to evade a potential Eighth Circuit invalidation of the Final Rule, especially when the lawsuit has been fully briefed and argued, and the Eighth Circuit's decision is forthcoming at any time.

- In addition, (1) challenging registration cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives prior to a decision by the Eighth Circuit would be overly burdensome and unfair and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit.

- In short, it would be improper and prejudicial to use the NOIC to circumvent judicial review and to force Gharda to pursue costly and time-consuming alternatives in parallel to the pending court proceeding. These inappropriate outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit's decision.

OBJECTION 3: The NOIC erroneously signals an urgent need for registration cancellation. To the contrary, there is no urgency for the NOIC to address because there are currently no chlorpyrifos products used on food in the stream of commerce, as EPA knows, and therefore no reason that the NOIC cannot be delayed until after the Eighth Circuit's decision.

- The NOIC makes statements implying that chlorpyrifos is currently being sold, distributed and/or used for food uses. *See, e.g.,* 87 Fed. Reg. at 76,477 ("It is a violation of FIFRA to sell and distribute pesticides that are misbranded…because the aforementioned [chlorpyrifos] products would result in pesticide residues in or on

food…continued sale and distribution [of chlorpyrifos products] would not comply with the provisions of FIFRA."), Ex. 1. This is misleading.

- In correspondence dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. Gharda responded on March 30, 2022. *See* Ex. 9. Gharda's response: (1) requested the voluntary cancellation of all of Gharda's food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda's commitment to the Agency well before the Final Rule); (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit."

- EPA has never provided evidence contrary to Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit.

- There is no evidence of or reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce for use on food, necessitating registration cancellation at this time. EPA's tolerance revocations made distribution or use unlawful. As noted above, in correspondence dated March 30, 2022, Gharda recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses" and "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit."

- The NOIC alleges no facts inconsistent with Gharda's commitments or otherwise demonstrating that chlorpyrifos products are being distributed, sold, and/or used in a manner inconsistent with the Final Rule.

- Oral argument in the lawsuit took place on December 15, 2022. For the Agency to wait nine months after Gharda's commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, demonstrates an inappropriate attempt by the NOIC to create urgency where EPA's conduct demonstrates none exists. In sum, there is no urgent need based on the facts for the NOIC to proceed with actions as extreme as cancellations before the Eighth Circuit's decision.

OBJECTION 4: The NOIC violates FIFRA by ignoring several of the statutorily required steps that *must* precede registration cancellation, including the requirement to consider alternatives to cancellation, and by improperly attempting to narrow the scope of the Administrative Law Judge's review.

- FIFRA Section 6(b) provides that "*[i]n taking any final action under this subsection*, the Administrator *shall* consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and *shall* include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact." 7 U.S.C. § 136d(b) (emphasis added).

- FIFRA does not permit EPA to ignore these statutory requirements simply because a tolerance action precedes a cancellation action. EPA is required to review the full record before the Agency in issuing a decision on a NOIC. *See* 40 C.F.R. § 164.90(b).

- EPA contends in the NOIC that only the Final Rule and the facts existing at the time of the Final Rule are relevant to the NOIC. The NOIC thus ignores FIFRA's requirement that alternatives to registration cancellation *must* be considered *in taking any final action under FIFRA Section 6(b)* and improperly attempts to limit the scope of the Administrative Law Judge's review.

- EPA did not consider the PID and the Safe Uses identified by the PID as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider Gharda's repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements. *See* Decl. of Ram Seethapathi in Support of Gharda's Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos ("Seethapathi Decl."), EPA-HQ-OPP-2021-0523, ¶¶ 21–36 and Exhibits to Seethapathi Decl. A–H (Oct. 22, 2021), Ex. 8; *see also* Ex. 9.

- EPA has never provided evidence contrary to Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit.

- EPA did not consider Gharda's submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider Gharda's submission of amended labels, which eliminated all food uses for chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA's registration cancellation requirements.

- EPA did not consider the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA's registration cancellation requirements.

- The Administrator of EPA did not publish in the Federal Register an analysis of the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA's registration cancellation requirements.

- FIFRA Section 6(b) requires EPA to respond to USDA's comments with respect to the NOIC.

- EPA gave no meaningful consideration to USDA's request that EPA re-establish tolerances for the Safe Uses based on EPA's own scientific findings and therefore violated FIFRA's cancellation requirements. *See* Letter from Kimberly Nesci, Dir., Office of Pest Mgmt. Pol'y, United States Dep't of Agriculture to Edward Messina, Dir., Office of Pesticide Programs ("USDA Comments Letter"), EPA, EPA-HQ-OPP-2022-0417 (Sept. 11, 2022) at 2, https://www.regulations.gov/document/EPA-HQ-OPP-2022-0417-0002.

- EPA gave no meaningful consideration to USDA's comments that, *inter alia*, EPA was not following "historical precedent and legal procedures" with respect to the Final Rule and NOIC and that the EPA's actions constituted "harmful precedent" and therefore violated FIFRA's registration cancellation requirements. *Id*. at 1–3.

- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA's comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 5: The NOIC violates Gharda's due process rights.

- Once a pesticide registration is granted, it becomes the registrant's property interest, *see, e.g., Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010), and cannot "be taken away without that procedural due process required by the Fourteenth Amendment," *Bell v. Burson*, 402 U.S. 535, 539 (1971). FIFRA protects these due process rights by establishing an elaborate scheme for EPA to follow before cancelling a pesticide registration. *See, e.g.*, 7 U.S.C. §§ 136d(b)(1), (2); 136d(d); 136a(g)(1)(v); *see also Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (FIFRA "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration.").

- Due process is denied when the statutorily mandated process for taking away a property right is not followed.

- EPA has failed to provide Gharda with due process by, *inter alia*: (1) instructing Gharda, before the Final Rule, to be prepared to submit a voluntary cancellation letter narrowing uses consistent with the PID and then abruptly terminating discussions; (2) not considering as an alternative to registration cancellation maintaining the Safe Uses as

registered uses in accordance with the PID and EPA's determination of Safe Uses; (3) not considering as an alternative to registration cancellation Gharda's repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses; (4) not considering as an alternative to registration cancellation Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit; (5) not considering as an alternative to registration cancellation Gharda's submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation; (6) not considering as an alternative to registration cancellation Gharda's submission of amended labels which eliminated all food uses for chlorpyrifos except the Safe Uses; (7) not considering the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (8) not publishing in the Federal Register an analysis of the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (9) failing to await the decision from the Eighth Circuit before issuing the NOIC when chlorpyrifos cannot be sold or used and there is otherwise no urgency for registration cancellation proceedings at this time; (10) overburdening Gharda and other adversely affected parties with the necessity to spend resources to defend the NOIC when an Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses would eliminate the need for the NOIC; (11) overburdening Gharda with the necessity to spend resources to challenge registration cancellation that may occur and be followed by a favorable Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses; and, (12) failing to consider or meaningfully consider USDA's comments in response to the NOIC, including, as set forth above, that EPA should re-establish tolerances for the Safe Uses and did not follow "historical precedent and legal procedures" regarding the Final Rule and NOIC.

- EPA's actions in issuing the NOIC compound the Agency's due process violations in issuing the Final Rule. EPA violated the due process rights of Gharda and others by revoking all tolerances in disregard of the Agency's own scientific findings as to the Safe Uses and Gharda's written commitment in advance of the Final Rule to modify its registration in accordance with the Agency's safety finding. *See* Gharda Objs. at 31–37, Ex. 8.

OBJECTION 6: Under the circumstances of this matter, EPA's demand in the NOIC that Gharda amend its registration labels to voluntarily cancel food uses for the Safe Uses is overly burdensome, unrealistic, punitive, and improperly seeks to interfere with the exercise of jurisdiction by the U.S. Court of Appeals for the Eighth Circuit.

- As noted above, on March 30, 2022, Gharda submitted a letter to EPA seeking cancellation of all food uses of chlorpyrifos in Gharda's registrations except the eleven

Safe Uses. Gharda explained in its letter that EPA's revocation of tolerances for the Safe Uses was currently under review by the Eighth Circuit. Ex. 9. Gharda also submitted amended labels to EPA omitting all food uses but the Safe Uses on June 10, 2022. Ex. 10.

- The NOIC states that "[w]hile Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, Gharda's products identified [in the NOIC] are subject to this Notice." 87 Fed. Reg. at 76,476, Ex. 1. The NOIC misleadingly omits that the only way Gharda's registrations do not align with the Final Rule is as to the Safe Uses currently under review by the Eighth Circuit.

- To the extent Gharda's prior commitments before the Final Rule and submissions to EPA after the Final Rule are somehow insufficient to satisfy EPA that label changes consistent with EPA's safety finding can be accomplished (a position Gharda views as contrary to the law and facts, *see* Pet'rs Br. at 23–28 (ID No. 5160660)), Gharda has submitted amended labels to EPA (included with this submission at Ex. 3) that once again limit food uses to the Safe Uses in the permitted geographic regions (that are the subject of the ongoing litigation) and also add application rate changes consistent with the PID safety finding. Gharda submits these changes to further demonstrate its commitment to conform its registrations to EPA's safety finding in the PID, despite that the changes proposed are based on information the Agency developed and has had in its possession for years. *See* Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-2008-0850-0941 at 33–34 (Sep. 22, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941, Ex. 11.

- The NOIC states that the cancellation proposed in the NOIC shall become final unless "the registrant makes the necessary corrections to the registrations" or a hearing is requested. 87 Fed. Reg. at 76,475, Ex. 1.

- Thus, EPA demands that Gharda voluntarily cancel all remaining food uses, the tolerances for which are currently under review by the Eighth Circuit. EPA's actions appear to be punitive, and an attempt to undermine and thwart Gharda's justified attempt to obtain judicial review of EPA's Final Rule as to the Safe Uses.

- If registration cancellation occurs before an Eighth Circuit decision invalidating the Final Rule, EPA would likely contend that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition processes. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule to the Agency as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. But (1) challenging cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives would

be overly burdensome and unfair, and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit. These outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit decision.

OBJECTION 7: The NOIC does not give due consideration to the USDA's views, contrary to FIFRA.

- FIFRA Section 6(b) requires EPA to respond to USDA's comments with respect to the NOIC. 7 U.S.C. § 136d.

- EPA gave no meaningful consideration to USDA's request that EPA re-establish tolerances for the Safe Uses in accordance with its scientific findings and therefore violated FIFRA's registration cancellation requirements. *See* USDA Comments Letter at 2.

- EPA gave no meaningful consideration to USDA's comments that, *inter alia*, EPA was not following "historical precedent and legal procedures" with respect to the Final Rule and NOIC and that the EPA's actions constituted "harmful precedent" and therefore violated FIFRA's registration cancellation requirements. *Id*. at 1–3.

- As noted by USDA, it is unprecedented for EPA to ignore FIFRA-mandated cancellation rights and processes in a situation where tolerance revocation occurs first.

- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA's comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 8: Issuance of the NOIC with a response deadline shortly after the holiday period is burdensome, unfair, and unnecessary.

- As set forth above, there is no urgency or any other good faith reason to force Gharda and other adversely affected parties to respond to the NOIC during the holiday period and to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, Gharda respectfully requests that the Administrative Law Judge stay action on the NOIC until after the Eighth Circuit's decision in the lawsuit.

REQUEST FOR STAY OF NOIC

Based on the foregoing, Gharda respectfully requests that the Administrative Law Judge delay any action with respect to the NOIC, including but not limited to the conduct of the hearing

requested herein, until after the Eight Circuit's decision in the lawsuit. A stay of the NOIC proceedings is warranted because proceeding with a potential registration cancellation now would prejudice the rights of Gharda and others to obtain judicial relief from the Final Rule underlying the NOIC in the ongoing litigation. Should a potential cancellation of the chlorpyrifos registrations precede a favorable ruling by the Eighth Circuit invalidating the Final Rule, EPA may nevertheless take the position that Gharda must initiate the FIFRA registration and tolerance petition processes for chlorpyrifos anew—destroying decades of investment, causing the needless expenditure of Agency and registrant resources, and further delaying access to a crop protection tool critical to U.S. growers. As discussed above, as there are no chlorpyrifos products approved for use on food currently in the stream of commerce, there are no public health concerns with simply delaying further action on the NOIC until the Eighth Circuit rules.[9]

CONCLUSION

For the reasons set forth above, EPA's unprecedented NOIC is contrary to FIFRA in many respects, violates the due process rights of Gharda, and is otherwise deficient. Moreover, there is no urgent need or other basis for the NOIC to proceed before the Eighth Circuit's decision in the lawsuit. Forcing Gharda to defend the NOIC before the Eighth Circuit's decision would be unfairly burdensome and unnecessary and is contrary to the Eighth Circuit's exercise of jurisdiction over the tolerances for the Safe Uses.

[9] In other administrative actions, EPA has applied the stay criteria set forth by the U.S. Food and Drug Administration at 21 CFR § 10.35(e)(1)–(4) ((1) petitioner will suffer irreparable injury; (2) petitioner's case is not frivolous and pursued in good faith; (3) sound public policy grounds support a stay; and (4) delay from a stay is not outweighed by public health or other public interests). For reasons outlined herein, Gharda has satisfied these criteria here.

Gharda respectfully requests a hearing on the NOIC and requests that the Administrative Law Judge find that the Administrator did not have a proper basis for issuing the NOIC and dismiss the NOIC. At a minimum, the Administrative Law Judge should delay action on the NOIC until after a decision from the Eighth Circuit in the lawsuit.

Respectfully submitted,

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Date: January 13, 2023

CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, true and correct copies of the foregoing Request for Hearing and Statement of Objections and Request for Stay, and all associated Exhibits, were filed electronically with the EPA OALJ E-Filing System for the OALJ's E-Docket Database, with a copy (without attachments) via electronic mail to the following:

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EXHIBIT 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations	Docket Nos. FIFRA-HQ-2023-0001; EPA-HQ-OPP-2022-0417

REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS

by

Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America

January 13, 2023

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MISCELLANEOUS

This Request for Hearing and Statement of Objections is submitted on behalf of the grower groups currently involved in litigation with the U.S. Environmental Protection Agency in the U.S. Court of Appeals for the Eighth Circuit[1] (Grower Petitioners) challenging EPA's Final Rule[2] revoking all tolerances for chlorpyrifos, including the 11 food uses EPA deemed to be safe (the Safe Uses).[3] The Grower Petitioners object to EPA's recent notice of intent to cancel (NOIC)[4] Gharda Chemicals International Inc.'s (Gharda's) products Chlorpyrifos Technical (EPA Reg. No. 93182-3),[5] Pilot 4E Chlorpyrifos Agricultural Insecticide (EPA Reg. No. 93182-7),[6] and Pilot 15G Chlorpyrifos Agricultural Insecticide (EPA Reg. No. 93182-8).[7] The Grower

[1] *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al*., Nos. 22-1422, 22-1530 (8th Cir. filed Feb. 28, 2022) (*Red River Valley Sugarbeet Growers Ass'n et al.*).

[2] "Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the Final Rule) (Exhibit 1).

[3] The Safe Uses of chlorpyrifos are the uses EPA unequivocally found to be safe in its Proposed Interim Registration Review Decision (PID) for Chlorpyrifos, Case Number 0100, December 2020 (Chlorpyrifos PID), EPA-HQ-OPP-2008-0850-0971 (Exhibit 2). These Safe Uses are the use of chlorpyrifos on alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat in specifically designated regions as set forth in EPA's PID. Petitioners have challenged EPA's revocation of the tolerances for the Safe Uses of chlorpyrifos.

[4] EPA Notice "Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations," 87 Fed. Reg. 76,474 (Dec. 14, 2022) (Exhibit 3).

[5] A copy of the label for EPA Reg. No. 93182-3 can be found here. (Exhibit 4).

[6] A copy of the label for EPA Reg. No. 93182-7 can be found here. (Exhibit 5).

[7] A copy of the label for EPA Reg. No. 93182-8 can be found here. (Exhibit 6).

Petitioners have urged EPA to immediately stay or withdraw the NOIC,[8] and EPA rejected this request.[9] The Grower Petitioners therefore request a hearing on the NOIC and these objections.

EPA's NOIC seeks a premature revocation of registrations for uses of an economically critical pesticide that EPA has unequivocally found to be safe. EPA announced this safety finding in the PID and has since that time reiterated to the public and to the Eighth Circuit that the Safe Uses present no risks of concern.[10] Each of the registrants of chlorpyrifos have cancelled (or requested cancellation) of all food uses for chlorpyrifos other than the Safe Uses. Thus, the only action EPA proposes to take in the NOIC is to cancel Gharda's registrations for the Safe Uses. EPA's NOIC will cause unnecessary and irreparable harm to the Grower Petitioners.

The Grower Petitioners include the following entities:

Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association

[8] Letter from South Dakota Soybean Association and 18 additional Grower Groups, to The Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 6, 2023) (Exhibit 7); Letter from Julie Gordon, President/Managing Director, Cherry Marketing Institute, to the Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 9, 2023) (Exhibit 8).

[9] Letter from Michael Goodis, Dir., Office of Pesticide Programs, EPA, to Grower Petitioners (Jan. 11, 2023) (Exhibit 9).

[10] Brief of Respondents 12-13, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. July 26, 2022) (EPA Br.) (Exhibit 10).

of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and the National Cotton Council of America.

The Grower Petitioners represent thousands of farmers around the country who need chlorpyrifos as a critical crop protection tool and who would be adversely affected by EPA's NOIC. The Grower Petitioners object to EPA's NOIC on multiple grounds, as described below.

I. EPA's Proposed Cancellation of Gharda's Registrations for the Safe Uses Is Contrary to Law Because it Would Interfere with the Jurisdiction of the U.S. Court of Appeals for the Eighth Circuit.

EPA's proposed cancellation of Gharda's registrations for the Safe Uses is contrary to law. EPA explains in its NOIC that its sole justification for cancelling the registrations of Gharda's products containing chlorpyrifos is the Agency's Final Rule revoking *all* tolerances for chlorpyrifos.[11] EPA explains that Gharda's chlorpyrifos products must be cancelled because they bear labeling for use on food crops, and, due to the lack of tolerances for residues of chlorpyrifos, these products pose unreasonable adverse effects on the environment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[12] In other words, EPA's position is that, because it has revoked all tolerances for chlorpyrifos, "chlorpyrifos residues in or on food are unsafe as a matter of law."[13]

However, the legality of the Final Rule is currently being decided by the Eighth Circuit. It is premature and contrary to law to cancel registrations for the Safe Uses ahead of the Eighth Circuit's decision. Commencing cancellation proceedings before the court has rendered a decision would unjustly interfere with the jurisdiction of the Eighth Circuit. The Eighth Circuit

[11] 87 Fed. Reg. at 76,474.

[12] *Id*. at 76,476.

[13] *Id*. at 76,477.

will decide if EPA's rule revoking chlorpyrifos tolerances is lawful and whether growers can resume using chlorpyrifos as outlined in EPA's Safe Uses. EPA's attempt to remove these products from the market now on the basis that the products are "unsafe as a matter of law" interferes with the Eighth Circuit's pending decision on this very issue.

II. EPA's Proposed Cancellation of Gharda's Registrations Is Contrary to Law Because it Is Based on an Unlawful Rule.

EPA's decision to cancel Gharda's registrations is contrary to law because it is based on an unlawful rule—EPA's Final Rule revoking all tolerances for chlorpyrifos.[14] The Grower Petitioners have demonstrated that EPA's Final Rule is unlawful on the following grounds.

First, EPA's Final Rule is arbitrary and capricious because it disregards its own scientific evidence.[15] EPA's Final Rule reaffirmed its own scientific conclusions about any neurodevelopmental effects of chlorpyrifos. As discussed in the Petitioners' opening brief, EPA

[14] The Grower Petitioners hereby incorporate by reference the entirety of the Petitioners' Opening Brief, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. May 24, 2022) (Pet'rs Br.) (Exhibit 11), and Reply Brief, *Red River Valley Sugarbeet Growers Ass'n et al.*, (8th Cir. Sept. 6, 2022) (Pet'rs Reply Br.) (Exhibit 12), submitted to the Eighth Circuit. These objections also incorporate by reference the objections filed by Grower Petitioners in response to EPA's Final Rule revoking chlorpyrifos tolerances. Letter from Cassie Bladow, President, U.S. Beet Sugar Association, and Luther Markwart, Executive Vice President, American Sugarbeet Growers Association, to EPA, Office of Administrative Law Judges, "Objections to Decision Revoking All Chlorpyrifos Tolerances" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0029 (U.S. Beet Sugar Ass'n & Am. Sugarbeet Growers Ass'n Objections) (Exhibit 13); Letter from Richard Gupton, Senior Vice President of Public Policy & Counsel, Agricultural Retailers Association, et al., to EPA, "Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 19, 2021), EPA-HQ-OPP-2021-0523-0007 (Exhibit 14); Letter from David Milligan, President, National Association of Wheat Growers (Oct. 28, 2021), EPA-HQ-OPP-2021-0523-0016 (Exhibit 15); Letter from Kevin Scott, President, American Soybean Association, "Formal Written Objections, Request for Evidentiary Hearing, and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0022 (Exhibit 16); Letter from Kyle Harris, Director, Grower Relations, Cherry Marketing Institute, "Formal Written Objections and Request for Evidentiary Hearing for Chlorpyrifos Tolerance Revocation" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0024 (Exhibit 17).

[15] Pet'rs Br. 38.

found the data to be insufficient to show that there are neurodevelopmental effects below current regulatory requirements, and it maintained its longstanding 10 percent red blood cell acetylcholinesterase (RBC AChE) inhibition regulatory standard and applied the Food Quality Protection Act (FQPA) Safety Factor of 10X.[16] EPA also updated its drinking water assessment in 2020 to be the most cutting-edge, sophisticated drinking water assessment yet, reflecting the most advanced methodologies for assessing drinking water exposures and risks. The assessment underwent extensive peer review. EPA analyzed risks from exposures from 11 high-benefit agricultural uses in certain regions where estimated drinking water concentrations of chlorpyrifos were below EPA's benchmark level of concern. The PID found that, based on the drinking water assessment, those uses were safe.[17] And yet, EPA's Final Rule refuses to apply its own findings from its risk assessments and does not even dispute its scientific findings. Rather, EPA's refusal is based on a new legal interpretation that EPA contends required it to conclude that none of the existing tolerances was safe.[18] EPA misstates the law, which nowhere justifies EPA's decision to ignore its safety finding for the Safe Uses. EPA's rejection of its own scientific evidence is arbitrary and capricious.

Second, EPA's Final Rule is arbitrary and capricious and contrary to law because it ignores the text of the law and the intent of Congress in FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Based on the FFDCA's plain language, EPA was required to assess safety by not only considering currently registered uses but also by looking to anticipated exposures (a forward-looking mandate). EPA must also make safety determinations for each

[16] *Id*. at 39.

[17] *Id*. at 40.

[18] *Id*. at 42.

tolerance on an individual basis.[19] EPA has authority to modify tolerances and thereby narrow uses if it finds based on scientific evidence that an existing tolerance is not safe. While EPA must look at aggregate exposures, the reference to aggregate exposure in the FFDCA means EPA must consider, in making individual tolerance determinations, all of the exposures a person is "anticipated" to encounter.[20] Therefore, EPA's position in the Final Rule that all tolerances must rise or fall together, and that it is required to assess only currently registered uses, misreads the statute.[21]

Third, EPA's Final Rule is contrary to law because EPA failed to harmonize its safety determination under the FFDCA with FIFRA. Instead, EPA took the unprecedented position that its actions under the two statutes are separate.[22] EPA could have (and has in the past with other pesticides) coordinated its actions under the FFDCA with FIFRA by modifying tolerances or registrations accordingly.[23] EPA did not need to have cancellation and label amendment requests from all registrants in hand before acting on its safety finding.[24] EPA never gave registrants or the public notice of any such requirement, and in fact told Gharda that EPA would notify Gharda if it needed anything more than the written commitment Gharda had given EPA to voluntarily give up all but the Safe Uses. EPA never provided such notice to Gharda or, upon information and belief, to any other registrant. EPA should have followed its science and banned any food uses other than the Safe Uses, anticipating that regulated parties would follow the law and give

[19] *Id*. at 43.

[20] Pet'rs Reply Br. 18.

[21] Pet'rs Br. 45.

[22] *Id*. at 48.

[23] *Id*. at 53.

[24] Pet'rs Reply Br. 19.

up uses made unlawful by a tolerance revocation.[25] EPA's failure to do so renders the Final Rule arbitrary, capricious, and contrary to law.

Fourth, EPA's Final Rule is arbitrary and capricious because it offers no reasoned explanation that addresses the relevant factors and evidence. EPA's reason for revoking all tolerances was the claim that it had no reason to believe that the registrations would be amended, and thus it was allegedly required to consider the safety of all currently registered uses collectively. This reasoning is contrary to the statute, contrary to EPA's prior practice, and contrary to logic.[26]

Fifth, EPA's post-hoc rationalization that the PID finding was only a proposal, and therefore EPA was not required to consider it in the Final Rule, is wrong. EPA cannot disregard the scientific evidence before it simply because it may be revised later.[27] It was required to make decisions on tolerances based on available data and information regardless of whether it has been through notice and comment rulemaking.[28] EPA certainly treated its PID scientific findings as final in discussions with Gharda on a voluntary narrowing of uses consistent with the PID.[29] EPA's decision in the Final Rule to ignore the PID findings was arbitrary, capricious, and contrary to law.

Sixth, EPA incorrectly claims that the PID was based on a FIFRA-based analysis separate from the safety standard applicable to tolerances under the FFDCA.[30] Congress requires

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[25] *Id*. at 20.

[26] Pet'rs Br. 55.

[27] *Id*. at 56.

[28] Pet'rs Reply Br. 8.

[29] Pet'rs Br. 60.

[30] Pet'rs Reply Br. 11-12.

the same safety standard for food use pesticides for both FIFRA and the FFDCA. The PID's safety finding was therefore directly applicable to EPA's decision concerning the safety of chlorpyrifos tolerances. Here again, EPA's post-hoc justification is arbitrary, capricious, and contrary to law.

Finally, EPA's argument that it lacked the necessary basis to act on its safety finding ignores the plain language of the statute and the undisputed facts. EPA had written commitments from Gharda to give up all uses other than the Safe Uses. EPA had a reasonable basis to expect modifications to chlorpyrifos registrations because the practical effect of tolerance revocation is a ban on the use of the pesticide.[31] EPA did in fact receive voluntary cancellation requests of chlorpyrifos registrations once it issued its notice requesting the same, after revocation of the tolerances went into effect. If EPA needed any additional information in order to support modifying tolerances by revoking all but those for the Safe Uses, it had the statutory duty to obtain it from the registrants and the tools to compel production of such information.[32] EPA's attempts to defend the Final Rule confirm that it was arbitrary, capricious and contrary to law.

For the reasons argued by Grower Petitioners to the Eighth Circuit, summarized above, the Final Rule is unlawful. Because EPA's NOIC relies on this unlawful rule, the NOIC is itself contrary to law.

III. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious Because it Is Contrary to the Evidence.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious because it is contrary to the evidence. First, EPA has not presented any evidence that chlorpyrifos products are being sold or distributed for food uses. There is no evidence of a safety risk because

[31] *Id*. at 23.

[32] 21 U.S.C. § 346a(f).

there is no continuing sale or distribution of chlorpyrifos for use on food. Gharda is the only technical registrant of chlorpyrifos seeking to maintain a registration for chlorpyrifos, and even there only with respect to the Safe Uses. Moreover, Gharda clearly committed to EPA in March 2022 that its chlorpyrifos products would not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit. EPA's justification for cancelling Gharda's products on the basis that these products are allegedly unsafe is unsupported, as evidenced by the fact that the products are not being sold or distributed.

Second, EPA's cancellation of Gharda's products is contrary to EPA's own evidence that chlorpyrifos is safe for certain food uses. EPA's chlorpyrifos risk assessments[33] show that the Safe Uses are safe and meet the FQPA standard for safety set forth in FFDCA and applicable to registration review under FIFRA. EPA concluded that the Safe Uses meet the FQPA's safety standard using the 10X margin of safety and announced that finding in the 2020 PID.[34] There is no scientific evidence in the record to support any conclusion that the Safe Uses do not meet the applicable safety standard under FIFRA. EPA continues to agree that the Safe Uses are indeed safe.[35]

Third, there is no evidence that the extreme step of registration cancellation is necessary to address EPA's purported concerns with certain food uses of chlorpyrifos. EPA has the information necessary to amend the chlorpyrifos registrations and labels in order to limit use of

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[33] *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review*, (Sept. 22, 2020), EPA-HQ-OPP-2008-0850-0944 (Exhibit 18); Memorandum from Rochelle F.H. Bohaty, Ph.D., Senior Chemist, et al., EPA, to Patricia Biggio, Chemical Review Manager, et al., EPA, "Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (Sept. 15, 2020), EPA-HQ-OPP-2008-0850-0941 (Exhibit 19).

[34] Chlorpyrifos PID.

[35] EPA Br. 12-13; 87 Fed. Reg. 11,222, 11,241 (Feb. 28, 2022) (Exhibit 20).

chlorpyrifos to be consistent with the EPA's identified Safe Uses. EPA can and should amend, rather than cancel, Gharda's registrations.[36] EPA's failure to do so violates FIFRA section 6(b),[37] requiring EPA to consider restricting pesticide use as an alternative to cancellation.

Fourth, EPA's conclusion that cancellation of the registrations "is not anticipated to have any impacts on the agricultural economy"[38] is contrary to the evidence. The tolerances for the Safe Uses must be reinstated, as the Grower Petitioners have explained to the Eighth Circuit. Cancellation of the registrations would deprive Grower Petitioners of a critical crop protection tool that will cause significant crop losses and significant harm to the agricultural economy.

IV. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious because it Fails to Consider Important Aspects of the Problem.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious because it fails to consider important aspects of the problem, including the extent to which EPA's decision would interfere with the Eighth Circuit's jurisdiction, the harm it would cause the Grower Petitioners, the lack of necessity for the cancellation, and the impact the cancellation would have on the economy.

A. EPA Fails to Consider the Extent to Which its Actions Would Interfere with the Jurisdiction of the Eighth Circuit.

EPA fails to consider the extent to which its cancellation of Gharda's registrations interferes with the jurisdiction of the Eighth Circuit. The Eighth Circuit is currently deciding the

[36] We note that these comments are relevant to the NOIC and not only to EPA's Final Rule revoking all chlorpyrifos tolerances because EPA's NOIC seeks to remove the last remaining chlorpyrifos products from the market, depriving growers from having access to chlorpyrifos in the future if the Eighth Circuit decides EPA's revocation of the tolerances for the Safe Uses is unlawful. EPA fails to justify why an NOIC is appropriate when it has the authority to amend registrations to remove the specific uses it determined to be unsafe.

[37] 7 U.S.C. § 136d(b).

[38] 87 Fed. Reg. at 76,478.

legality of EPA's revocation of the tolerances for the Safe Uses. EPA's preemptive cancellation of Gharda's registrations will cause serious consequences for Grower Petitioners. A favorable decision from the Eighth Circuit would allow Grower Petitioners to use chlorpyrifos for the Safe Uses in the 2023 growing season. But cancellation of Gharda's registrations for these Safe Uses would prevent Grower Petitioners from resuming use of chlorpyrifos in the upcoming growing season. The Grower Petitioners would have to wait years while registrants undertake the process to obtain new registrations for chlorpyrifos, all the while suffering the crop loses and year-on-year increases in pest pressure, as detailed in their sworn declarations before the Eighth Circuit.

B. EPA Fails to Consider the Harm this Action Would Cause the Petitioners and Other Growers.

EPA has failed to consider the substantial harm that growers are already facing and will continue to face by EPA's attempt to keep chlorpyrifos off the market. EPA has found chlorpyrifos critical to the agricultural economy.[39] In many instances, there is no available substitute for the effective control of pests. Growers are in desperate need of chlorpyrifos for the 2023 growing season. The Grower Petitioners have demonstrated in their objections to EPA and in their attestations to the Eighth Circuit[40] the dire situation they are facing and will continue to suffer for the survival of their businesses and the crops they supply for U.S. consumers with the loss of chlorpyrifos.

EPA's assumption that its NOIC will not have an impact on the economy, because chlorpyrifos tolerances have been revoked, is a fallacy. If the Eighth Circuit rules in favor of the

[39] EPA, "Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)," (Nov. 18, 2020), EPA-HQ-OPP-2008-0850-0969 (Exhibit 21).

[40] Pet. for Review, Attachment 2, Exhibits A-W, Supporting Declarations of Grower Petitioners, *Red River Valley Sugarbeet Growers Ass'n et al.* (8th Cir. Feb. 28, 2022). We hereby incorporate by reference the entirety of Attachment 2, Exhibits A-W (Exhibit 22).

Grower Petitioners, and EPA has already cancelled all chlorpyrifos registrations, growers will have no chlorpyrifos products available to protect the crops at issue. Growers would have to wait for registrants to submit new registrations to EPA and obtain approvals from EPA prior to sale or distribution of the pesticide. As explained below, this hurdle would cause significant harm to growers and disruptions in the economy.

On average, 8.8 million acres of agricultural crops were treated with chlorpyrifos annually from 2014-2018, and EPA estimated the total annual economic benefit of chlorpyrifos to crop production to be $19-130 million.[41] In the state of North Dakota alone, the per acre benefits of chlorpyrifos could be as high as $500 in parts of the state, leading the EPA-estimated high-end benefits over $30 million overall nationwide.[42] Therefore, the loss of chlorpyrifos has significant negative economic impacts for the agriculture industry.

The Grower Petitioners already suffer and will continue to suffer immediate, unrecoverable, significant irreparable harm in the form of economic losses and reputational damage unless EPA withdraws or stays this NOIC as soon as possible. The loss of chlorpyrifos as a pest management tool will result in substantially increased costs, lost profits, a larger environmental impact from the more frequent use of less effective alternatives, and decreased crop yields. All of these harms are compounded by the fact that growers reasonably relied on EPA's PID to plan for crop management, and several states took a measured approach to phase out uses of chlorpyrifos rather than immediately banning chlorpyrifos without a phase-out

[41] *Id*., Exhibit J at 3.

[42] *Amicus Curiae* Br. of the State of North Dakota in Support of Petitioners 16, *Red River Valley Sugarbeet Growers Ass'n et al.* (8th Cir. June 1, 2022) (North Dakota *Amicus* Br.) (Exhibit 23).

period.[43] And growers and states face burdens of having to address the tons of "stranded" and unusable chlorpyrifos stocks remaining that will need to be disposed of.[44] EPA's NOIC ignores these economic impacts.

1. Irreparable Harm to Sugarbeet Growers

For the sugarbeet industry, the estimated high-end benefits for the use of chlorpyrifos is $32.2 million per year, and this is likely an underestimate.[45] Chlorpyrifos is the most effective control against the sugarbeet root maggot (SBRM) and flies, and in some cases is the *only* effective pesticide. The industry depends significantly on chlorpyrifos as a critical crop protection tool to meet the sugar demands of the U.S. economy.[46] EPA has acknowledged that the lack of alternatives to chlorpyrifos can lead to potential yield loss in sugarbeet crops. The continued loss of chlorpyrifos products would be devastating to sugarbeet growers because registered alternatives can only suppress but not control the SBRM or are only registered for use on adult flies and not larvae.

For one sugarbeet farm located in a "hot spot" with a high incidence of SBRM infestation, 65 percent of its annual revenue comes from sugarbeets, and 75 percent of its annual revenue comes from crops on which it applies chlorpyrifos.[47] The farm estimated that without chlorpyrifos unrecoverable losses could be up to $200 per acre.[48] For another farm, where 50 percent of its annual revenue comes from crops on which it applies chlorpyrifos, it estimated

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[43] *Id*.

[44] *Id*. at 26.

[45] U.S. Beet Sugar Ass'n & Am. Sugarbeet Growers Ass'n Objections.

[46] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit A at 4-5.

[47] *Id*., Exhibit B at 3.

[48] *Id*. at 8.

unrecoverable losses of about $60,000 per year of its sugarbeet crop alone.[49] Another cooperative estimated unrecoverable losses of up to $30,000,000 per year for its members.[50] One cooperative estimated unrecoverable losses of approximately $34,436,634 in 2022 for its grower members .[51] Growers in this region cannot source sugarbeets from elsewhere because they cannot be shipped thousands of miles or be grown in other areas to make up for the losses.[52] Another cooperative estimated unrecoverable losses of up to $17,500,000 per year of its members.[53]

The State of North Dakota found that there would be a reduction of 1,565 pounds of sugar per acre produced and $201 per acre in revenue losses, resulting in $20,904,000 in losses in North Dakota SBRM areas and $18,395,642 in additional total production costs for a total of $39,299,642 in losses.[54] And these losses will compound with every year of using less effective alternatives. Without chlorpyrifos, SBRM can decrease crop yields by as much as 45 percent.[55]

Sugarbeet growers also face concerns about their healthy crops being impacted by being stored with crops from other farms that are damaged by destructive pests. Costs to sugarbeet growers are exacerbated by inflation, which has increased the cost of operating a farming business (fertilizer costs, fuel costs, chemical costs, and equipment costs) by over 30 percent.[56]

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[49] *Id*., Exhibit E at 7.

[50] *Id*., Exhibit F at 9.

[51] *Id*., Exhibit G at 11.

[52] *Id*. at 15.

[53] *Id*., Exhibit I at 10.

[54] North Dakota *Amicus* Br. 18-19.

[55] *Id*. at 22.

[56] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit B at 8.

In North Dakota, the sugarbeet industry is also suffering from impacts from extreme weather, early freezes, drought, and, in 2022, the latest spring on record caused by persistent cool and wet weather.[57]

For these farms and many others, chlorpyrifos is the only tool that has been consistently effective at controlling SBRM. Alternatives require multiple applications and are less effective, resulting in increased costs and a larger environmental impact. The problem cannot be ameliorated through methods like crop rotation because it is not an effective substitute for chlorpyrifos for SBRM control. SBRM larvae overwinter in fields and emerge the next year.[58] Without chlorpyrifos use in the future, this will likely lead to greater harm every year as the population of destructive SBRM grows with each growing season.[59]

Sugarbeet growers are also concerned that the loss of chlorpyrifos in the future will result in less protection for sugarbeets from symphylans, as chlorpyrifos is the only fully registered rescue option available in early spring to control symphylans.[60] One cooperative estimated that, if chlorpyrifos is not available, 25-33 percent of the sugarbeet seed production acreage will likely be affected, with up to a 50 percent loss of seed production.[61] Further, the loss of chlorpyrifos will negatively impact sugarbeet growers not only economically but also through reputational harm, creating uncertainty regarding the safety of food products in commerce.[62]

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[57] North Dakota *Amicus* Br. 25.

[58] *Id.* at 24.

[59] Pet. for Review, Attach. 2 Supporting Declarations of Grower Petitioners, Exhibit B at 6.

[60] *Id*., Exhibit C at 4.

[61] *Id*., Exhibit G at 14.

[62] *Id*., Exhibit C at 7.

2. Irreparable Harm to Soybean Growers

As the soybean industry has demonstrated, growers have relied on chlorpyrifos to control numerous insect pests, with the most critical uses being for the control of soybean aphids and two-spotted spider mites (TSM). These pests are notoriously difficult to control and can result in up to 60 percent yield loss.[63]

Some of these pests can vector plant pathogenic viruses which can result in double-digit yield loses and, in rare instances, reduce yields greater than 90 percent.[64] There are only a limited number of options to control aphids and TSM, and removal of any options such as chlorpyrifos will result in rapid build-up of insecticide resistance to the remaining options.[65] For growers who lose access to chlorpyrifos, there is no one-to-one replacement, meaning that growers will have to spray at least two active ingredients to control these pests, increasing their purchase and application costs. Soybean farmers estimate over $1.26 million in annual cost increases to protect their crops if they are forced to continue to use alternatives.[66]

3. Irreparable Harm to Fruit Growers

For cherry growers, chlorpyrifos has been one of the most effective tools and, according to one Grower Petitioner, is used on almost all of its cherry tree acres.[67] And there is no equivalent replacement for chlorpyrifos. Chlorpyrifos is unique in that it is the only effective chemistry to protect the cherry industry from trunk borers. Chlorpyrifos is active on adult, egg, and larval stages of most trunk boring pests. EPA has even acknowledged that borers are a

[63] *Id*., Exhibit K at 4.

[64] *Id*., Exhibit M at 4.

[65] *Id*.

[66] *Id*., Exhibit K at 6.

[67] *Id*., Exhibit T at 3.

growing problem for which effective alternatives to chlorpyrifos are not available.[68] Tree loss from trunk borers can cost a grower $300 per tree in lost revenue.[69] Chlorpyrifos has also been important for peach growers to protect against lesser peach tree borers, as well as apple growers to protect against scale, stink bugs, aphids, and borers in apple production.[70]

Citrus growers in Florida also depend on chlorpyrifos. They currently face a dire situation with the growing problem citrus greening caused by the Asian citrus psyllid. The importance of chlorpyrifos in the management of citrus greening cannot be overemphasized. Already, the U.S. Department of Agriculture (USDA) reported in 2019 that citrus production overall in Florida has decreased by more than 74 percent since the introduction of the Asian citrus psyllid and the subsequent citrus greening infections.[71] Asian citrus psyllids, rust mites, spider mites, broad mites, scales, and Diaprepes root weevils all cause economic damage to citrus in Florida. All of these pests are targeted directly and managed effectively by chlorpyrifos. Other alternatives are less effective, have increased costs, and result in lower crop yields.

4. Irreparable Harm to Wheat and Cotton Growers

Chlorpyrifos has been used on winter and spring wheat and allows growers the flexibility needed to address pest pressures.[72] It has also been used to protect cotton crops from whitefly and late season cotton aphid infestations. If not controlled, the entire cotton chain is impacted from sugar excretions on the cotton from the pests. The resulting "sticky cotton" slows down the

[68] *Id*. at 4.

[69] *Id*. at 5-6.

[70] *Id*., Exhibit V at 4.

[71] *Id*., Exhibit U at 3.

[72] *Id*., Exhibit S at 3.

ginning process by up to 25 percent and will lower the grade and value of cotton. Over time, wheat and cotton growers will experience yield losses and increased costs.

As outlined above, grower groups will suffer immediate, irreparable harm in the form of significant yield losses, lost profits, and, consequently, lost jobs if they can no longer use chlorpyrifos to protect their crops. Chlorpyrifos is urgently needed because it has broad-spectrum effectiveness, has a relatively short persistence (making it less harmful to beneficial insects), and can be used in multiple delivery systems—all key attributes of an integrated pest management program.[73] The loss of chlorpyrifos will only expedite insect resistance to the few remaining alternatives and result in greater crop damage. These growers will also be forced to apply less effective alternatives in greater volumes, reducing their ability to be good environmental stewards.

C. EPA Fails to Consider That There Is No Purpose Served by Cancelling Gharda's Registrations.

EPA fails to consider that its proposed cancellation of Gharda's products does not serve the cited purpose. In fact, there is no legitimate purpose for cancelling Gharda's registrations. Chlorpyrifos cannot be used on food crops while the Eighth Circuit considers the validity of the Final Rule revoking all tolerances for chlorpyrifos. And, as stated previously, Gharda has committed to ensure chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit. EPA has not presented any evidence that chlorpyrifos products are being sold or distributed in violation of its revocation order. All EPA's NOIC accomplishes is prematurely revoking pesticide registrations for economically critical pesticide products on the basis of an unlawful Final Rule that the Grower Petitioners have asked

[73] *Id*., Exhibit J at 4.

to be vacated. EPA's NOIC would create more barriers and delays for growers who will need access to chlorpyrifos products in the future.

D. EPA Fails to Consider the Impact on the Economy.

EPA fails to consider, as required by FIFRA section 6(b) for registration cancellations, "restricting [chlorpyrifos's] use or uses as an alternative to cancellation" and fails to "take[] into account the impact" of cancellation of chlorpyrifos registrations "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."[74] As demonstrated by the Grower Petitioners, the economic impact of the total removal of all chlorpyrifos registrations for all food uses is devastating for the crops that, based on EPA's own evidence and safety finding for the Safe Uses, should not be restricted. While significant economic impacts are already being felt by growers, the harms will continue and be exacerbated with the cancellation of Gharda's products, the sole remaining approved chlorpyrifos products for the Safe Uses. Rather than have growers go out of business and consumers be deprived of critical food supply, EPA can simply amend chlorpyrifos registrations to restrict the non-safe food uses and allow the safe food uses to continue to be approved.

V. EPA's Proposed Cancellation of Gharda's Registrations Is Arbitrary and Capricious and an Abuse of Discretion Because it Offers No Reasoned Analysis for the Agency's Change in Course.

EPA's proposed cancellation of Gharda's registrations is arbitrary and capricious and an abuse of discretion because it fails to provide a reasoned analysis for its sudden shift in position. EPA fails to explain why it is deviating from historical precedent and procedures. The USDA Office of Pest Management Policy (OPMP) believes EPA can retain certain chlorpyrifos uses

[74] 7 U.S.C. § 136d(b).

that meet EPA's safety standard based on its PID—the Safe Uses.[75] EPA provides no analysis for why its drastic actions to cancel all registrations is appropriate when specific uses it has determined to be safe can be preserved. EPA also inappropriately brushes aside the comments and concerns from USDA.[76]

VI. EPA's Refusal to Stay this Proceeding, Seeking Cancellation of Gharda's Registrations, Is Arbitrary, Capricious and Contrary to Law.

Petitioners in the Eighth Circuit, by letter dated January 6, 2023, asked EPA to withdraw or stay this proceeding in light of the pending Eighth Circuit litigation. Unfortunately, EPA rejected that request. As discussed, EPA's cancellation of Gharda's registrations would interfere with the jurisdiction of the Eighth Circuit and would force Grower Petitioners and other parties to needlessly expend additional resources fighting the cancellation while the Eighth Circuit litigation continues. Any cancellation of Gharda's registrations based upon the fact that tolerances have been revoked by EPA's Final Rule would become void upon an Eighth Circuit's ruling invalidating the Final Rule.

Because no use of chlorpyrifos can occur while the Final Rule is in effect, there is no legitimate purpose served by proceeding with cancellation of Gharda's registrations. EPA does not have reason to believe that chlorpyrifos is being sold or distributed in violation of the Final Rule. EPA waited to issue this NOIC for over nine months after Gharda's written commitment to ensuring its chlorpyrifos products do not enter the U.S. food supply. EPA's decision to issue the NOIC appears to be an attempt to interfere with the jurisdiction of the Eighth Circuit and the

[75] Letter from The Honorable Thomas J. Vilsack, Secretary, USDA, to The Honorable Rep. Vicky Hartzler (Sept. 20, 2022) (Exhibit 24).

[76] 87 Fed. Reg. at 76,478-79.

relief it might award Petitioners for EPA's unlawful Final Rule, rather than an action based on a legitimate concern about the unlawful sale and distribution of chlorpyrifos products for food use.

If the Eighth Circuit decides in favor of the Grower Petitioners, and growers can thereafter resume use of chlorpyrifos on the crops identified in the Safe Uses, cancelling Gharda's registrations will have unnecessarily created significant difficulties for growers in their ability to fight pests. It could take years before registrants of products containing chlorpyrifos apply for and obtain approval from EPA for new products or new food uses. In the meantime, growers will continue to suffer crop losses and/or increased costs of production.

The Grower Petitioners will suffer irreparable harm from EPA's cancellation of chlorpyrifos registrations for the Safe Uses. For the reasons set forth above, sound public policy supports a stay of the NOIC, and a stay would not harm public health or any public interest. The Grower Petitioners' objections to the NOIC are made in good faith and not frivolous. EPA should therefore stay the NOIC.[77]

VII. Grower Petitioners Request a Hearing on EPA's Proposed Cancellation of Gharda's Registrations.

For the reasons outlined above, Grower Petitioners object to EPA's NOIC and request a hearing on EPA's cancellation of Gharda's registrations. The Grower Petitioners are adversely affected by EPA's NOIC and EPA's refusal to withdraw or stay that action. EPA should not proceed with cancelling Gharda's chlorpyrifos product registrations until the litigation pending before the Eighth Circuit is resolved. Neither should EPA cancel Gharda's chlorpyrifos registrations until EPA first complies with the requirements of FIFRA. For the reasons set forth

[77] *Cf.*, 21 C.F.R. § 10.35(e)(1)-(4).

above, cancellation of Gharda's registrations is unlawful, arbitrary, capricious, and an abuse of discretion.

January 13, 2023

Respectfully submitted,

/s/ Nash E. Long

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EXHIBIT 7

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products **Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.,** **Petitioners**	)	**Docket No. FIFRA-HQ-2023-0001**

RESPONSE TO REQUEST FOR STAY OF
NOTICE OF INTENT TO CANCEL PESTICIDE REGISTRATIONS

In response to the Order to Respondent to Respond dated February 8, 2023, Respondent the U.S. Environmental Protection Agency ("EPA," "Agency," or "Respondent") respectfully submits this Response to Request for Stay of Notice of Intent to Cancel Pesticide Registrations.

On December 14, 2022, EPA published in the Federal Register a Notice of Intent to Cancel ("NOIC") the registrations of three pesticide products pursuant to section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136d(b). Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022). That NOIC identifies Petitioner Gharda Chemicals International, Inc. ("Gharda") as the registrant for the products subject to the NOIC. *Id*. at 76,474. Consistent with section 6(b) of FIFRA, the NOIC specifies that a request for a hearing by a registrant must be submitted in writing within 30 days after the date of receipt of the NOIC, or within 30 days after publication of the NOIC in the Federal Register, whichever occurs later. 7 U.S.C. § 136d(b); 87 Fed. Reg.

76,474, 76,480 (Dec. 14, 2022). On January 13, 2023, Petitioner Gharda filed its Request for Hearing and Statement of Objections and Request for Stay ("Objections"). In the Objections, Petitioner Gharda requests a stay of any action by the EPA Office of Administrative Law Judges with respect to the NOIC, including but not limited to the conduct of a hearing, pending resolution of its challenge to the Agency's rule revoking chlorpyrifos tolerances.[1] Objections at 12-13 (referring to *Red River Valley Sugarbeet Growers Ass'n v. Regan (RRVSGA)*, Nos. 22-1422, 22-1530 (8th Cir. argued Dec. 15, 2022) (challenging Chlorpyrifos: Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the "Final Rule")). That lawsuit is currently pending before the U.S. Court of Appeals for the Eighth Circuit. For the reasons set forth in more detail herein, Respondent respectfully requests that this Tribunal deny Petitioner Gharda's request for a stay.

STANDARD OF REVIEW

In a recent matter, this Tribunal set forth its standard for reviewing a request to stay a proceeding pending the resolution of a matter before a U.S. Circuit Court of Appeals:

> In deciding whether to stay a proceeding, EPA administrative law judges have considered the following factors: whether or not the stay will serve the interests of judicial economy,

[1] Respondent notes that a collection of grower groups ("Grower Petitioners") also filed with this Tribunal a Request for Hearing and Statement of Objections dated January 13, 2023 ("Grower Petitioners' Objections"). In Grower Petitioners' Objections, Grower Petitioners argue that they "already suffer and will continue to suffer immediate, unrecoverable, significant irreparable harm in the form of economic losses and reputational damage unless *EPA* withdraws or stays this NOIC as soon as possible." Grower Petitioners' Objections at 12 (emphasis added). Grower Petitioners further argue that "sound public policy supports a stay of the NOIC, and a stay would not harm public health or any public interest…[t]he Grower Petitioners' objections to the NOIC are made in good faith and not frivolous…[and] *EPA* should therefore stay the NOIC." Grower Petitioners' Objections at 21 (emphasis added).

It is unclear whether Grower Petitioners, in asserting that *EPA* should stay the NOIC, were requesting a stay by EPA, which is also identified as the Respondent in this action, or a stay by this Tribunal. To the extent the Grower Petitioners were referring to EPA as the Respondent in this matter, *see* Order to Respondent to Respond at 1, EPA has already declined to stay the NOIC, as Grower Petitioners acknowledge. *See* Grower Petitioners' Objections at 2. To the extent the Grower Petitioners were asking this Tribunal to stay the NOIC, the Respondent has addressed their claims in this Response.

result in unreasonable or unnecessary delay, or eliminate any unnecessary expense and effort; the extent, if any, of hardship resulting from the stay, and of adverse effect on the judge's Docket; and the likelihood of records relating to the case being preserved and of witnesses being available at the time of any hearing.

In the Matter of: Borla Performance Industries, Inc., Respondent, EPA Docket No. CAA-09-2020-0044, 2022 WL 887454, at *3 (ALJ, Mar. 15, 2022) (citing *John Crescio*, EPA Docket No. 5-CWA-98-004, 1999 WL 362862, at *1 (ALJ, Feb. 26, 1999) (Order on Joint Motion for Staying Proceedings)). This Tribunal further noted that "[a] federal trial court generally may not grant a stay so extensive that it is 'immoderate or indefinite' in duration, and a trial court abuses its discretion by issuing 'a stay of indefinite duration in the absence of a pressing need,'"[2] and "[i]n determining whether to stay proceedings indefinitely, a 'pressing need' is identified by balancing interests favoring a stay against interests frustrated by a stay, but '[o]verarching this balancing is the court's paramount obligation to exercise jurisdiction timely in cases before it."[3]

Respondent disagrees with Petitioner Gharda to the extent that Gharda is asserting that the criteria at 21 C.F.R. § 10.35(e)(1)-(4) provide the standard of review for this stay request. See Objections at 13, n.9. Those regulations contain the factors that the U.S. Food and Drug Administration uses for determining whether to stay an administrative action under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Due to the similarity between FDA's administrative process and EPA's administrative process under the FFDCA, EPA has applied those criteria to evaluate whether to stay action under FFDCA section 408(g). *See, e.g.*, Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule (the "Denial Order"), 87 Fed. Reg. 11,222 (Feb. 28, 2022); Carbofuran;

[2] *Id*. at *2 (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 255, 257 (1936)).
[3] *Id*. (quoting *Cherokee Nation of Okla. v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997)).

Final Tolerance Revocations, 74 Fed. Reg. 23,045, 23,088 (May 15, 2009). Those criteria are not relevant here, however, since this stay request is occurring in the context of a FIFRA cancellation proceeding, not an administrative action under the FFDCA. Even if those criteria did apply, Petitioner Gharda does not enumerate how exactly it has satisfied these criteria in its Objections, simply stating "[f]or reasons outlined herein, Gharda has satisfied these criteria here." *Id*.

OBJECTIONS TO RESPONSE TO REQUEST FOR STAY

I. A Stay Would Unreasonably and Unnecessarily Delay Respondent's Efforts to Timely Modify or Cancel Noncompliant Pesticide Registrations.

As noted above, one of the factors previously considered by this Tribunal in deciding whether to stay a proceeding is "whether or not the stay will serve the interests of judicial economy, result in unreasonable or unnecessary delay, or eliminate any unnecessary expense and effort." *See supra* pp. 2-3. Respondent acknowledges the potential of a stay of these proceedings pending the outcome of the Eighth Circuit litigation to conserve resources; however, Respondent notes that it is unclear when the Eighth Circuit will issue its decision in that matter and what that decision will be. It could be many months until the Eighth Circuit issues its decision, and if the court rules in favor of Respondent, Petitioner Gharda's registrations subject to the NOIC will have remained in effect despite the fact that no tolerances for residues of chlorpyrifos exist. As discussed in this section, this potential is outweighed by the fact that the delay caused by such a stay would be both unreasonable and unnecessary.

A. The Ninth Circuit Ordered EPA to Cancel or Modify Pesticide Registrations Consistent with the Tolerance Rule.

Respondent has been working diligently since the revocation of the chlorpyrifos tolerances to comply with the Ninth Circuit's mandate and to conform chlorpyrifos registrations

with the reality that food uses can no longer be maintained. Petitioner Gharda asserts that "there is no urgent need or other basis to proceed with the NOIC before the Eighth Circuit's decision" pointing to the "15 months" between the issuance of the Final Rule and the issuance of the NOIC as evidence of a lack of urgency. Objections at 5. This assertion is contradicted by both the Agency's track record of action on chlorpyrifos as well as the plain language of the Ninth Circuit's order to Respondent to modify or cancel pesticide registrations consistent with its tolerance decision "in a timely fashion." *League of United Latin Am. Citizens v. Regan (LULAC II)*, 996 F.3d 673, 704 (9th Cir. 2021).

In *LULAC II*, the Ninth Circuit found that the Agency had abdicated its statutory obligation to make a safety finding in its retention of chlorpyrifos tolerances and directed Respondent to take swift action on the chlorpyrifos tolerances and then to cancel or modify pesticide registrations consistent with that tolerance action "in a timely fashion." *LULAC II* at 704. The Ninth Circuit pointedly and repeatedly expressed its frustration with the Agency's history of delays with respect to chlorpyrifos;[4] hence the court's direction to Respondent to modify or cancel pesticide registrations "in a timely fashion" instead of an open-ended mandate. *See LULAC II*, 996 F.3d at 704.

Moreover, Respondent notes that the "15 months" statement is a red herring, as the Final Rule is not the appropriate reference point here. First, the Final Rule allowed the chlorpyrifos tolerances to remain in effect for six months—until February 28, 2022. Final Rule at 48,334. In addition, after the Final Rule was issued on August 30, 2021, the Agency had a statutory obligation to consider objections, hearing requests, and requests to stay the Final Rule, 21 U.S.C.

[4] *See, e.g.*, *LULAC II*, 996 F.3d at 678 ("[T]his delay tactic was a total abdication of the EPA's statutory duty under the FFDCA."), 702 ("Indeed, further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself."), and 703 ("[T]he EPA's time is now up.").

§ 346a(g)(2), which Respondent satisfied via the Denial Order. The Denial Order completed the Agency's administrative process for the Final Rule. Once that process was complete and the tolerances were revoked, in early March 2022, the Agency sent letters to all chlorpyrifos registrants requesting that registrants voluntarily cancel chlorpyrifos registrations with food uses and/or amend registrations to remove such food uses. *See*, *e.g.*, Letter from U.S. Environmental Protection Agency to Ram Seethapathi, Gharda Chemicals International, Inc., (Mar. 1, 2022), Ex. 1. The Agency noted that if requests were not submitted, EPA would initiate cancellation proceedings by issuing a NOIC under section 6(b) of FIFRA. *Id*. at 2.

In response to those letters, nearly all chlorpyrifos registrants, with the exception of Petitioner Gharda, submitted requests to voluntarily cancel their chlorpyrifos registrations or terminate food uses and amend their registered products. Respondent has since been diligently processing those voluntary cancellation requests. Specifically, EPA has issued a final cancellation order cancelling 16 chlorpyrifos products[5] and a notice of receipt of requests to voluntarily cancel 14 other chlorpyrifos products as well as to terminate food uses on 3 additional chlorpyrifos products.[6]

In contrast, in its March 30, 2022 letter seeking voluntary cancellation of certain registered chlorpyrifos food uses, Petitioner Gharda requested termination of some uses but expressed an intent to retain uses that the Agency proposed to retain in the 2020 Proposed Interim Registration Review Decision for Chlorpyrifos ("2020 PID"). Objections, Ex. 9 at 1.[7] In

[5] *See* Notice of Receipts of Requests to Voluntarily Cancel Certain Pesticide Registrations, 87 Fed. Reg. 25,256 (Apr. 28, 2022); Cancellation Order for Certain Chlorpyrifos Registrations, 87 Fed. Reg. 53,471 (Aug. 31, 2022); Chlorpyrifos; Amendment to Provisions for Disposition of Existing Stocks, 88 Fed. Reg. 5,332 (Jan. 27, 2023).
[6] Chlorpyrifos; Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations To Terminate/Amend Certain Uses, 87 Fed. Reg. 76,191 (Dec. 13, 2022).
[7] Respondent notes that this letter is identified in the Objections as Exhibit 9, *see, e.g.*, Objections at 7, but is identified in the exhibits themselves as Exhibit 4. *See* pp. 664-668 of the PDF file containing the exhibits to the Objections.

fact, Petitioner Gharda made clear to the Agency in that letter that it would not voluntarily submit the changes necessary for its product registrations to conform to the Final Rule because of its pending challenge to the Final Rule. *Id*. at 4. Also, on June 10, 2022 Petitioner Gharda submitted amended product labels to the Agency consistent with its intent to retain those food uses identified in the 2020 PID. Objections, Ex. 10. In light of the Ninth Circuit's clear directive and Petitioner Gharda's refusal to submit the necessary requests for voluntary cancellation and label amendments to bring its registrations into compliance with FIFRA and the FFDCA, it was appropriate for Respondent to prepare and publish the NOIC. Accordingly, Respondent requests that this Tribunal allow this cancellation process to move forward.

B. The Eighth Circuit's Actions to Date Do Not Support a Stay of this Cancellation Action.

Further underscoring that a stay of these proceedings would result in an unnecessary delay, the Eighth Circuit has already made clear that there is no reason for Respondent's administrative process with respect to chlorpyrifos registrations to wait on the outcome of the litigation pending before it. Prior to merits briefing and oral argument in that matter, the petitioners in that case, including Petitioner Gharda, sought to stay implementation of the Final Rule "pending judicial review of that decision." Petitioners' Renewed Motion for a Partial Stay Pending Review ("Eighth Circuit Stay Motion") at 27, *RRVSGA*, No. 22-1422 (8th Cir. Mar. 3, 2022), Entry ID 5132688, Ex. 2.

The plaintiffs in the *RRVSGA* litigation had a full opportunity to brief the issue before the Eighth Circuit, and included arguments similar to those being made before this Tribunal. *See*, *e.g.*, Eighth Circuit Stay Motion at 22, *RRVSGA*, No. 22-1422 (8th Cir. Mar. 3, 2022) ("[t]he threat of unrecoverable economic loss qualifies as irreparable harm") and at 26 ("[t]he public interest…support[s] Petitioners' request for a stay…the agricultural commodities grown by the

farmers represented here contribute significantly to the U.S. economy as a whole and to local communities in particular."). The Agency responded that it would not be good public policy to allow unsafe tolerances to remain in place inconsistent with the safety standard in the FFDCA while the litigation was pending.[8] The Eighth Circuit rejected the plaintiffs' stay request. Order Exercising Jurisdiction and Denying Motion for a Partial Stay Pending Review, *RRVSGA*, Nos. 22-1422 (8th Cir. Mar. 15, 2022), Entry ID 5136844, Ex. 3. Although the Eighth Circuit did not elaborate on its reasoning for denying the request for a stay of the Final Rule, the denial itself leaves the Final Rule in place and in full effect; thus, the status of the chlorpyrifos tolerances is that they remain revoked and not on hold. Consequently, it is appropriate to proceed with the cancellation and/or termination of food uses associated with those revoked tolerances.

II. An Indefinite Stay of this Proceeding Is Not Justified by a Pressing Need.

When assessing "whether to stay proceedings indefinitely," this Tribunal has specified that it will seek to identify whether there is a "pressing need" for a stay by "balancing interests favoring a stay against interests frustrated by a stay." *See supra* p. 3. While Petitioner Gharda requests a stay of further action on the NOIC "until the Eighth Circuit rules," that time period is indefinite at the moment, since it is unclear when the Eighth Circuit might rule on the matter or what the next steps might be after the Eighth Circuit issues its order. It is also unclear whether Petitioner Gharda would employ a similar argument to further stay these proceedings pending appeal of an unfavorable decision by the Eighth Circuit. On balance of the interests here, Respondent believes that Petitioner Gharda has not demonstrated a pressing need for a stay.

[8] *See*, *e.g.*, Respondents' Opposition to Petitioners' Motion for Stay Pending Review, *RRVSGA*, No. 22-1422 (8th Cir. Mar. 11, 2022), Entry ID 5135786, at 18 ("Petitioners have failed to demonstrate irreparable harm."), 23 ("[g] granting Petitioners' stay request would also undermine judicial process and comity among sister circuits."), and 23 ("[t]he public interest and balance of harms also weigh strongly in favor of denying Petitioners' stay request." Ex. 4.

Petitioner Gharda's primary arguments in favor of a stay revolve around its claim that proceeding with this matter "would prejudice the rights of Gharda and others to obtain judicial relief from the Final Rule underlying the NOIC" and is "contrary to the Eighth Circuit's exercise of jurisdiction over [chlorpyrifos] tolerances" are misplaced. Objections at 13. While, as noted above, Petitioner Gharda did not enumerate its arguments by reference to the standards in 21 CFR 10.35(e)(1)-(4) or those previously employed by this Tribunal, *see supra* pp. 3-4, these concerns are unfounded and do not establish a "pressing need" for a stay.

First, as discussed above, the Eighth Circuit has already denied Gharda's requests to put the Final Rule on hold, which supports moving forward with the implementation of that Final Rule, including cancellation of food uses for chlorpyrifos. *See supra* pp. 7-8. Second, regardless of Petitioner Gharda's attempt to muddy the waters, the concurrence of this cancellation proceeding while the challenge to the Final Rule is pending has no effect on the Eighth Circuit's jurisdiction over that matter. The Final Rule and the NOIC are separate agency actions based on distinct statutory provisions and are properly before their respective tribunals.

The petitioners in the Eighth Circuit litigation – including Petitioner Gharda – have not been prejudiced in their ability to seek review of the Final Rule. The petitioners took full advantage of the administrative objections process under the FFDCA by filing objections, hearing requests, and requests to stay the Final Rule. Then, after Respondent denied those objections, petitioners filed two petitions in the Eighth Circuit seeking judicial review of that Denial Order pursuant to FFDCA section 408(h)(1),[9] which were subsequently consolidated by the court.[10] Pursuant to FFDCA section 408(h)(2), 21 U.S.C. § 346a(h)(2), the Eighth Circuit is

[9] *See* Petition for Review, *RRVSGA*, No. 22-1422 (8th Cir. Feb. 28, 2022), Entry ID 5131400, Ex. 5; Petition for Review, *RRVSGA*, No. 22-1530 (8th Cir. Mar. 14, 2022), Entry ID 5136561, Ex. 6.
[10] Order Granting Motion to Consolidate Cases 22-1422 and 22-1530, *RRVSGA*, Nos. 22-1422 and 22-1530 (8th Cir. Apr. 21, 2022), Entry ID 5149661, Ex. 7.

properly exercising its exclusive jurisdiction to affirm or set aside the Denial Order or Final Rule. Respondent is not seeking to usurp the jurisdiction of the Eighth Circuit regarding the Final Rule; to the contrary, the challenge to chlorpyrifos tolerances is – and should remain – within the exclusive jurisdiction of the Eighth Circuit.

The initiation of the NOIC under FIFRA does not impact the jurisdiction of the Eighth Circuit over the currently pending challenge; rather, it simply takes one more step to implement the Final Rule that the Eighth Circuit left in place pending its decision. Although the conclusion of this NOIC process could result in the cancellation of Petitioner Gharda's registered food uses, that conclusion is entirely consistent with the fact that no tolerances for residues of chlorpyrifos exist. If tolerances for residues of chlorpyrifos are established in the future, Petitioner Gharda or any registrant that has voluntarily cancelled uses would need to follow the applicable process(es) for registration under FIFRA and the regulations promulgated thereunder. *See* 7 U.S.C. § 136a(c) and 40 C.F.R. part 152. In any event, Respondent does not believe that moving forward with this cancellation proceeding will prejudice Petitioner Gharda, since it is likely that the Eighth Circuit will issue its decision prior to the cancellation of the registrations in question. This is particularly so in light of the parties' ability to appeal an initial decision or an accelerated decision of this Tribunal to the Environmental Appeals Board. 40 C.F.R. §§ 164.101, 164.102. The Environmental Appeals Board's final decision and order is also subject to judicial review pursuant to FIFRA section 16(b). 7 U.S.C. § 136n(b). Respondent also notes that any decision of the Eighth Circuit and the implications, if any, of that decision for these proceedings can be taken into consideration at the time it is issued.

Furthermore, Grower Petitioners' arguments that they will suffer "immediate, unrecoverable, significant irreparable harm in the form of economic losses and reputational

damage" in the absence of a stay of this proceeding are misplaced. The NOIC and the cancellation of chlorpyrifos food uses is simply an administrative process to implement the Final Rule, which revoked tolerances for residues of chlorpyrifos and rendered adulterated any food treated with chlorpyrifos after February 28, 2022. That is, any such harms alleged by Grower Petitioners would properly be attributable to the Final Rule, and not the NOIC which is the subject of these proceedings.

In contrast, there are significant public policy interests that would be frustrated by a stay. Delaying this cancellation proceeding would simply allow Gharda's products to remain out of compliance with FIFRA for an indefinite period, which is inconsistent with public policy to bring violative products into compliance in a timely manner and with the Ninth Circuit's order to cancel associated registrations "in a timely fashion". *LULAC II* at 704.

Petitioner Gharda's stay request places significant emphasis on its commitment to ensuring that its "chlorpyrifos product does not enter the U.S. food supply" and its assertion that Respondent has not demonstrated that "chlorpyrifos products are being distributed, sold, and/or used in a manner inconsistent with the Final Rule." Objections at 7. It is true that chlorpyrifos products bearing labels for use on food cannot be distributed or sold at the current time as doing so would involve distribution of a misbranded pesticide and violate FIFRA section 12(a)(1)(E). 7 U.S.C. § 136j(a)(1)(E). As such, Respondent has provided guidance to the regulated community warning against distribution of such products. [11] Cancellation would provide clarity for disposition of these chlorpyrifos products and would allow for the movement of the product for disposal. *See* 40 C.F.R. § 152.30(f); *see also* Cancellation Order for Certain Chlorpyrifos

[11] *See* Frequent Questions about the Chlorpyrifos 2021 Final Rule, U.S. ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule (last updated Feb. 1, 2023).

Registrations, 87 Fed. Reg. 53,471, 53,473 (Aug. 31, 2022) (discussing provisions for disposition of existing stocks of certain chlorpyrifos products). Notwithstanding this fact, Petitioner Gharda's arguments on this point miss the point. As discussed below, because the chlorpyrifos tolerances have been revoked, all food uses for chlorpyrifos must be terminated or chlorpyrifos products bearing food use labeling must be cancelled. Most chlorpyrifos registrants have submitted compliant cancellation and use termination requests already that the Agency is processing. Even if Petitioner Gharda's incomplete cancellation request were processed, impermissible food uses would remain registered on Petitioner Gharda's chlorpyrifos products. Those products therefore pose unreasonable adverse effects on the environment as a matter of law under FIFRA section 2(bb)(2) and cancellation is appropriate. 7 U.S.C. § 136(bb)(2). This NOIC has been issued in order to address Petitioner Gharda's registrations for which an inadequate cancellation request was submitted. FIFRA section 6(b) is straightforward; if the product or labeling does not comply with FIFRA or the pesticide causes unreasonable adverse effects on the environment, then a NOIC is appropriate. *See* 7 U.S.C. § 136d(b). The purpose of this statutory provision would thus be frustrated by a stay of the NOIC, as would the Agency's interest in ensuring compliance with FIFRA and preventing unreasonable adverse effects on the environment.

CONCLUSION

As discussed in more detail above, Respondent believes it is appropriate for the cancellation process for the three chlorpyrifos products listed in the NOIC to proceed without a stay. Doing so avoids unreasonable and unnecessary delay and is consistent with both the Agency's track record of action on chlorpyrifos as well as the actions of the Ninth Circuit and Eighth Circuit Courts of Appeals. Furthermore, the balancing of interests in this matter indicate

there is no pressing need to justify an indefinite stay of this cancellation proceeding. As a result, Respondent respectfully requests that this Tribunal deny Petitioner Gharda's (and Grower Petitioners') request for a stay.

Respectfully submitted,

Dated: February 22, 2023

/s/ Aaron Newell
Aaron Newell
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency

Counsel for Respondent

CERTIFICATE OF SERVICE

I hereby certify that the foregoing RESPONSE TO REQUEST FOR STAY OF NOTICE OF INTENT TO CANCEL PESTICIDE REGISTRATIONS, dated February 22, 2023, was filed electronically with the U.S. Environmental Protection Agency, Office of Administrative Law Judges E-filing system.

I also certify that a true and correct copy of the foregoing RESPONSE TO REQUEST FOR STAY OF NOTICE OF INTENT TO CANCEL PESTICIDE REGISTRATIONS was served on Petitioners via electronic mail to:

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Dated: February 22, 2023

/s/ Aaron Newell
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Counsel for Respondent

EXHIBIT 8

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners.	)	

ORDER ON PETITIONER GHARDA CHEMICALS INTERNATIONAL, INC.'S MOTION TO STAY

This matter relates to the U.S. Environmental Protection Agency's ("EPA's" or "Agency's") Notice of Intent to Cancel Pesticide Registrations for chlorpyrifos, which the Agency published to the Federal Register on December 14, 2022. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76474-02 (Dec. 14, 2022) ("NOIC"). Through the NOIC, the Agency proposes to cancel three pesticide product registrations for products containing the insecticide chlorpyrifos. *Id.* The registrant for the noticed products, Gharda Chemicals International, Inc. ("Gharda"), and a group of grower organizations styled the "Grower Petitioners,"[1] each have filed objections to the NOIC and have requested a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the registrations' cancellation. Gharda's Request for Hearing & Statement of Objections & Request for Stay (Jan. 13, 2023) ("Gharda Hearing Request"); Grower Petitioners' Request for Hearing & Statement of Objections (Jan. 13, 2023) ("Grower Hearing Request").

In connection with its Hearing Request, Gharda moved to stay this proceeding pending the outcome of related litigation before the U.S. Court of Appeals for the Eighth Circuit.[2]

[1] The Grower Petitioners include: Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America. Grower Hr'g Req. 1.

[2] The Grower Petitioners have not moved for this Tribunal to stay this proceeding. They do, however, contest the Agency's denial of their request to stay the NOIC as part of their Hearing Request. The Grower Petitioners'

Gharda Hr'g Req. 12–13. For the reasons that follow, Gharda's motion to stay is **DENIED**.

I. Background

This action serves as the latest in a series of disputes that have asked whether chlorpyrifos may be used safely in connection with food production. Loosely speaking, that series began when, in 2007, a pair of environmental organizations filed a petition asking the Agency to revoke all chlorpyrifos tolerances[3] on the grounds that even low levels of chlorpyrifos exposure can cause neurological harm to children. NOIC 76475. The Agency did not formally respond to the petition until 2017, and when it did so the Agency retained the tolerances without making a finding as to chlorpyrifos's safety. NOIC 76475–76. The dispute came before the Ninth Circuit Court of Appeals, which ruled that by retaining the chlorpyrifos tolerances without a safety finding, the Agency had abdicated its statutory duties. *League of United Latin Am. Citizens v. Regan (LULAC II)*, 996 F.3d 673, 678 (9th Cir. 2021). Not mincing words, the Court stated:

> In short, the EPA has spent more than a decade assembling a record of chlorpyrifos's ill effects and has repeatedly determined, based on that record, that it cannot conclude, to the statutorily required standard of reasonable certainty, that the present tolerances are causing no harm. Yet, rather than ban the pesticide or reduce the tolerances to levels that the EPA *can* find are reasonably certain to cause no harm, the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties. The [Federal Food, Drug, and Cosmetic Act ("FFDCA")] permits no further delay. Accordingly, for the reasons that follow, the Court grants the petitions for review and orders the EPA within 60 days after the issuance of the mandate either to modify chlorpyrifos tolerances *and* concomitantly publish a finding that the modified tolerances are safe, including for infants and children – or to revoke all chlorpyrifos tolerances. The Court also orders the EPA to

objections to the Agency's stay denial are generally similar to Gharda's arguments in favor of staying this action and do not offer additional insight helpful to my decision here. *See* Grower Hr'g Req. 20–21 (Grower Petitioners' objections to Agency stay denial). Grower Petitioners also appear to argue that they are currently suffering irreparable harm as a result of the NOIC. Grower Hr'g Req. 12 ("The Grower Petitioners already suffer and will continue to suffer . . . significant irreparable harm in the form of economic losses and reputational damage unless EPA withdraws or stays this NOIC as soon as possible."). This cannot be so, as the noticed cancellations have not yet come into effect. NOIC 76477 (in the event of a timely hearing request, cancellation will come into effect only upon issuance of a final administrative order). Any present harms to the Grower Petitioners result from the rulemaking revoking tolerances for chlorpyrifos, Chlorpyrifos: Tolerance Revocations, 86 Fed. Reg. 48315-01 (Aug. 30, 2021) ("Final Rule"), and those alleged harms seemingly were not enough to convince the Eighth Circuit to stay that Rule. *See* Agency Resp. Ex. 3 (denying Petitioners' request to stay Final Rule).

[3] "Tolerances" are "threshold levels of pesticide residue that the [Agency] is reasonably certain will cause no harm." *League of United Latin Am. Citizens v. Regan* (*LULAC II*), 996 F.3d 673, 678 (9th Cir. 2021) (citing 21 U.S.C. § 346a(b)(1), (b)(2)(A)). The Federal Food, Drug, and Cosmetic Act ("FFDCA") provides that "any pesticide chemical residues in or on a food shall be deemed unsafe," unless a tolerance or exemption for such residues "is in effect." 21 U.S.C. § 346a(a)(1).

> correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1).

Id. With these marching orders, the Agency revisited the chlorpyrifos tolerances and, on August 30, 2021, issued a final rule revoking the tolerances entirely. Chlorpyrifos: Tolerance Revocations, 86 Fed. Reg. 48315-01 (Aug. 30, 2021) ("Final Rule").

The Petitioners here sought judicial review of the Final Rule from the Eighth Circuit, alleging *inter alia* that the Agency had needlessly revoked tolerances for a subset of safe uses. *Red River Valley Sugarbeet Growers Ass'n v. Regan* (*RRVSGA*), Nos. 22-1422, 22-1530 (8th Cir.). At the outset of that case, Petitioners asked the Eighth Circuit to stay the Final Rule pending the outcome of litigation. *RRVSGA*, No. 22-1422 (8th Cir. Mar. 3, 2022), Entry ID 5132688, Agency Resp. Ex. 2. The Eighth Circuit denied the requested stay without elaborating on its reasoning for doing so. Order Exercising Jurisdiction & Denying Motion for a Partial Stay Pending Review, *RRVSGA*, Nos. 22-1422 (8th Cir. Mar. 15, 2022), Entry ID 5136844, Agency Resp. Ex. 3. *RRVSGA* has since been fully briefed, and the Eighth Circuit heard oral argument on December 15, 2022. *RRVSGA*, Nos. 22-1422, 22-1530.

Meanwhile, having revoked the chlorpyrifos tolerances, the Agency proceeded to address existing FIFRA registrations of chlorpyrifos for food use. The Agency represents that after the administrative process for the Final Rule was complete, all chlorpyrifos product registrants except Gharda voluntarily cancelled their registrations or terminated food uses and amended their registered products. Agency Resp. to Request for Stay 6 (Feb. 22, 2023). After some attempts to negotiate voluntary cancellation or modification, the Agency moved forward with involuntary cancellation of Gharda's registrations. *Id.* at 6-7. On December 14, 2022, the Agency published the NOIC, which gave notice that the Agency planned to cancel three of Gharda's pesticide registrations for chlorpyrifos (the "Contested Registrations").[4] NOIC 76474. The NOIC states that the Contested Registrations, which continue to bear labeling for use on food crops, must be cancelled because the Final Rule revoked all chlorpyrifos tolerances, rendering chlorpyrifos products' use in connection with food production unsafe as a matter of law and leaving the registered products misbranded. NOIC 76476–77 (outlining bases for cancellation).

Petitioners asked the Agency to stay the NOIC pending *RRVSGA*'s resolution, and the Agency denied the request. *See, e.g.*, Grower Hr'g Req. Ex. 9 at 2 (Jan. 11, 2023 letter from Agency to Petitioners rejecting stay request). Petitioners then proceeded to file their Hearing Requests and Objections. Petitioners object to the NOIC on various grounds, including that it is based on the Final Rule, which Petitioners maintain to be unlawful, and that the Agency did not follow required processes before issuing the NOIC. Petitioners also fault the Agency for failing to stay the NOIC pending the outcome of litigation before the Eighth Circuit. Most relevant

[4] The Contested Registrations are: (i) EPA Reg. No. 93182–3 Chlorpyrifos Technical; (ii) EPA Reg. No. 93182–7 Pilot 4E Chlorpyrifos Agricultural Insecticide; and (iii) EPA Reg. No. 93182–8 Pilot 15G Chlorpyrifos Agricultural Insecticide. NOITC 76474.

here, Gharda asks me to do what the Agency would not and to stay these proceedings pending resolution of *RRVSGA*. Gharda Hr'g Req. 12–13.

II. Legal Standard on a Motion to Stay Proceedings

A stay of proceedings is in the discretion of the presiding judge. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936). When deciding motions to stay proceedings, this Tribunal's judges have considered the following factors:

> whether or not the stay will serve the interests of judicial economy, result in unreasonable or unnecessary delay, or eliminate any unnecessary expense and effort; the extent, if any, of hardship resulting from the stay and of adverse effect on the judge's docket; and the likelihood of records relating to the case being preserved and of witnesses being available at the time of any hearing.

Borla Performance Indus., Inc., EPA Docket No. CAA-09-2020-0044, 2022 WL 887454, at *3 (ALJ, Mar. 15, 2022) (Order on Respondent's Motion to Stay the Proceedings) (quoting *John Crescio*, EPA Docket No. 5-CWA-98-004, 1999 WL 362862, at *1 (ALJ, Feb. 26, 1999) (Order on Joint Motion for Staying Proceedings)). I will consider these same factors here to the degree they are relevant, bearing also in mind my duty in this matter to "take actions and decisions in conformity with statute or in the interests of justice." 40 C.F.R. § 164.40(d). !

Motions to stay should be granted when doing so will save judicial resources, but motions should also set forth sufficient reasons to delay the proceeding. *See Diomed, Inc. v. Total Vein Solutions, LLC*, 498 F. Supp. 2d 385, 386–87 (D. Mass. 2007). Moreover, a federal trial court generally may not grant a stay so extensive that it is "immoderate or indefinite" in duration, and a trial court may abuse its discretion by issuing "a stay of indefinite duration in the absence of a pressing need." *Landis*, 299 U.S. at 255, 257. "In determining whether to stay proceedings indefinitely, a 'pressing need' is identified by balancing interests favoring a stay against interests frustrated by a stay, but '[o]verarching this balancing is the court's paramount obligation to exercise jurisdiction timely in cases properly before it.'" *Borla Performance Indus., Inc.*, 2022 WL 887454, at *3 (quoting *Cherokee Nation of Okla. v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997)).

In this proceeding, Gharda requests a stay for an indefinite duration because the time at which the Eighth Circuit will issue a decision in *RRVSGA* is unknown. A stay is therefore warranted only if there is a pressing need for one.[5]

[5] Gharda proposes that the appropriate standard is the one found in the U.S. Food and Drug Administration's ("FDA's") regulations, 21 CFR § 10.35(e), which include whether "(1) petitioner will suffer irreparable injury; (2) petitioner's case is not frivolous and pursued in good faith; (3) sound public policy grounds support a stay; and (4) delay from a stay is not outweighed by public health or other public interests." Gharda Hr'g Req. 13. The Agency correctly observes that the referenced regulations contain factors that the FDA uses to decide whether to stay an administrative action under the FFDCA. The NOIC gives rise to an action under FIFRA, not the FFDCA, and the regulatory factors Gharda cites do not control here.

III. Party Arguments

Gharda principally argues that a stay is warranted because continuing this action "would prejudice the rights of Gharda and others to obtain judicial relief from the Final Rule underlying the NOIC in the ongoing litigation" before the Eighth Circuit in *RRVSGA*. Gharda Hr'g Req. 13. Gharda claims that (1) acting on the NOIC would be contrary to the Eighth Circuit's jurisdiction in *RRVSGA*; (2) allowing this cancellation to go forward would undermine any victory Petitioners secure in the Eighth Circuit, because if the Agency succeeds here it is likely that the Agency would nevertheless require Gharda to seek a new registration, delaying growers' ability to restart use of chlorpyrifos products; and (3) in the same vein, if the Eighth Circuit vacates the Final Rule, Gharda will have wasted resources litigating this cancellation and/or petitioning for a new registration. *Id.* at 6, 13.

Gharda also argues that there is no urgent need to cancel the Contested Registrations, because they present no current threat to public health. Gharda notes that as of March 30, 2022, Gharda (1) requested the voluntary cancellation of all of its food use registrations for chlorpyrifos except for the subset of eleven uses at issue in *RRVSGA*; (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit." Gharda Hr'g Req. 7. Gharda asserts that because no chlorpyrifos products approved for food uses are currently in the stream of commerce, cancellation is not necessary to protect against harmful exposures. Gharda Hr'g Req. 13. In addition to its safety arguments, Gharda claims that the Agency waited 15 months after the Final Rule before issuing the NOIC and suggests this delay underscores the lack of urgency for cancellation. Gharda Hr'g Req. 5.

Through its Response, the Agency disputes Gharda's position that a stay would avoid prejudice to the Petitioners. The Agency argues that this case presents no threat to the Eighth Circuit's jurisdiction, because cancellation represents a separate process governed by a separate statute. Agency Resp. 9–10. The Agency agrees that if new tolerances for chlorpyrifos residue are established in the future, Gharda and other potential registrants would need to apply for new registrations pursuant to FIFRA, but notes that the harms Gharda foresees from cancellation are unlikely to come to pass until after the Eighth Circuit has ruled in *RRVSGA*. *Id.* at 10. Finally, the Agency notes that the Eighth Circuit's own actions indicate that no stay is warranted here, as the court denied Petitioners' request to stay the Final Rule pending resolution of *RRVSGA*. *Id.* at 7–8.

The Agency also disputes Gharda's claim that there is no urgent need to undertake these proceedings. The Agency observes that the NOIC's timing, like that of the Final Rule, is the product of the Ninth Circuit's decision in *LULAC II*, which denounced the Agency's delay in addressing chlorpyrifos's potential health impacts and which directed the Agency, if consistent with its safety finding, to cancel or modify relevant pesticide registrations "in a timely fashion." Agency Resp. 11 (quoting *LULAC II*, 996 F.3d at 704). The Agency also argues that Gharda's victory in *RRVSGA* is not assured, "and if the court rules in favor of Respondent, Petitioner Gharda's registrations subject to the NOIC will have remained in effect despite the fact that no tolerances for residues of chlorpyrifos exist." Agency Resp. 4. The Agency rejects Gharda's

position that delaying cancellation will have no on-the-ground impacts, noting that the NOIC provides for disposition of existing stocks of the products for which cancellation is proposed and warns the public against distribution of those products. *Id.* at 11–12. And the Agency asserts that, from its perspective, FIFRA straightforwardly demands cancellation here, meaning the urgency here relates in part to the Agency's ability to properly administer the law. *Id.* at 12. Finally, the Agency denies Gharda's accusation that the Agency dawdled in filing the NOIC, emphasizing that the Final Rule left the chlorpyrifos tolerances in effect for six months—until February 28, 2022—and that the Agency's subsequent, unsuccessful back-and-forth with Gharda about voluntary cancellation did not conclude until July 2022. *Id.* at 5–6.

IV. Discussion

I find that Gharda has not demonstrated a "pressing need" for a stay of indefinite duration.

First, I disagree that this case presents any risk to the Eighth Circuit's jurisdiction. The FFDCA provides that once a petition for review of a final agency order revoking tolerances "or any regulation that is the subject of such an order" has been filed with the appropriate Circuit Court, "the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part." 21 U.S.C. § 346a(h)(1), (2). Lest there be any doubt that the FFDCA forecloses secondary review of such an order or regulation, the statute further provides that "[a]ny *issue* as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law." *Id.* § 346a(h)(5) (emphasis added). Here, the Eighth Circuit has exercised jurisdiction over the *RRVSGA* petitioners' challenge to the Final Rule. Agency Resp. Ex. 3. There may be, therefore, no overlap between the Eighth Circuit's review of issues related to the Final Rule and this Tribunal's review of the NOIC. This does not mean the case at bar conflicts with the Eighth Circuit's jurisdiction; it simply limits the issues the parties may raise here.

Second, I am unconvinced by Gharda's arguments that, absent a stay, it may face unreasonable reregistration expenses or a protracted reregistration process. Gharda's Hearing Request contemplates that it will need to revise the Contested Registrations even if it succeeds before the Eighth Circuit. For example, Gharda states:

> To the extent Gharda's prior commitments before the Final Rule and submissions to EPA after the Final Rule are somehow insufficient to satisfy EPA that label changes consistent with EPA's safety finding can be accomplished . . . Gharda has submitted amended labels to EPA (included with this submission at Ex. 3) that once again limit food uses to the Safe Uses in the permitted geographic regions (that are the subject of the ongoing litigation) and also add application rate changes consistent with the PID safety finding. Gharda submits these changes to further demonstrate its commitment to conform its registrations to EPA's safety finding in the PID, despite that the changes proposed are based on information the Agency developed and has had in its possession for years.

Gharda Hr'g Req. 11. Gharda offers no explanation of how the cost of further negotiations over these necessary revisions would compare to reregistration. Furthermore, Gharda implies that in the event of cancellation, it will be left at square one if it must reregister any products. *See id.* at 13 (stating that if "Gharda must initiate the FIFRA registration and tolerance petition processes for chlorpyrifos anew" that would "destroy[] decades of investment"). This cannot be so. If Gharda prevails before the Eighth Circuit and then seeks wholesale reinstatement of its registrations, it will have as support the registrations' immediate precedents and all associated evidence and findings. Nor will Gharda need to reinvent the wheel if it must newly seek *updated* registrations. Gharda and the Agency appear to agree that they have undertaken significant background work to develop registrations that would fit Petitioners' wants and the Agency's public-health mandate. *E.g.* Gharda Hr'g Req. 6 (describing proposed label changes); Agency Resp. Ex. 4 at 15 (Agency brief in opposition to stay request in *RRVSGA*, discussing Agency negotiations with Gharda regarding cancellation of chlorpyrifos registrations). Cancellation would not erase those efforts; Gharda would be free to use them as a starting point in a later registration proceeding if one became necessary.

And *third* and finally, while I credit Gharda's claim that a stay might avoid some litigation costs if the Eighth Circuit restores the chlorpyrifos tolerances (and, of course, it might not), that possibility does not override the Ninth Circuit's imperative. The *LULAC II* court carefully evaluated the extensive history that underlies the Final Rule, rebuked the Agency for its past delays, and directed the Agency to proceed apace with any warranted registration cancellations. *LULAC II*, 996 F.3d at 678; *see also id.* at 703 ("[T]he EPA's egregious delay exposed a generation of American children to unsafe levels of chlorpyrifos. By remanding back to the EPA one last time, rather than compelling the immediate revocation of all chlorpyrifos tolerances, the Court is itself being more than tolerant. But the EPA's time is now up."). Given this background, I would not bar the path to cancellation indefinitely without a significant showing of likely harm.[6]

In the absence of a pressing need for an indefinite stay of this matter, the motion to stay is appropriately **DENIED**.

SO ORDERED.

Christine Donelian Coughlin
Administrative Law Judge

[6] I am mindful also that the Eighth Circuit declined to stay the Final Rule pending litigation of *RRVSGA*. While the court's single-sentence denial order offers no insight into its reasoning for doing so, Agency Resp. Ex. 3, the parties' briefing would have alerted the court that the Agency planned to begin involuntary cancellation proceedings imminently. *See, e.g.*, Agency Resp. Ex. 4 at 8 (Agency response to *RRVSGA* petitioners' stay request, noting that "EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not submitted.").

Dated: March 31, 2023
Washington, D.C.

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products, Docket No. FIFRA-HQ-2023-0001
Gharda Chemicals International, Inc., and Red River Valley Sugarbeet Growers Association, et al., Petitioners

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order on Petitioner Gharda Chemicals International, Inc.'s Motion to Stay**, dated March 31, 2023, and issued by Administrative Law Judge Christine Donelian Coughlin, was sent this day to the following parties in the manner indicated below.

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Dated: March 31, 2023
Washington, D.C.

ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

In re Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.	)	**FIFRA Appeal No. 23-02**
Docket No. FIFRA-HQ-2023-0001	)	

PETITIONERS' REPLY IN SUPPORT OF MOTION FOR APPEAL OF ORDER DENYING STAY TO ENVIRONMENTAL APPEALS BOARD

Petitioners[1] hereby submit this Reply in support of their Motion for Appeal. Petitioners respectfully request that the EAB grant the Motion for Appeal, and review and vacate the ALJ's March 31, 2023 Order Denying Stay.

I. Exceptional Circumstances Exist, and Delaying Review Would Be Deleterious to Vital Public and Private Interests

It will be deleterious to vital public or private interests if the EAB does not review the Order Denying Stay until *after* Petitioners have expended significant time and resources to arrive at a judgment by the ALJ. EPA argues there were factors in addition to wasted resources in the *Chautauqua Hardware*[2] case. But other key factors warranting review are present here as well, including: (1) both EPA and the ALJ already agree that post-judgement review would be ineffective[3], and (2) review of the Order Denying Stay presents an issue of first impression because the tribunal has not addressed carrying out an NOIC proceeding while the underlying rule's legality is challenged in parallel judicial review. *See* Pet'rs' Reply in Support of Req. for Certification at 3, n. 1.

[1] Capitalized terms not defined herein are given the definitions in the Motion for Appeal of Order Denying Stay to Environmental Appeals Board ("Motion for Appeal").
[2] *See In the Matter of Chautauqua Hardware Corp*., 3 E.A.D. 616, 2-3 (EAB 1991) ("A waste of EPA resources would be a waste of taxpayers' money and would therefore be contrary to the public interest.").
[3] Order Den. Req. for Certification at 2 ("As the Agency does not contest, post-judgment review of the Stay Order would be ineffective.").

Moreover, it is undisputed that cancellation of Gharda's registrations would make it significantly more difficult to bring chlorpyrifos products back to market if the Eighth Circuit overturns the Final Rule. *See* Stephens Declaration[4] ¶ 6 ("If Gharda were to submit applications for registration of new food uses and associated tolerances after EPA revoked all tolerances and cancelled all food uses, it would take approximately 38 months from the time of submission of the applications until possible EPA approval. EPA's fees for reestablishing U.S. food uses and associated tolerances would be approximately $875,000."). Grower Petitioners and their members also have a vital interest in the EAB reviewing and vacating the Order Denying Stay, so that no cancellation can occur pending an Eighth Circuit decision, because Grower Petitioners have a demonstrated need for chlorpyrifos in current and future growing seasons to avoid unrecoverable losses.

II. There is No Risk to Public Interest & No Urgent Need For Registration Cancellation

Intervenors argue that growers who previously bought Gharda's products "might unwittingly apply chlorpyrifos to food crops." Intervenors' Resp. to Motion for Appeal at 4. EPA argues there is a public interest in cancelling chlorpyrifos food uses in a "timely fashion" and in "clarifying the disposition of chlorpyrifos products." EPA's Resp. to Motion for Appeal at 5. But both Intervenors and EPA fail to acknowledge that there is *no evidence* that Gharda's products are being used illegally on food or that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce for use on food. *See* Gharda's Objs. and Req. for Hr'g at 6-7. This is consistent with Gharda's previous commitment to EPA to "work[] to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order

[4] *See* Ex. 5 to Gharda's Req. for Hr'g and Statement of Objs. and Req. for Stay ("Gharda's Objs. and Req. for Hr'g") n.8, Ex. 7 (citing Pet'rs Reply Br., *Red River Valley Sugarbeet Growers Ass'n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 2, 2022) (ID No. 5194647) (citing Pet. App. 1795, Stephens Declaration)).

remains under review by the Eighth Circuit." *Id.* at 7, Ex. 9. Respondents ignore the reality that Gharda's products are not being misused in an inappropriate attempt to create a risk to the public warranting immediate cancellation of chlorpyrifos registrations.

Subsequent to Petitioners' Motion for Appeal, EPA published a notice[5] of Gharda's request for voluntary cancellation of certain registrations' uses. The voluntary cancellation seeks cancellation of all food uses except the 11 Safe Uses that are the subject of the Eighth Circuit litigation.[6] In EPA's notice, the Agency proposes a 180-day comment period before intending to grant Gharda's request and implementing the voluntary cancellation. If, as EPA and Intervenors argue, there was a public interest in moving forward with the cancellation proceeding before the Eighth Circuit's decision, EPA would not permit a 180-day comment period during which the chlorpyrifos registrations remain unchanged. EPA is essentially proposing the status quo with respect to the registrations, exactly what Petitioners seek by way of a stay of the cancellation proceeding while the Eighth Circuit makes its decision.

III. Conclusion

As discussed above, in Petitioners' Motion to Appeal, and in the briefing before the ALJ, Petitioners respectfully request that the EAB review and vacate the Order Denying Stay.

This 16th day of June, 2023,

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[5] *See* 88 Fed. Reg. 37,875, 37,877 (Jun. 9, 2023) *available at* https://www.govinfo.gov/content/pkg/FR-2023-06-09/pdf/2023-12354.pdf. Attached as Exhibit A is EPA's filing before the ALJ of the Notice of Publication of Notice of Receipt of Request to Voluntarily Amend Registrations to Terminate Certain Uses, dated June 9, 2023.

[6] It took EPA 14 months from the date of Gharda's voluntary cancellation request (March 30, 2022) to publish the Federal Register notice of the voluntary cancellation request (June 9, 2023).

CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2023, true and correct copies of the foregoing was filed electronically with the EAB E-Filing System for the EAB's E-Docket Database, with a copy via electronic mail to the following:

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 21, 2020

SUBJECT: Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review.

PC Code: 059101
Decision No.: 559846
Petition No.: NA
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: NA

DP Barcode: D456427
Registration No.: NA
Regulatory Action: Registration Review
Case No.: NA
CAS No.: 2921-88-2
40 CFR: §180.342

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THROUGH: Michael S. Metzger, Chief
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TO: Patricia Biggio, Chemical Review Manager
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Pesticide Re-evaluation Division (PRD) (7508P)

As part of Registration Review, the Pesticide Re-evaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that Health Effects Division (HED) evaluate the hazard and exposure data and conduct dietary (food and drinking water), residential, aggregate, and occupational exposure assessments to estimate the risk to human health that will result from the currently registered uses of pesticides. This memorandum serves as HED's draft human health risk assessment (DRA) for chlorpyrifos to support Registration Review.

The most recent human health risk assessment for chlorpyrifos was completed in 2016 (W. Britton *et al*, D436317, 11/03/2016). The following revisions have been included in the current risk assessment:

- The toxicological points of departure (PODs) are derived from 10% red blood cell (RBC) acetyl cholinesterase (AChE) inhibition using a physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) model, as reported in the 2014 revised chlorpyrifos Human Health Risk Assessment (HHRA) (2014 (D. Drew *et al.*, D424485, 12/29/2014);
- Because the science addressing neurodevelopmental effects remains unresolved, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

As part of an international effort, the EPA's Office of Research and Development (ORD) has been developing a battery of new approach methodologies (NAMs)[1] for evaluating developmental neurotoxicity (DNT). The suite of *in vitro* assays developed by ORD evaluates the majority, but not all, of the critical processes of neurodevelopment. The ORD assays will be presented, using the organophosphates (OPs) as a case study, to the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Scientific Advisory Panel (SAP) in September 2020.[2] Additional assays that evaluate processes not covered by the ORD assays are currently under development by researchers funded by the Europen Food Safey Authority (EFSA). Once data are available from these additional assays, any OP data may be considered in combination with the results of the ORD assays in the future as part of an overall weight of evidence evaluation of the DNT potential for individual OPs, including chlorpyrifos.

[1] The term NAM has been adopted as a broadly descriptive reference to any non-animal technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment.
[2] https://www.epa.gov/sap/use-new-approach-methodologies-nams-derive-extrapolation-factors-and-evaluate-developmental

Table of Contents

1.0 Executive Summary

This document presents the third revision to the human health risk assessment for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Registration Review of the organophosphate (OP) insecticide chlorpyrifos.

Background
A preliminary human health risk assessment (HHRA) for chlorpyrifos was completed on June 30, 2011 (D. Drew *et al.*, D388070, 06/30/2011) as part of the FIFRA Section 3(g) Registration Review program. A revised HHRA was completed in 2014 (D. Drew *et al.*, D424485, 12/29/2014) to address comments received on the preliminary HHRA and to incorporate new information and new approaches that became available since the June 2011 risk assessment. Most notably, the 2014 revised HHRA incorporated the following: (1) a physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) model for deriving toxicological points of departure (PODs) based on 10% red blood cell (RBC) acetyl cholinesterase (AChE) inhibition; and (2) evidence on neurodevelopmental effects in fetuses and children resulting from chlorpyrifos exposure as reported in epidemiological studies, particularly the results from the Columbia Center for Children's Environmental Health (CCCEH) study on pregnant women which reported an association between fetal cord blood levels of chlorpyrifos and neurodevelopmental outcomes. The 2014 HHRA retained the 10X Food Quality Protection Act (FQPA) Safety Factor (SF) because of the uncertainties around doses that may cause neurodevelopmental effects.

Based on the aggregate risks identified in 2014 (D. Drew *et al.*, D424485, 12/29/2014), a proposed rule (PR) for revoking all tolerances of chlorpyrifos was published in the Federal Register on November 6, 2015 (80 FR 69079). At that time, the EPA had not completed a refined drinking water assessment or an additional analysis of the hazard of chlorpyrifos that was suggested by several commenters to the EPA's 2014 revised HHRA. Those commenters raised the concern that the use of 10% RBC AChE inhibition for deriving PODs for chlorpyrifos may not provide a sufficiently health protective human health risk assessment given the potential for neurodevelopmental outcomes. Accordingly, following the issuance of the proposed rule, the EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood (reported by the CCCEH study investigators) as the source for PODs for the 2016 risk assessment (W. Britton *et al.*, D436317, 11/03/2016). In the 2016 assessment, the 10X FQPA SF was retained.

In the current risk assessment, EPA is utilizing the same endpoint and points of departure as those used in the 2014 HHRA (i.e., the PBPK-PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon). Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

This 2020 human health risk assessment substantially relies on the previous documents developed for chlorpyrifos, along with an updated animal toxicity literature review, and an updated drinking water assessment. Those primary documents include the following:

- D. Drew *et al.,* Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, December 29, 2014, D424485;
- U.S. Environmental Protection Agency, Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides, September 15, 2015, D331251;
- R. Bohaty, Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, September 15, 2020, D459269.
- R. Bohaty, Evaluating the Impact of Removal of the 10x FQPA Safety Factor on Chlorpyrifos, September 15, 2020, D459270.
- U.S. Environmental Protection Agency, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies, March 11, 2016 and supporting analyses presented to the FIFRA Scientific Advisory Panel's (SAP) meeting on April 19-21, 2016, (EPA-HQ-OPP-2016-0062).
- W. Britton *et al*., Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, November 3, 2016, D436317.
- E. Méndez, Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Lifestage Exposure, June 1, 2020, D457378.

Hazard Characterization

The hazard characterization for chlorpyrifos and its oxon is based on adverse health effects in animals and humans related to two different endpoints - AChE inhibition and potential for neurodevelopmental effects. A weight-of-the-evidence (WOE) analysis on the potential for neurodevelopmental effects following chlorpyrifos exposure has been completed using OPP's *Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment* (USEPA, 2010; FIFRA SAP 2010). The Agency is using a robust PBPK-PD model to estimate human PODs for chlorpyrifos and/or its oxon for multiple exposure pathways (e.g., food, water, occupational, non-occupational, and residential) and using the PBPK-PD model to replace default inter- and intra-species factors for risk assessment.

The key issues considered in the WOE are 1) whether chlorpyrifos causes long-term effects from prenatal and/or early lifestage exposure and 2) whether adverse effects can be attributed to doses lower than those which elicit 10% inhibition of RBC AChE. Evidence from 1) the experimental toxicology studies evaluating adverse outcomes such as behavior and cognitive function; 2) mechanistic data on possible modes of action/ adverse outcome pathways (MOAs/AOPs); and 3) epidemiologic and biomonitoring studies, must be considered in making these determinations.

Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with and without retention of the 10X FQPA safety factor; the occupational risk assessments have been conducted both with and without retention of a 10X UF_{DB}.

EPA has applied the Data-Derived Extrapolation Factor (DDEF) guidance (USEPA, 2014), in its use of the PBPK-PD model; the human model replaces the use of default intra-species uncertainty factor for some populations. The PBPK-PD model simulates human RBC AChE inhibition from exposures via oral, dermal, and inhalation routes and thus obviates the need for a default inter-species uncertainty factor to convert an animal POD to a human POD. In addition, the PBPK-PD model incorporates inter-individual variation in response to chlorpyrifos to estimate a distribution of administered doses that could have resulted in 10% RBC AChE inhibition in humans. The DDEF for intra-species extrapolation can then be estimated as the ratio between the mean dose and a dose at the tail of the distribution representing sensitive individuals. For this risk assessment, the 99th percentile of the distribution is being used to account for variation of sensitivity; the intra-species DDEF is 4X for chlorpyrifos and 5X for the oxon for all groups except women who are pregnant or may become pregnant for whom the 10X intra-species factor was retained (Dow, 2014b). While the current PBPK-PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, this model does not include any descriptions on physiological, anatomical and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women of childbearing age, the Agency is applying the standard 10X intra-species extrapolation factor for women of childbearing age.

In addition to DDEF, the PBPK-PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute studies. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with OPs show a consistent pattern of inhibition reaching steady state at or around 2-3 weeks of exposure in adult laboratory animals (U.S. EPA, 2002). This pattern observed with repeated dosing is a result of the amount of inhibition coming to equilibrium (or steady state) with the production of new enzyme. As such, AChE studies of 2-3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.*, up to 2 years of exposure), so the model simulates a 21-day exposure as a steady-state condition.

Separate PODs have been calculated for dietary (food, drinking water), residential, non-occupational, and occupational exposures by varying inputs on exposure routes (dermal, oral, inhalation), exposure duration and frequency (such as 2 hours per day), and populations exposed based on body weights at different life stages (such as infants or adults).

Use Profile

Chlorpyrifos is a broad-spectrum, chlorinated OP insecticide. Registered use sites include a large variety of food crops and non-food use settings. Public health uses include aerial and ground-based fogger adulticide treatments to control mosquitoes. There is a wide range of registered formulations, application rates, and application methods. Registered labels generally require that handlers use normal work clothing (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. Also, some products are marketed in engineering controls such as water-soluble packets. The restricted entry

intervals (REIs) on the registered chlorpyrifos labels range from 24 hours to 5 days. The pre-harvest intervals (PHIs) range from 0 days (Christmas trees) to 365 days (ginseng).

Dietary Risk Assessment
The acute and steady state dietary (food only) exposure analyses are highly refined. The majority of food residues used were based upon U.S. Department of Agriculture's (USDA's) Pesticide Data Program (PDP) monitoring data. Percent crop treated information and food processing factors were included, where available. All commodities with U.S. tolerances for residues of chlorpyrifos are included in the assessment.

Acute dietary (food only) risk estimates are all <100 % of the acute population adjusted dose for food ($aPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is females (13-49 years old) at 3.2 % $aPAD_{food}$. With the FQPA SF reduced to 1X, the acute dietary risk estimates are <1% of the $aPAD_{food}$ for all populations.

Steady state dietary (food only) risk estimates are all <100 % of the steady state PAD for food ($ssPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is children (1-2 years old) at 9.7 % $ssPAD_{food}$. With the FQPA SF reduced to 1X, the steady state dietary risk estimates are <1% of the $ssPAD_{food}$ for all populations.

The total dietary exposure to chlorpyrifos is through both food and drinking water. The acute and steady state dietary exposure analyses discussed above only include food and do not include drinking water; the drinking water exposure and risk assessment is discussed in the aggregate exposure/risk characterization portion of this document (Section 7).

Residential (Non-occupational) Risk Assessment
Based upon review of all chlorpyrifos registered uses, only the registered roach bait products may be applied by a homeowner in a residential setting. Residential handler exposure from applying roach bait products has not been quantitatively assessed because these exposures are considered negligible. Residential post-application exposures can occur for adults and children golfing on chlorpyrifos-treated golf course turf and from contacting treated turf following a mosquitocide application. The residential post-application assessment considered and incorporated all relevant populations and chemical-specific turf transferable residue (TTR) data. The residential post-application risk assessment results incorporate PODs derived from 10% RBC AChE inhibition using the PBPK-PD model and assuming both that the FQPA SF is retained at 10X and reduced to 1X.

There are no residential post-application risk estimates of concern for adults or children from chlorpyrifos use on golf course turf or as a mosquitocide on the day of application assuming either the FQPA SF is retained at 10X or reduced to 1X.

Non-Occupational Spray Drift Exposure and Risk Assessment
An updated quantitative non-occupational spray drift (from treatment of agricultural fields) assessment was conducted to assess the potential for residential bystander (who live on, work in,

or frequent areas adjacent to chlorpyrifos-treated agricultural fields) exposures. The potential risks from spray drift and the impact of potential risk reduction measures were assessed in a July 2012[3] memorandum. To increase protection for children and other bystanders, chlorpyrifos technical registrants voluntarily agreed to lower application rates and adopt other spray drift mitigation measures such as buffer zones.[4] The spray drift risk assessment results incorporate PODs derived from 10% RBC AChE inhibition using the PBPK-PD model and assuming both that the FQPA SF is retained at 10X and reduced to 1X. There are no risk estimates of concern incorporating the agreed-upon buffer distances[5] and droplet sizes/nozzle types by the EPA and the technical registrants in 2012 if the FQPA SF FQPA SF is retained at 10X or reduced to 1X.

Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Assessment
In January 2013, a preliminary assessment of the potential risks from chlorpyrifos volatilization was conducted.[6] However, this assessment was revised in June 2014[7] following submission of two high-quality vapor phase nose-only inhalation toxicity studies for chlorpyrifos and chlorpyrifos oxon[8]. The studies were conducted to address the uncertainty surrounding exposure to aerosol versus vapor phase chlorpyrifos. At the saturation concentration there was no statistically significant inhibition of AChE activity in RBC, plasma, lung, or brain at any time after the six-hour exposure period in either study. Under actual field conditions, exposures are likely to be much lower to vapor phase chlorpyrifos and its oxon as discussed in the January 2013 preliminary volatilization assessment. Because these studies demonstrated that no toxicity occurred even at the saturation concentration, which is the highest physically achievable concentration, there are no anticipated risks of concern from exposure through volatilization of either chlorpyrifos or chlorpyrifos oxon.

Aggregate Risk Assessment
The Agency has considered aggregate exposures and risks from combined food, drinking water, and residential exposures to chlorpyrifos and chlorpyrifos oxon. The acute aggregate assessment includes only food and drinking water. The steady state aggregate assessment includes exposures from food, drinking water, and residential uses. Exposure to the parent compound chlorpyrifos is

[3] J. Dawson, W. Britton, R. Bohaty, N. Mallampalli, and A. Grube. Chlorpyrifos: Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures. 7/13/12. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399483, D399485.
[4] R. Keigwin. Spray Drift Mitigation Decision for Chlorpyrifos (059101). 7/2012. U.S. EPA Office of Chemical Safety and Pollution Prevention. EPA-HQ-OPP-2008-0850-0103.
[5] The 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of 80 feet are required for coarse or very coarse droplets and buffer distances of 100 feet are required for medium droplets for aerial applications for application rates $\geq$ 2.3 lb ai/A. In addition, the 2012 agreement requires buffer distances of $\geq$ 25 feet and medium to coarse drops for airblast applications at rates >3.76 lb ai/A.
[6] R. Bohaty, C. Peck, A. Lowit, W. Britton, N. Mallampalli, A. Grube. Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization. 1/31/13. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399484, D400781.
[7] W. Britton. W. Irwin. J. Dawson. A. Lowit. E. Mendez. Chlorpyrifos: Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies. 6/25/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D417105.
[8] W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D411959. TXR# 0056694. EPA MRID# 49119501.

expected for food and residential uses. Exposure to either chlorpyrifos or chlorpyrifos oxon may be expected from drinking water sources. The drinking water assessment assumed 100% conversion of chlorpyrifos to the more toxic chlorpyrifos oxon (the predominant chlorpyrifos transformation product formed during drinking water treatment (*e.g.*, chlorination)).

For acute and steady state aggregate assessments, EPA has used a drinking water level of comparison (DWLOC) approach to calculate the amount of exposure available in the total "risk cup" for chlorpyrifos in drinking water after accounting for any chlorpyrifos exposures from food and residential uses. This DWLOC can be compared to the estimated drinking water concentrations (EDWCs) of chlorpyrifos oxon to determine if there is an aggregate risk of concern. The EDWCs are presented in the Environmental Fate and Effects Division's (EFED) updated drinking water assessment (DWA) (see R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

The acute aggregate assessment includes only food and drinking water. Acute DWLOCs were calculated for infants, children, youths, and adult females. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb. With the FQPA SF reduced to 1X, the lowest acute DWLOC calculated was for infants (<1 year old) at 230 ppb.

The steady state aggregate assessment includes dietary exposures from food and drinking water and dermal exposures from residential uses (dermal exposures represent the highest residential exposures). Steady state DWLOCs were calculated for infants, children, youths, and adult females. With the 10X FQPA SF retained, the lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb. With the FQPA SF reduced to 1X, the lowest steady state DWLOC calculated was for infants (<1 year old) at 43 ppb.

Occupational Handler Risk Assessment
In this assessment for the non-seed treatment scenarios, a total of 288 steady state occupational handler exposure scenarios were assessed. Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X database uncertainty factor has been retained (LOC = 100), 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Risks of concern for 45 additional exposure scenarios could potentially be mitigated if engineering controls are used. If the 10X database uncertainty factor is reduced to 1X (LOC = 10), 19 scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 10). Risks of concern for 15 additional scenarios could potentially be mitigated if engineering controls are used.

For the seed treatment scenarios, a total of 93 steady state scenarios were assessed. These scenarios are assessed using default amount handled assumptions for short-term and intermediate exposure durations. These assumptions are appropriate for the steady state exposures. Assuming the 10X database uncertainty factor has been retained (LOC = 100), 12 short-term exposure and 10 intermediate-term scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Assuming the 10X database uncertainty factor has been reduced to 1X (LOC = 10), there are no short- or intermediate-term

risk estimates of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs > 10).

Occupational Post-Application Risk Assessment
Steady state occupational post-application exposures and risks were assessed for any crops where hand labor is anticipated following applications of chlorpyrifos. The assessment was completed using seven chlorpyrifos dislodgeable foliar residue (DFR) studies. Chlorpyrifos parent compound is the residue of concern for occupational post-application exposures that occur outdoors; however, it may be possible that the formation of chlorpyrifos oxon is greater and its degradation slower in greenhouses when compared to the outdoor environment. Occupational post-application assessments were performed for: 1) exposures to the parent compound chlorpyrifos in outdoor environments (uses other than greenhouse), 2) exposures to the parent chlorpyrifos (only) in greenhouses and 3) exposures to both the parent and chlorpyrifos oxon in greenhouses.

Current labels require a Restricted Entry Interval (REI) of 24 hours for most crops and activities, but in some cases such as tree fruit, REIs are up to 5 days after application. All post-application worker risks have been updated in the current assessment to incorporate PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the database uncertainty factor has been either retained at 10X and reduced to 1X. Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} of 10X has been retained, the majority of the post-applications scenarios are not of concern 1 day after application (REI = 24 hours). However, for some activities such as irrigation, hand harvesting, scouting, and thinning result in risks of concern up to as many as 10 days following application for the non-microencapsulated formulations and > 35 days for the microencapsulated formulation. Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} has been reduced to 1X, the majority of the post-application risk estimates are not of concern 1 day after application (REI = 24 hours).

Due to uncertainty regarding the formation of chlorpyrifos oxon in greenhouses, HED also estimated risks for reentry into treated greenhouses (all 4 formulations) for the parent chlorpyrifos plus chlorpyrifos oxon using a total toxic residue approach. The total toxic residue approach[9] estimates the chlorpyrifos oxon equivalent residues by 1) assuming a specific fraction of the measured chlorpyrifos dislodgeable foliar residues are available as the oxon and 2) factoring in the relative potency of chlorpyrifos oxon with use of a TAF of 18. It was conservatively assumed that 5% (0.05) of the total chlorpyrifos present as DFR in greenhouses is available for worker contact during post-application activities. When the total toxic residue approach is used and with the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X UF_{DB} has been retained, MOEs are not of concern 0 to 6 days after treatment for non-microencapsulated formulations. For the microencapsulated formulation, MOEs are not of concern 3 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

When the total toxic residue approach is used and with the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the 10X UF_{DB} has been reduced to 1X, there

[9] Total DFR (µg/cm^2) = [Chlorpyrifos DFR (µg/cm^2) * TAF] + [Chlorpyrifos DFR (µg/cm^2)]

are no risk estimates of concern with the current labeled REI (24 hours), except for the microencapsulated formulation. For the microencapsulated formulation, MOEs are of concern 0 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

2.0 Risk Assessment Conclusions

Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e*., FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}). There are no acute or steady state dietary (food only) risks of concern with or without the retention of the 10X FQPA SF. There are no residential post-application risk estimates of concern for adults or children with or without the 10X FQPA SF. The aggregate risks are variable and can be determined by comparison of the calculated DWLOCs presented herein with the EDWCs presented in EFED's DWA. Many occupational handler scenarios are of concern with the retention of a 10X $UF_{DB.}$ With the 10X UF_{DB} removed, there are still some handler scenarios of concern. For occupational post-application exposures, even with the 10X UF_{DB} removed, some scenarios are of concern one day after application.

2.1 Data Deficiencies

Toxicology
None.

Residue Chemistry

860.1500:
Separate magnitude of the residue studies for lemons are needed after application of Lorsban 4E and 75% WDG formulations in order to reevaluate the existing tolerance for chlorpyrifos for the citrus fruit crop group.

Magnitude of the residue studies are needed to establish a tolerance for residues of chlorpyrifos on wheat hay.

860.1520:
Processing studies are needed for soybean meal, hulls and refined oil.

Occupational/Residential

No new data requirements have been identified for chlorpyrifos; however, in the 2011 preliminary HHRA, additional studies to address the uncertainties regarding the formation and degradation of chlorpyrifos oxon in greenhouses were recommended. To date, those data have not been submitted. In the absence of the recommended data, and to account for the potential for

oxon to form in greenhouses, EPA has used a conservative total toxic residue approach for parent chlorpyrifos plus the chlorpyrifos oxon.

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

The methods in the Pesticide Analytical Manual (PAM) Volume II are adequate to analyze the residue of concern for tolerance enforcement purposes, chlorpyrifos only. The limit of detection of these methods is adequate to cover the lowest tolerance level included in the 40 CFR 180.342 for detection of chlorpyrifos only, 0.01 ppm. In addition, chlorpyrifos is completely recovered using FDA multiresidue protocols D and E (nonfatty matrices) and partially recovered using multiresidue method protocol E (fatty matrices).

2.2.2 Recommended & Established Tolerances

According to HED's *Guidance on Tolerance Expressions* (S. Knizner, 05/27/2009), the tolerance expression for chlorpyrifos in the 40 CFR§180.342 should read as follows:

> "(a) General. (1) Tolerances are established for residues of chlorpyrifos, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorpyrifos (*O,O* -diethyl *O* -(3,5,6-trichloro-2-pyridyl) phosphorothioate."

The current tolerance expression reads "Tolerances are established for residues of the pesticide chlorpyrifos *per se* (*O,O*-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate) in or on the following food commodities."

Based on residue data, HED is recommending tolerances for chlorpyrifos on the following: cotton, gin byproducts (15 ppm); grain, aspirated fractions (30 ppm); corn, field, milled byproducts (0.1 ppm); and wheat, milled byproducts (1.5 ppm). These recommendations, along with recommendations for revisions to current tolerances based on the Organization for Economic Cooperation and Development (OECD) rounding class practice, commodity definition revisions, crop group conversions/revisions, and harmonizition with Codex, are presented in Tables 2.2.2.1 and 2.2.2.2.

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Alfalfa, forage	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Grain, aspirated fractions	--	22	Recommended tolerance based on submitted residue data.
Beet, sugar, dried pulp	5.0	5	Corrected values to be consistent with OECD Rounding Class Practice.
Beet, sugar, roots	1.0	1	Corrected values to be consistent with

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
			OECD Rounding Class Practice.
Beet, sugar, leaves [2]	--	8	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Beet, sugar, tops	8.0	remove	
Brassica, leafy greens, subgroup 4-16B	--	1	Crop group conversion/revision.[3,4]
Cherry, sweet	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Cherry, tart	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10-10, dried pulp	--	5	Crop group conversion/revision. Corrected values to be consistent with OECD Rounding Class Practice.
Citrus, dried pulp	5.0	remove	
Fruit, citrus, group 10-10, oil	--	20	Crop group conversion/revision.
Citrus, oil	20	remove	
Corn, field, forage	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, field, stover	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, milled byproducts	--	0.1	Recommended tolerance based on submitted residue data.
Corn, sweet, forage	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, sweet, stover	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Cotton, gin byproducts	--	15	Recommended tolerance based on submitted residue data.
Cotton, undelinted seed	0.2	0.3	Harmonization with Codex.
Cranberry	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10-10	--	1	Crop group conversion/revision. Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10	1.0	remove	
Kohlrabi	--	1	Crop group conversion/revision.[3,4]
Kiwifruit, fuzzy	--	2	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Kiwifruit	2.0	remove	
Milk	--	0.01	Commodity definition revision.
Milk, fat	--	0.25	
Milk, fat (Reflecting 0.01 ppm in whole milk)	0.25	remove	
Pepper, bell	--	1	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Pepper, nonbell	--	1	
Pepper	1.0	remove	
Peppermint, fresh leaves	--	0.8	Commodity definition revision.
Peppermint, tops	0.8	remove	
Peppermint, oil	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Radish, roots	--	2	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice
Radish	2.0	remove	

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Rutabaga, roots	--	0.5	Commodity definition revision.
Rutabaga	0.5	remove	
Spearmint, fresh leaves	--	0.8	Commodity definition revision.
Spearmint, tops	0.8	remove	
Spearmint, oil	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Sorghum, grain, stover	2.0	2	Corrected values to be consistent with OECD Rounding Class Practice.
Strawberry	0.2	0.3	Harmonization with Codex.
Sweet potato, tuber	--	0.05	Commodity definition revision.
Sweet potato, roots	0.05	remove	
Turnip, roots	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Turnip, leaves	--	0.3	Commodity definition revision.
Turnip, tops	0.3	remove	
Vegetable, brassica, head and stem, group 5-16	--	1	Crop group conversion/revision.[3] Corrected values to be consistent with OECD Rounding Class Practice.
Vegetable, brassica, leafy, group 5	1.0	remove	
Wheat, forage	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Wheat, milled byproducts	--	1.5	Recommended tolerance based on submitted residue data.
Wheat, straw	6.0	6	Corrected values to be consistent with OECD Rounding Class Practice.

[1] This table only includes recommended revisions to established tolerances and recommended establishment of new tolerances. For a complete list of all established tolerances see the International Residue Level Summary (IRLS) in Appendix 4.
[2] Sugar beet leaves/tops are no longer considered a significant livestock feed item. Commodity/tolerance may be removed.
[3] The recommended conversion of existing tolerance in/on **Vegetable, brassica, leafy, group 5** is to the following: **Vegetable, brassica, head and stem, group 5-16; Brassica, leafy greens, subgroup 4-16B;** and **Kohlrabi (“**Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)” dated 11/3/2015).
[4] HED is recommending for individual tolerances of 1 ppm for Kohlrabi based on the currently established tolerance for this commodity as part of crop group 5 (Vegetable, brassica, leafy). Kohlrabi is displaced by the crop group conversion noted in the footnote 3 above.

Table 2.2.2.2. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(c))[1, 2]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Asparagus	5.0	5	Corrected values to be consistent with OECD Rounding Class Practice.

[1] This table only includes recommended revisions to established tolerances. For a complete list of all established tolerances see the IRLS in Appendix 4.
[2] Regional registrations.

2.2.3 International Harmonization

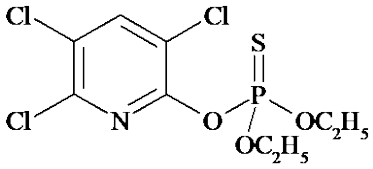
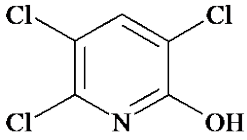
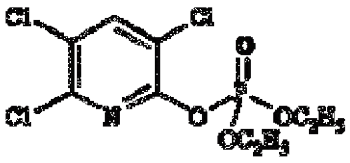
The Codex Alimentarius Commission and Canada Pesticide Management Rgulatory Agency (PMRA) have established Maximum Residue Limits (MRLs) for chlorpyrifos. Mexico generally adopts U.S. tolerances and/or Codex MRLs for its export purposes. The residue definition for enforcemnt is harmonized for U.S. tolerances and Codex MRLs and includes parent compound

chlorpyrifos only. However, Canada MRLs are for chlorpyrifos for a few commodities and for both parent chlorpyrifos and its metabolite TCP (3,5,6-trichloro-2-pyridinol) which is not a U.S. residue of concern, for other commodities.

Except for apple commodities, Canada MRLs are currently not harmonized with the U.S. tolerances because of the difference in residue definition. Codex MRLs are currently harmonized with U.S. tolerances for the following commodities: field corn grain; citrus; cranberry; egg; sorghum grain (and stover); wheat grain; and head and Chinese cabbage. HED is recommending that the current tolerances for strawberry and cotton, undelinted seed be increased to harmonize with the Codex MRLs. There are several U.S. tolerances that are not harmonized with Codex MRLs; harmonization is not currently being recommended for these commodities because the large difference in residue levels indicates that domestic and foreign use patterns are much different. A summary of the U.S. tolerances and international MRLs is included in Appendix 4.

3.0 Introduction

3.1 Chemical Identity

Table 3.1 Chlorpyrifos Degradate/ Residues of Concern Nomenclature.	
Chlorpyrifos	
IUPAC name	*O,O*-diethyl *O*-3,5,6-trichloro-2-pyridyl phosphorothioate
CAS name	*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridinyl) phosphorothioate
CAS registry number	2921-88-2
TCP Metabolite/Degradate (Residue of Concern for Canada) IUPAC Name 3,5,6 Trichloro-2-pyridinol	
Oxon Metabolite/Degradate Common Name Chlorpyrifos Oxon IUPAC Name O,O-diethyl. O-3,5,6-trichloro-2-pyridyl phosphate	

3.2 Physical/Chemical Characteristics

Technical chlorpyrifos is a white crystalline solid. Chlorpyrifos is stable in neutral and acidic aqueous solutions; however, stability decreases with increasing pH. Chlorpyrifos is practically insoluble in water, but is soluble in most organic solvents (i.e., acetone, xylene and methylene

chloride). Chlorpyrifos is moderately volatile based on its vapor pressure of $1.87x10^{-5}$ mmHg at 25°C. See Appendix 3.

Laboratory studies show chlorpyrifos is susceptible to hydrolysis under alkaline conditions and that volatilization and photo-degradation are not likely to play a significant role in the dissipation of chlorpyrifos in the environment. Nonetheless, chlorpyrifos has been detected in air samples, and so volatilization may play more of a role in dissipation than laboratory studies indicate. The major route of dissipation appears to be aerobic and anaerobic metabolism, as well as partitioning to the soil (partition coefficient of 6040). The aerobic aquatic metabolism half-life is 30.4 days (~6% remaining in 4 months). The water peak half-lives were ~1 day in a monitoring study (MRID 44711601). Based on available data, chlorpyrifos degrades slowly in soil under both aerobic and anaerobic conditions. Degradation begins with cleavage of the phosphorus ester bond to yield 3,5,6-trichloro-2-pyridinol (TCP). Field dissipation studies show that chlorpyrifos is moderately persistent under field conditions—dissipation half-life less than 60 days. Chlorpyrifos is only slightly soluble in water (1400 ppb). However, if it reaches aquatic environments the Log K_{ow} (4.7) indicates that chlorpyrifos may bioaccumulate in fish and other aquatic organisms. A fish bioaccumulation study shows that chlorpyrifos is absorbed by fish; however, it rapidly depurates when exposure ceases.

Oxidation of chlorpyrifos to chlorpyrifos oxon could potentially occur through photolysis, aerobic metabolism, and chlorination as well as other oxidative processes. Chlorpyrifos oxon is expected to have similar fate characteristics as chlorpyrifos except chlorpyrifos oxon is more soluble in water and undergoes hydrolysis faster. The hydrolysis half-life of chlorpyrifos oxon is significantly shorter than that observed for chlorpyrifos (5 days vs 81 days). Chlorpyrifos oxon hydrolyses to form TCP. For chlorpyrifos, water purification (chlorination) has been shown to be a major route of chlorpyrifos oxon formation and degradation.

3.3 Pesticide Use Pattern

Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro -2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated OP insecticide. Registered use sites include a large variety of food crops (including fruit and nut trees, many types of fruits and vegetables, and grain crops), and non-food use settings (e.g., golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products). Public health uses include aerial and ground-based fogger adulticide treatments to control mosquitoes. There are also residential uses of roach bait products and ant mound treatments. Permanent tolerances are established (40 CFR§180.342) for the residues of chlorpyrifos in/on a variety of agricultural commodities, including meat, milk, poultry and eggs. There are also tolerances for use in food handling/service establishments (FHE or FSE). Chlorpyrifos is manufactured as granular, microencapsulated liquid, soluble concentrate liquid, water dispersible granular in water soluble packets (WSP), wettable powders in WSPs, impregnated paints, cattle ear tags, insect bait stations and total release foggers. There is a wide range of application rates and methods. Registered labels generally require that handlers use normal work clothing/baseline attire (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. The REIs on the registered chlorpyrifos labels range from 24 hours to 5 days. The master use table is provided in Appendix 5.

3.4 Anticipated Exposure Pathways

Chlorpyrifos applications may be made directly to growing crops (food and feedstuffs) which may result in human exposure to chlorpyrifos in food and to chlorpyrifos or chlorpyrifos oxon in drinking water (from surface and ground water sources). Registered uses that may result in residential (non-occupational) exposures to chlorpyrifos include aerial and ground-based fogger adult mosquitocide applications and golf course turf applications. There are also potential exposures for residential bystanders who live on, work in, or frequent areas adjacent to chlorpyrifos-treated agricultural fields from spray drift and volatilization. In occupational settings, exposure may occur while handling the pesticide prior to application, as well as during application. There is also a potential for post-application exposure for workers re-entering treated fields.

3.5 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf). As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age and ethnic group. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Spray drift can also potentially result in post-application exposure and it was considered in this analysis. Further considerations are also currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

4.0 Hazard Characterization and Dose-Response Assessment

The 2014 chlorpyrifos HHRA provided summary information and weight of evidence findings integrating multiple lines of evidence from experimental toxicology and epidemiology with respect to AChE/ChE inhibition (acetylcholinesterase/cholinesterase) and neurodevelopmental outcomes. The 2014 HHRA also describes the use of a robust PBPK-PD model for PODs and refined intra-species factors. Full details of the science and data analysis that support these

conclusions can be found in the 2014 chlorpyrifos HHRA (D. Drew *et al.,* D424485, 12/29/2014).

4.1 Safety Factor for Infants and Children (FQPA Safety Factor)[10]

The dietary, residential, aggregate, and non-occupational assessments have been conducted both with and without the retention of the 10X FQPA Safety Factor based on the following considerations:

- The toxicology database for chlorpyrifos is complete for deriving risk assessment PODs based on cholinesterase inhibition.
- Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Regulatory history of the scientific evaluation is contained in Appendix 2.
- Chlorpyrifos is an OP insecticide with an established neurotoxic MOA; neurotoxicity is the most sensitive effect in all species, routes, and lifestages. AChE inhibition is being used to derive the PODs for risk assessment. These PODs are protective for neurotoxic effects related to AChE inhibition and potential downstream neurotoxic effects. Although the dose response relationship of AChE inhibition across different lifestages is established quantitatively, the MOAs/AOPs for postulated neurodevelopmental effects occurring at doses below those eliciting cholinesterase inhibition have not been established.
- A literature search identified epidemiological studies with results suggesting an association between neurodevelopmental effects and exposure to chlorpyrifos even in the absence of AChE inhibition.
- There are no residual uncertainties in the exposure database. The chlorpyrifos residue chemistry database is robust. The exposure assessment in drinking water provides a conservative approach for estimating chlorpyrifos parent and oxon concentrations in ground and surface water sources of drinking water and is unlikely to underestimate exposure. The dietary (food) exposure analyses, although highly refined, incorporate conservative assumptions that are unlikely to underestimate exposures. Residue levels are based on either monitoring data reflecting actual residues found in the food supply, or high-end residues in foods. Furthermore, processing factors used were either those measured in processing studies, or default high-end factors representing the maximum concentration in the processed commodity. Residential exposure assessments use data from surrogate and chemical-specific sources and rely on the 2012 Residential Standard Operating Procedures (SOPs). Although some refinements have been incorporated into the exposure assessments, the exposure assumptions will not underestimate risks.

As discussed above and in Appendix 2, despite several years of study, the science addressing neurodevelopmental effects remains unresolved, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF

[10] HED's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children).

(*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

4.2 Dose Response Assessment

4.2.1 Durations of Exposure, Critical Windows of Exposure, & Temporality of Effects

In risk assessment, exposure is evaluated considering the toxicology profile. More specifically, a variety of toxicokinetic and toxicodynamic factors are considered when determining the appropriate exposure durations to assess for risk potential. In the case of chlorpyrifos, exposure can occur from a single event or on a single day (*e.g.*, eating a meal) or from repeated days of exposure (*e.g.*, worker, residential).

With respect to AChE inhibition, these effects can occur from a single exposure or from repeated exposures. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute exposures. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with most OPs show a consistent pattern of inhibition reaching steady state at or around 2-3 weeks of exposure in adult laboratory animals (U.S. EPA, 2002). This pattern observed with repeated dosing is a result of the amount of inhibition comes at equilibrium with production of new enzyme. As such, AChE studies of 2-3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.*, up to 2 years of exposure). Thus, for most of the human health risk assessments for the OPs, the Agency is focusing on the critical durations ranging from a single day up to 21 days (*i.e.*, the approximate time to reach steady state for most OPs). As described below, PODs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations.

With respect to effects on the developing brain, very little is known about the duration of chlorpyrifos exposure needed to precipitate adverse effects in the developing brain. There are critical windows of vulnerability (Rice & Barone, 2000; Rodier, 2004) with regard to toxicant effects on brain development. This vulnerable period in humans spans early pregnancy to adolescence (Rice & Barone, 2000). In fact, evidence shows that synapse formation peaks quite late in human brain development at 4-8 years of age (Glantz *et al.,* 2007). Within these vulnerable periods there are key neurodevelopmental processes (*e.g.* cell division, migration, differentiation, synaptogenesis, and myelination) and each of these is region and stage specific. Consequently, the time of toxicant exposure will be a major determinate in the spectrum of neurotoxic effects. Because of the dynamic processes in the developing brain (*i.e.*, vulnerable windows) it is difficult to determine if the effect or differences in effects is due to duration of exposure or if different vulnerable windows were affected. As such, it is impossible at this time to rule out even a single day of high exposure to chlorpyrifos having a potential adverse neurodevelopmental effect in humans.

For the chlorpyrifos risk assessment, PODs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations.

4.2.2 Use of the PBPK-PD Model

Evaluation of PBPK-PD models intended for risk assessments includes a review of the model purpose, model structure, mathematical representation, parameter estimation (calibration), and computer implementation (USEPA, 2006b). The chlorpyrifos PBPK-PD model has been through several quality assurance reviews by various individuals or groups, including the Agency, and found that the model reasonably predicts both blood/urine dosimetry of chlorpyrifos and 3,5,6-trichloro-2-pyridinol (TCPy), and ChE inhibition in two controlled, deliberate oral human dosing studies (Nolan *et al.,* 1982; Kisicki *et al.,* 1999) and a dermal human study (Nolan *et al.,* 1984). The PBPK-PD model predictions for rats inhaled chlorpyrifos compare well with observed data (Hotchkiss *et al.,* 2013) with respect to chlorpyrifos, oxon, and TCPy concentrations in plasma, and ChE in plasma, RBC and brain (Poet *et al.,* 2014). Significant improvements have been made to the PBPK-PD model in response to the 2008, 2011, and 2012 SAPs, the Agency, and peer reviewers from academic journals. The Agency believes that the model is sufficiently robust for use in HHRA. Age-specific parameters are incorporated in the model to allow for lifestage-specific evaluations from infant through adulthood. Since the model accounts for human specific metabolism and physiology, using the human model obviates the need for the inter-species extrapolation factor. The deterministic model can be used to simulate an "average individual" for all age groups. As such, as described below, the Agency is using the PBPK-PD model to derive the scenario-specific PODs for all age groups (See Table 4.2.2.1.2 below).

At the 2011 SAP meeting, the Panel specifically noted the lack of maternal and fetal PK and PD compartments in the current PBPK-PD model to inform about tissue dosimetry and AChE inhibition during lactation (FIFRA SAP 2011). As described in detail below, the Agency has assessed exposure to bottle-feeding infants exposed to the oxon through water used with infant formula. With respect to chlorpyrifos or oxon exposure to infants through breast milk, any exposure to chlorpyrifos would be far lower than drinking water levels predicted by EFED. Thus, the Agency is already accounting for oral exposure to chlorpyrifos to infants via bottle-feeding and a lactation component in the PBPK-PD model is not necessary.

The SAP noted the lack of maternal and fetal PK and PD compartments in the PBPK-PD model to inform tissue dosimetry and AChE inhibition to pregnant women and their fetuses (FIFRA SAP 2011). With respect to exposure to the fetus during gestation, there are multiple studies on chlorpyrifos (Mattsson et al., 1998, 2000) and other OPs (U.S. EPA, 2006a) which show that the pregnant dam exhibits similar or more AChE inhibition than the fetus at a given dose to the dam. As such, for AChE inhibition, protecting against AChE inhibition in the pregnant female is expected to be protective for AChE inhibition in the fetus. Biomonitoring data from rats and humans support the findings of these AChE studies. Specifically, Whyatt *et al.* (2003) have shown that levels of chlorpyrifos in maternal blood are similar to the levels measured in human umbilical cord blood (Whyatt *et al.,* 2003). With respect to the pregnant dam during gestation, metabolic activities and physiological parameters can be altered during pregnancy (for citations, see Appendix 1 of D424485 (D. Drew *et al.,* 12/29/2014)). While the PBPK-PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, the model does not include any descriptions

on physiological, anatomical and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women who may be pregnant, **the Agency is applying the standard 10X intra-species extrapolation factor for women of childbearing age.**

4.2.2.1 Derivation of Human Equivalent Doses/Concentrations

In typical risk assessments, PODs are derived directly from laboratory animal studies and inter- and intra-species extrapolations are accomplished by use of 10X factors. In the case of chlorpyrifos and its oxon, PBPK-PD modeling is being used as a data-derived approach to estimate PODs for all age groups and Data-Derived Extrapolation Factors (DDEF) for intra-species extrapolation for some groups (USEPA, 2014). The Agency typically uses a 10% response level for AChE inhibition in human health risk assessment. This response level is consistent with the 2006 OP cumulative risk assessment (USEPA, 2006a) and other single chemical OP risk assessments. As such, the model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following single day (acute; 24 hours) and 21-day exposures for a variety of exposure scenarios (see Table 4.2.2.1.2 below).

The PBPK-PD model accounts for PK and PD characteristics to derive age, duration, and route specific PODs (Table 4.2.2.1.2 below). Separate PODs have been calculated for dietary (food, drinking water), residential, and occupational exposures by varying inputs on types of exposures and populations exposed. Specifically, the following characteristics have been evaluated: duration [acute, 21 day (steady state)]; route (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency [events per day (eating, drinking)].

For each exposure scenario, the appropriate body weight for each age group or sex was modeled as identified from the Exposure Factors Handbook (USEPA, 2011) for occupational and residential exposures and from the NHANES/What We Eat in America (WWEIA) Survey[11] for dietary exposures. All body weights used are consistent with those assumed for dietary, occupational, and residential exposure assessments. The Agency assesses dietary exposures for children 6-12 years old, and children between 6-11 years old for residential exposures. For purpose of aggregate assessment, these age groups are combined. The Agency assesses dietary exposures for youths 13-19 years old, and youths between 11-16 years old for residential exposures. For purpose of aggregate assessment, these age groups are combined. The body weights used in the chlorpyrifos PBPK model are summarized in Table 4.2.2.1.1.

[11] http://www.ars.usda.gov/Services/docs.htm?docid=13793

Table 4.2.2.1.1 Body Weight Assumptions Incorporated into PBPK Model for Chlorpyrifos.						
			Population & Body Weight (kg)			
Exposure Scenario	**Exposure Pathway**	**Infants (<1 year old)**	**Young Children (<1 - 2 years old)**	**Children (Residential:6 -11 years old; Dietary:6-12 years old)**	**Youths (Residential:1 1-16 years old; Dietary:13-19 years old)**	**Females (13 – 49 years old)**
Dietary	Food and Drinking Water	4.8[1]	12.6[2]	37.1[2]	67.3[2]	72.9[2]
Residential (Contact with Treated Turf from Mosquitocide Application)	Oral		11[3]			
	Dermal			32[5]	57[6]	69[4]
	Inhalation		11[3]			69[4]
Residential (Golfing)	Dermal			32[5]	57[6]	69[4]
Non-Occupational Spray Drift	Oral		11[3]			
	Dermal					69[4]
Occupational	Dermal, Inhalation					69[4]

1 For infants from birth to < 1 year old, the Agency has selected the body weight for the youngest age group, birth to < 1 month old, 4.8 kg (Exposure Factors Handbook, Table 8-3, mean body weight for the birth to < 1 month age group).
2 NHANES/WWEIA
3 Exposure Factors Handbook, Table 8-3, mean body weight for the 1 to < 2 year old age group.
4 Exposure Factors Handbook, Table 8-5, mean body weight for females 13 to < 49 years old.
5 Exposure Factors Handbook, Table 8-3, mean body weight for the 6 to < 11 year old age group.
6 (Exposure Factors Handbook, Table 8-3, mean body weight for the 11 to < 16 year old age group).

In order to derive the scenario specific PODs, assumptions were incorporated into the PBPK model on routes of exposure, surface area exposed, etc. The following scenarios were evaluated: dietary exposure to the oxon exposures via drinking water (24-hour and 21-day exposures for infants, children, youths, and female adults); exposure to chlorpyrifos exposures via food (24-hour and 21-day exposures for infants, children, youths, and female adults); 21-day residential exposures to chlorpyrifos via skin for children, youths, and female adults; 21-day residential exposures to chlorpyrifos via hand-to-mouth ingestion for children 1- 2 years old; 21-day residential exposures to chlorpyrifos via inhalation for children 1-2 years old and female adults.

Steady state dietary exposure was estimated daily for 21 days. For drinking water exposure, infants and young childrens (infants < 1 year old, children between 1-2 years old, and children between 6-12 years old) were assumed to consume water 6 times per day, with a total consumption volume of 0.69 L/day[12]. For youths and female adults, they were assumed to consume water 4 times per day, with a total consumption volume of 1.71 L/day[13].

[12] The daily volumes consumed and number of daily consumption events for all populations are mean values by age group based on USDA What We Eat in America, NHANES survey for dietary exposures. The mean daily water consumption values for children 1- 2 years old (0.35 L/day) and children 6-12 years old (0.58 L/day), were less than that for the infants (0.69 L/day); however, the infant daily water consumption volume was selected to be protective for PBPK-PD POD derivation for these age groups.
[13] For youths 13-19 years old, the mean daily water consumption (0.93 L/day), was less than that for the female adults (1.71 L/day); however, the adult daily water consumption was also selected to be protective.

All residential steady state exposures were set to be continuous for 21 days. For all residential dermal exposures to chlorpyrifos the dermal PODs were estimated assuming 50% of the skin's surface was exposed. Exposure times for dermal exposure assessment were consistent with those recommended in the 2012 Residential Standard Operating Procedures (SOPs)[14]. For residential inhalation exposures following public health mosquitocide application, the exposure duration was set to 1 hour per day for 21 days. The incidental oral PODs for children 1 to < 2 years old for other turf activities were estimated assuming that there were six events, 15 minutes apart, per day.

In addition to dietary and residential exposures, the PBPK-PD model was also used to estimate exposure levels resulting in 10% RBC AChE inhibition following steady state occupational exposures. For occupational handlers and post-application workers, the dermal PODs were estimated assuming a body weight of 69 kg (to represent a female aged 13-49), 100% of the skin's surface was exposed for 5 days/week and the exposure duration was 8 hours/day for 21 days. For occupational handlers, the inhalation PODs were estimated exposure for 8 hours/day, 5 days/week, for 21 days.

[14] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

Table 4.2.2.1.2. Chlorpyrifos PBPK Modeled Doses (PODs) Corresponding to 10% RBC AChE Inhibition.

RA Type	Exposure Pathway (all chlorpyrifos unless noted)	Infants (< 1 yr old)		Young Children (1 - 2 years old)		Children (Residential: 6-11 years old; Dietary: 6-12 years old)		Youths (Residential: 11-16 years old; Dietary: 13-19 years old)		Females (13 – 49 years old)	
		Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)
Dietary	Drinking Water (oxon conc, ppb)	1,183	217	3,004	548	7,700	1,358	4,988	878	5,285	932
	Food (mg/kg/day)	0.60	0.103	0.581	0.099	0.53	0.09	0.475	0.080	0.467	0.078
Residential (Golfers)	Dermal (mg/kg/day)						25.75		13.95		11.89
Residential (Mosquitocide Application) and Spray Drift	Dermal (mg/kg/day)				134.25						23.6
	Oral (mg/kg/day)				0.101						
	Inhalation (concn. in air mg/m^3)				2.37						6.15
Occupational	Dermal (mg/kg/day)										3.63
	Inhalation (mg/kg/day)										0.138

*PODs and exposure and risk estimates for females 13-49 yrs covers all youths >13 yrs

4.2.2.2 Intra-species Extrapolation

With respect to intra-species extrapolation, the PBPK-PD model can be run in 'variation' mode which allows for age-specific parameters to vary across a distribution of values. The model will not be described in detail here as it is described in multiple recent publications, including a detailed report reviewed by the FIFRA SAP in 2011; summary information is provided here. All model code for the PBPK-PD variation model are available to the public.

Significant improvements have been made to the PBPK-PD model in response to the 2008, 2011, and 2012 SAPs, the Agency, and peer reviewers from academic journals in addition to the input of new data. At the 2011 SAP, the panel was critical of some aspects of how the registrant proposed to assess intra-species extrapolation. The registrant made multiple changes, including the addition of a global sensitivity analysis, improvements to the quantitative approach to evaluate population variability across individuals at a given age, and an uncertainty analysis on metabolism data from human hepatic microsomes to address variation in metabolic capabilities. .

Of the more than 120 parameters in the PBPK-PD model, 16 parameters were selected for varying in the DDEF intra-species analysis. They were selected using local and global sensitivity analyses (MRID 49248201, Dow, 2014a,b). The distributions for these 16 parameters are provided in Table 4.2.2.2.1 below. Inter-individual variations for the 16 sensitive parameters (listed above) were assumed to follow a lognormal distribution. The distributions are truncated at far extreme values only to permit the model to compute but functionally not truncated with respect to assessing human variability. References cited in the table are listed in the report "Development of Chemical Specific Adjustment Factors for Chlorpyrifos and Chlorpyrifos Oxon" (MRID number 49248201) and also provided in Dow, 2014a,b,c.

Table 4.2.2.2.1. Sixteen parameters in variation model. Extracted from Dow, 2014c.				
Parameter	**Mean value**	**Standard Deviation**	**CV**	**Variability Reference**
Total Blood Volume (L/kg body	0.08	0.0022	0.027	P^{3}M; Price *et al.,* 2003
Plasma PON1 (µmol/hr×L)	162,000	92,000	0.57	Smith et al., 2011
Hepatic Blood Flow (L/hr×kg tissue)	50	14	0.27	Materne et al., 2000
RBC ChE Inhibition Rate (l/µmol×hr)	100	17	0.17	Dimitriadis and Syrmos,
Hepatic PON1 (µmol/hr×kg tissue)	154,000	88,000	0.57	Smith et al., 2011
Hematocrit (%)	0.45	0.031	0.068	P^{3}M; Price *et al.,* 2003
RBC ChE Degradation Rate (l/hr)	0.01	0.0014	0.14	Chapman *et al.,* 1968
Hepatic P450 Bioactivation to Oxon (µmol/hr×kg tissue)	690	410	0.59	Smith et al., 2011
Hepatic P450 Detoxification to TCPy (µmol/hr×kg tissue)	1500	800	0.53	Smith et al., 2011
RBC ChE Reactivation Rate (l/hr)	0.014	0.0050	0.36	Mason et al., 2000
Intestinal CYP Bioactivation to Oxon (µmol/hr×kg tissue)	82	43	0.52	Obach *et al.,* 2001
Intestinal CYP Detoxification to TCPy (µmol/hr×kg tissue)	53	28	0.52	Obach *et al.,* 2001
Transfer Rate to Intestine (hr-1)	0.31	0.081	0.26	Singh et al., 2006
Volume of the Liver (L/kg body weight)	0.032	0.0010	0.032	P^{3}M; Price *et al.,* 2003
Hepatic Carboxyl Basal Activity Rate (l/hr/kg tissue)	1,270,000	460,000	0.36	Pope *et al.,* 2005
Hepatic Carboxyl Reactivation Rate (l/hr)	0.014	0.0050	0.36	Mason et al., 2000

Of these 16 parameters, four metabolism-related parameters (hepatic CYP450 activation of chlorpyrifos to chlorpyrifos oxon, hepatic CYP450 detoxification of chlorpyrifos oxon to TCPy, hepatic PON1 detoxification of chlorpyrifos oxon to TCPy, PON1 detoxification of chlorpyrifos oxon to TCPy in plasma) were found to drive more than 80% of the total variation in RBC AChE inhibition (Table 4.2.2.2.2). The human variability for these four parameters were assessed using *in vitro* data from 30 human hepatic microsome samples and 20 human plasma samples (Smith et al., 2011). Twenty of the hepatic microsome samples came from individuals < 12 years of age; and 10 of the samples came from adults > 17 years old. Ten of the plasma sample came from individuals < 2 years of age; and 10 of the samples came from adults. Because the findings from Smith et al (2011) account for more than 80% of the total variation in RBC AChE inhibition, it was determined that evaluating the uncertainty associated with the data (i.e., small number of samples compared to the large U.S. population) from this study was important to having confidence in the DDEFs derived from the variation model. Although some other *in vitro* studies shown in Table 4.2.2.2.1 also have small numbers of samples, these parameters make relatively small contributions to the overall variability. As such, additional quantitative uncertainty analysis on these *in vitro* studies is not needed.

Table 4.2.2.2.2. Four Metabolism Related Parameters in Variation Model. Extracted from Dow, 2014c.			
hepatic CYP450 activation of chlorpyrifos to chlorpyrifos oxon	total blood volume	RBC ChE degradation rate	transfer rate of chlorpyrifos or oxon from the stomach to the intestine
hepatic PON1 detoxification of chlorpyrifos oxon to TCPy	hepatic blood flow	RBC ChE reactivation rate	volume of the liver
PON1 detoxification of chlorpyrifos oxon to TCPy in plasma	RBC AChE inhibition rate	intestinal CYP bioactivation to chlorpyrifos oxon	hepatic carboxyl basal activity rate
hepatic PON1 detoxification of chlorpyrifos oxon to TCPy	hematocrit	intestinal CYP detoxification to TCPy	hepatic carboxyl reactivation rate

The uncertainty associated with these four critical parameters were incorporated in the subsequent Monte Carlo analysis by generating 50 sets of unbounded parametric distributions using the following approach. First, the parametric bootstrap approach was used to sample 1000 values, with replacement, from the *in vitro* data. Then, this process was repeated for 50 iterations, and the resulting 50 sets of distribution all have equally probable sets of means and coefficient of variation as the observed data, except for the coefficient of variation of the plasma PON1 metabolism rate. Since the liver is the origin of PON1 in plasma, the variation of the plasma PON1 metabolism rate was set to be the same as the hepatic PON1 metabolism rate. Even though the distributions have similar means and coefficient of variation as the observed data, they included values outside of the range of the observed data because the distributions were assumed to be unbounded. These 50 sets of distributions, for each of the four parameters, were found to cover the entire range of the observed data; and the ratios of maximum value to minimum value in the simulated distributions were at least three times the ratios of maximum value to minimum value in the observed data.

According to EPA's Data-Derived Extrapolation Factor guidance, when calculating a DDEF intra-species extrapolation (USEPA, 2014), administered doses leading to the response level of interest (10% change in RBC AChE inhibition) are compared between a measure of average response and response at the tail of the distribution representing sensitive individuals. Oral doses that cause 10% RBC AChE inhibition in both adults and 6-month old infants (example provided in Figure 1 a,b) were estimated using the model. The ratio of the adult ED_{10} to the infant ED_{10} was then used to derive intraspecies extrapolation factors. In the subsequent Monte Carlo simulations, the target age group is six-month-old individuals. Some model parameters are specific to this age group (e.g., PON1 metabolism in plasma), and some parameters are scaled by body weight that reflect this age group (e.g., tissue volume). Based on the 5th percentile of the distributions, the DDEF for intraspecies extrapolation is 2.8X for chlorpyrifos and 3.1X for the oxon (Dow, 2014b). Based on the 99th percentile of the distributions, the DDEF for intraspecies extrapolation is 4X for chlorpyrifos and 5X for the oxon (Dow, 2014b). For this revised HHRA, the 99th percentile is being used to account for sensitivities (i.e., the intra-species factor is 4X for chlorpyrifos and 5X for the oxon for all groups except women who are pregnant or may become pregnant). As shown in Figure 1b, at the 99th-ile, only 1% of infants will experience 10% or greater RBC AChE inhibition at the POD.

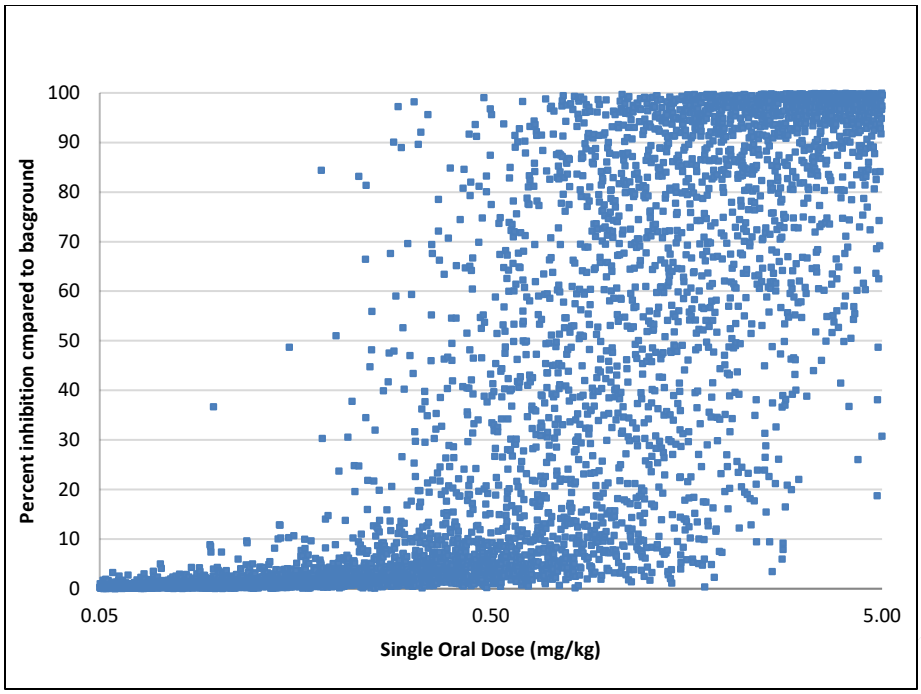


Figure 1a. Simulated population of 6 month olds for intra-species extrapolation DDEF derivation. Percent RBC AChE inhibition from exposure to single oral doses of chlorpyrifos ranging from 0.05 to 5.0 mg/kg/day (X and Y axes provided on the log scale).

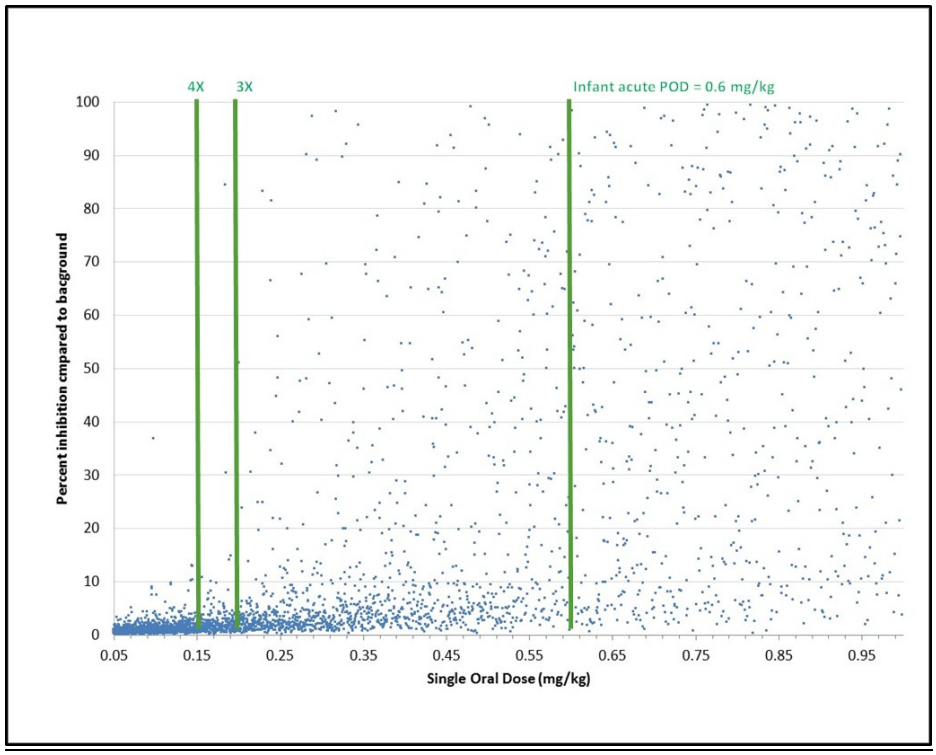


Figure 1b. Simulated population of 6 month olds for intra-species extrapolation DDEF derivation. Percent RBC AChE inhibition from exposure to single oral doses of chlorpyrifos ranging from 0.05 to 1.0 mg/kg/day. Green lines represent the infant acute POD for chlorpyrifos, the POD adjusted for the 3X and 4X intraspecies factors for the 95 and 99th-%ile, respectively.

In summary, for the chlorpyrifos HHRA, the human PBPK-PD model has been used to derive PODs for RBC AChE inhibition for various populations, durations, and routes (Table 4.2.2.1.2). As such, the interspecies factor is not needed. To account for variations in sensitivities, an intra-species factor of 4X for chlorpyrifos and 5X for the oxon is applied for all groups except women of childbearing age. For women of childbearing age, the typical 10X intra-species factor is being applied due the lack of appropriate information and algorithms to characterize physiological changes during pregnancy. Risks are being presented throughout the document assuming both the 10X FQPA SF is being retained for all subpopulations and reduced to 1X for all subpopulations. The individual and total uncertainty factors are summarized in Table 4.2.2.2.3.

Table 4.2.2.2.3 Uncertainty Factor Summary.

Uncertainty Factor	FQPA 10X Retained			FQPA 10X Reduced to 1X		
	Females	All other Subpopulations		Females	All other Subpopulations	
		Food (parent)	Drinking Water (oxon)		Food (parent)	Drinking Water (oxon)
Interspecies	1	1	1	1	1	1
Intraspecies	10	4	5	10	4	5
FQPA	10	10	10	1	1	1
Total	**100**	**40**	**50**	**10**	**4**	**5**

4.3 Endocrine Disruptor Screening Program

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision for chlorpyrifos, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), chlorpyrifos is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[15] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

Chlorpyrifos is on List 1 for which EPA has received all of the required Tier 1 assay data. The Agency has reviewed all of the assay data received for the appropriate List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets (see Docket # EPA-HQ-OPP-2008-0850 for chlorpyrifos)."For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[16]

5.0 Dietary Exposure and Risk Assessment

HED had previously conducted both acute and steady state dietary (food only) exposure analyses for chlorpyrifos using DEEM and Calendex software with the Food Commodity Intake Database (FCID) (D. Drew *et al.,* D424486, 11/18/2014), respectively.

For the current assessment, the resulting acute and steady state food exposure values are compared to the PBPK-derived aPAD or ssPAD. When the dietary exposure exceeds 100% of the aPAD or ssPAD there is a potential risk concern.

All details pertaining to the assumptions, data inputs, and exposure outputs for the dietary analysis may be found in the 2014 dietary assessment memorandum (D. Drew *et al.,* D425586, 11/18/2014).

[15] See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[16] https://www.epa.gov/endocrine-disruption

Table 5.0.1. Chlorpyrifos Population Adjusted Doses (PADs) Derived from PBPK Modeled Doses Corresponding to 10% RBC AChE Inhibition – FQPA SF 10X Retained[1].

RA Type	Infants (< 1 year old)			Children (1 – 2 Years old)			Children (6-12 Years Old)			Youths (13-19 Years Old)			Females (13-49 Years Old)		
	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State
Drinking Water (oxon conc, ppb)	50	23.66	4.34	50	60.08	10.96	50	154	27.16	50	99.76	17.56	100	52.85	9.32
Food (µg/kg/day)	40	15	2.6	40	15	2.5	40	13	2.3	40	12	2.0	100	4.7	0.78

1. Population Adjusted Dose (PAD) = POD ÷ LOC (including all applicable uncertainty factors). PODs for each scenario and subpopulation are provided in Table 4.2.2.1.2.

Table 5.0.2. Chlorpyrifos Population Adjusted Doses (PADs) Derived from PBPK Modeled Doses Corresponding to 10% RBC AChE Inhibition – FQPA SF Reduced to 1X[1].

RA Type	Infants (< 1 year old)			Children (1 – 2 Years old)			Children (6-12 Years Old)			Youths (13-19 Years Old)			Females (13-49 Years Old)		
	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State	LOC	Acute	Steady State
Drinking Water (oxon conc, ppb)	5	236	43.4	5	600.8	109.6	5	1540	271.6	5	997.6	175.6	10	528.5	93.2
Food (µg/kg/day)	4	150	26	4	150	25	4	130	23	4	120	20	10	47	7.8

1. Population Adjusted Dose (PAD) = POD ÷ LOC (including all applicable uncertainty factors). PODs for each scenario and subpopulation are provided in Table 4.2.2.1.2.

5.1 Residues of Concern Summary and Rationale

The qualitative nature of the residue in plants and livestock is adequately understood based on acceptable metabolism studies with cereal grain (corn), root and tuber vegetable (sugar beets), and poultry and ruminants. The residue of concern, for tolerance expression and risk assessment, in plants (food and feed) and livestock commodities is the parent compound chlorpyrifos.

Based on evidence (various crop field trials and metabolism studies) indicating that the metabolite chlorpyrifos oxon would be not be present in edible portions of the crops (particularly at periods longer than the currently registered PHIs), it is not a residue of concern in food or feed at this time. Also, the chlorpyrifos oxon is not found on samples in the U.S. Department of Agriculture's Pesticide Data Program (USDA PDP) monitoring data. In fact, from 2007 to 2012, out of several thousand samples of various commodities, only one sample of potato showed presence of the oxon at trace levels, 0.003 ppm where the LOD was 0.002 ppm, even though there are no registered uses of chlorpyrifos on potato in the U.S.

The oxon metabolite was not found in milk or livestock tissues in cattle and dairy cow feeding studies, at all feeding levels tested, and is not a residue of concern in livestock commodities.

Oxidation of chlorpyrifos to chlorpyrifos oxon could potentially occur through photolysis, aerobic metabolism, and chlorination as well as other oxidative processes. Because of the toxicity of the oxon and data indicating that chlorpyrifos rapidly converts to the oxon during typical drinking water treatment (chlorination), the drinking water risk assessment considers the oxon as the residue of concern in treated drinking water and assumes 100% conversion of chlorpyrifos to chlorpyrifos oxon (see DWA, R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

Table 5.1. Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression.

Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	Chlorpyrifos	Chlorpyrifos
	Rotational Crop	Chlorpyrifos	Chlorpyrifos
Livestock	Ruminant	Chlorpyrifos	Chlorpyrifos
	Poultry	Chlorpyrifos	Chlorpyrifos
Drinking Water		Chlorpyrifos Oxon	Not Applicable

5.2 Food Residue Profile

Acute and steady state dietary (food only) exposure analyses for chlorpyrifos were conducted using the Dietary Exposure Evaluation Model (DEEM) and Calendex software with the Food Commodity Intake Database (FCID) (D. Drew, 11/18/2014, D424486, *Chlorpyrifos Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review*). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). These analyses were performed for the purpose of obtaining food exposure values for comparison to the chlorpyrifos doses predicted by the PBPK-PD model to cause RBC ChEI. The acute and steady state dietary exposure analyses do not include drinking

water which is assessed separately as discussed in Section 7 (Aggregate Exposure/Risk Characterization).

Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed. OPP's Biological and Economic Analysis Division (BEAD) provided estimated percent crop treated information. Food processing factors from submitted studies were used as appropriate.

5.3 Percent Crop Treated Used in Dietary Assessment

The acute and steady state dietary exposure assessment used percent crop treated (%CT) information from BEAD's Screening Level Usage Analysis **(**SLUA; May 2014). BEAD has recently issued an updated SLUA (March 2020) for chlorpyrifos which includes a comparison of the percent crop treated estimates of 2016 and 2020.[17] Those results indicate that there were no appreciable increases in estimated percent crop treated and that most reported crop commodities had a decrease in percent crop treated as well as a decrease in the average yearly amount of chlorpyrifos applied. The use of the 2014 crop treated estimates do not underestimate the dietary exposures.

5.4 Acute Dietary (Food Only) Risk Assessment

Chlorpyrifos acute (food only) dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 3.16, which incorporates consumption data from NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. Acute dietary risk estimates are presented below for the sentinel population subgroups for acute risk assessment: infants (< 1 year old), children (1-2 years old), youths (6-12 years old) and adults (females 13-49 years old). The assessment of these index lifestages will be protective for the other population subgroups.

Acute dietary (food only) risk estimates are all <100 % of the acute PAD for food ($aPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is females (13-49 years old) at 3.2 % $aPAD_{food}$. With the FQPA SF reduced to 1X, the acute dietary risk estimates are <1% of the $aPAD_{food}$ for all populations.

Table 5.4. Acute Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.

Population Subgroup	Food Exposure[1] (µg/kg/day)	$aPOD_{food}$[2] (µg/kg/day)	10X FQPA SF		1X FQPA SF	
			$aPAD_{food}$[3] (µg/kg/day)	% of $aPAD_{food}$	$aPAD_{food}$[4] (µg/kg/day)	% of $aPAD_{food}$
Infants (< 1 yr)	0.273	600	15	1.8	150	<1

[17] L. Hendrick, 03/05/2020, Updated Chlorpyrifos (059101) Screening Level Usage Analysis (SLUA)

Table 5.4. Acute Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.						
Population Subgroup	**Food Exposure[1] (µg/kg/day)**	**$aPOD_{food}$[2] (µg/kg/day)**	**10X FQPA SF**		**1X FQPA SF**	
			$aPAD_{food}$[3] (µg/kg/day)	**% of $aPAD_{food}$**	**$aPAD_{food}$[4] (µg/kg/day)**	**% of $aPAD_{food}$**
Children (1-2 yrs)	0.423	581	15	2.8	150	<1
Youths (6-12 yrs)	0.189	530	13	1.4	130	<1
Adults (Females 13-49 yrs)	0.150	467	4.7	3.2	47	<1

[1] Acute food only exposure estimates from DEEM (at 99.9th percentile). Refined with monitoring data and %CT.
[2] Acute point of departure; daily dose predicted by PBPK-PD model to cause RBC ChEI of 10% for acute dietary (food) exposures. Table 4.8.4.1.2.
[3]aPAD= acute population adjusted dose = PoD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =100X for females 13-49 yrs (10X intraspecies factor and 10X FQPA uncertainty factor) and 40X for other populations (4X intraspecies factor and 10X FQPA uncertainty factor). Table 5.0.1.
[4]aPAD= acute population adjusted dose = PoD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =10X for females 13-49 yrs (10X intraspecies factor and 1X FQPA uncertainty factor) and 4X for other populations (4X intraspecies factor and 1X FQPA uncertainty factor). Table 5.0.2.

5.5 Steady State Dietary (Food Only) Exposure and Risk Estimates

A chlorpyrifos steady state dietary (food only) exposure analysis was conducted using Calendex-FCID™. HED's steady state assessment considers the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year. For this assessment, the same food residue values used in the acute assessment were used for the 21-day duration. In the Calendex software, one diary for each individual in the WWEIA is selected to be paired with a randomly selected set of residue values for each food consumed. The steady state analysis calculated exposures for the sentinel populations for infant, child, youths, and adult (infants <1 yr, children 1-2 yrs, youths 6-12 yrs, females 13-49 yrs). The assessment of these index lifestages will be protective for the other population subgroups.

Calendex reported dietary exposures for each population subgroup at several percentiles of exposure ranging from 10th percentile to 99.9th percentile. The dietary (food only) exposures for chlorpyrifos were all <100% $ssPAD_{food}$ (all populations, at all percentiles of exposure). Only the 99.9th percentile of exposure is presented in Table 5.5 below. Calendex exposure results for other percentiles of exposure can be found in D424486.

Steady state dietary (food only) risk estimates are all <100 % of the steady state PAD for food ($ssPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is children (1-2 years old) at 9.7 % $ssPAD_{food}$. With the FQPA SF reduced to 1X, the steady state dietary risk estimates are <1% of the $ssPAD_{food}$ for all populations.

Table 5.5. Steady State Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.						
Population Subgroup	Food Exposure[1] (µg/kg/day)	$ssPoD_{food}$[2] (µg/kg/day)	10X FQPA SF		1X FQPA SF	
			$ssPAD_{food}$[3] (µg/kg/day)	% of $ssPAD_{food}$	$ssPAD_{food}$[4] (µg/kg/day)	% of $ssPAD_{food}$
Infants (< 1 yr)	0.186	103	2.6	7.2	26	<1
Children (1-2 yrs)	0.242	99	2.5	9.7	25	<1
Youths (6-12 yrs)	0.128	90	2.3	5.6	23	<1
Adults (Females 13-49 yrs)	0.075	78	0.78	9.6	7.8	<1

[1] Steady state food only exposure estimates from DEEM (at 99.9th percentile). Refined with monitoring data and %CT.
[2] Steady state point of departure; daily dose predicted by PBPK-PD model to cause RBC ChEI of 10% for acute dietary (food) exposures. Table 4.8.4.1.2.
[3]ssPAD= steady state population adjusted dose = POD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =100X for females 13-49 yrs (10X intraspecies factor and 10X FQPA uncertainty factor) and 40X for other populations (4X intraspecies factor and 10X FQPA uncertainty factor). Table 5.0.1.
[4] ssPAD= steady state population adjusted dose = POD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =10X for females 13-49 yrs (10X intraspecies factor and 1X FQPA uncertainty factor) and 4X for other populations (4X intraspecies factor and 1X FQPA uncertainty factor). Table 5.0.2.

5.6 Dietary Drinking Water Risk Assessment

The total dietary exposure to chlorpyrifos is through both food and drinking water. EFED has provided a revised drinking water assessment (DWA) for chlorpyrifos (R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270) which includes the updated EDWCs for dietary risk assessment. A DWLOC approach is used to calculate the amount of exposure available in the total dietary 'risk cup' for chlorpyrifos in drinking water after accounting for chloropyrifos exposure from food and from residential uses. This DWLOC can be compared to the EDWCs to determine if there is a risk of concern for drinking water exposures (See D. Drew, D424485, 12/29/2014 for details on the DWLOC approach and calculations). The acute and steady state dietary exposure analyses discussed above only include food and do not include drinking water; the aggregate assessment, which does incorporate drinking water, is discussed in Section 7 (Aggregate Exposure/Risk Characterization).

6.0 Residential Exposure/Risk Characterization

Residential exposures to chlorpyrifos are currently expected from chlorpyrifos use in residential settings. Formulations/use sites registered for use in residential areas include a granular ant mound use and roach bait in child-resistant packaging. Additionally, chlorpyrifos is labeled for public health aerial and ground-based fogger ULV mosquito adulticide applications and for golf course turf applications. All residential exposures and risks were previously assessed in support of the 2014 HHRA (W. Britton, D424484, 12/29/2014) and 2016 HHRA (W. Britton, D436317, 11/3/2016). The previous assessments included evaluation of residential post-application risks from playing golf on chlorpyrifos-treated courses and from exposures which can occur following aerial and ground-based ULV mosquito adulticide usage. The potential for residential exposures

from the roach bait product was determined to be negligible. Further, residential exposures from the ant mound use were also determined to be negligible since these products can only be applied professionally and direct exposure with treated ant mounds is not anticipated.

The previously assessed residential post-application assessments have been updated to incorporate the approach applied for PBPK-derivation of PODs for infants, children, and adults based on 10% RBC AChE inhibition. The results have been summarized assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. If the FQPA SF is retained, the total LOC for residential exposure assessment is 100X for adults (represented by females 13-49) and 40X for all other subpopulations, including children.

6.1 Residential Handler Exposure/Risk Estimates

HED uses the term "handlers" to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. Residential handlers are addressed somewhat differently by HED as homeowners are assumed to complete all elements of an application without use of any protective equipment.

Based upon review of all chlorpyrifos registered uses, only the roach bait products can be applied by a homeowner in a residential setting, but the application of roach bait products has not quantitatively assessed because these exposures are negligible. The roach bait product is designed such that the active ingredient is contained within a bait station which eliminates the potential for contact with the chlorpyrifos containing bait material. Therefore, updated residential handler risks are not required for these uses.

6.2 Residential Post-Application Exposure/Risk Estimates

Residential post-application exposures are likely from being in an environment that has been previously treated with chlorpyrifos. Chlorpyrifos can be used on golf courses and as an aerial and ground based ULV mosquito adulticide application in residential areas. Post-application exposure from residential ant mount treatment was assessed qualitatively because post-application exposures to treated ant mounts are expected to be negligible.

All of the residential post-application exposure scenarios, data and assumptions, and algorithms used to assess exposures and risks from activities on golf course turf following chlorpyrifos application and from aerial and ground based ULV mosquito adulticide applications are the same as those used in the 2016 HHRA. Additionally, this updated assessment makes use of the same chemical-specific turf transferable residue (TTR) data to assess exposures and risks. In the 2016 HHRA (W. Britton, D436317, 11/03/2016), the residential post-application exposures and risks resulting from aerial and ground-based ULV mosquito adulticide applications were updated to reflect 1) the current default deposition fraction recommended for ground applied ULV mosquitocides (i.e., 8.7 percent of the application rate vs the previous 5 percent) and 2) several iterations of aerial applications modeled assuming differing winds speeds and release heights allowed by chlorpyrifos mosquitocide ULV labels. The previously assessed residential post-application assessment has been updated to incorporate the approach applied for PBPK-derivation of PODs for infants, children, and adults based on 10% RBC AChE inhibition and

assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. The AgDISP (v8.2.6) model input parameters, outputs, and the algorithms used to estimate residential post-application exposures following aerial and ground based ULV mosquitocide application can be found in Appendix 7.

Combining Exposure and Risk Estimates

Since dermal, incidental oral, and inhalation exposure routes share a common toxicological endpoint, RBC AChE inhibition, risk estimates have been combined for those routes. The incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios with the dermal and inhalation exposure scenarios would be unrealistic because of the conservative nature of each individual assessment. Therefore, the post-application exposure scenarios that were combined for children 1 < 2 years old are the dermal, inhalation, and hand-to-mouth scenarios (the highest incidental oral exposure expected). This combination should be considered a protective estimate of children's exposure to pesticides.

Summary of Residential Post-Application Non-Cancer Exposure and Risk Estimates

Whether the FQPA SF is retained at 10X or reduced to 1X, there are no residential post-application risk estimates of concern for the registered uses of chlorpyrifos. If the FQPA SF is retained at 10X, the assessment of steady state residential golfing post-application exposures (dermal only) to chlorpyrifos treated turf results in no risks of concern for adults or children/youths [i.e., MOEs $\geq$ 40 for children 6 to < 11 years old and youths 11 to < 16 years old and MOEs $\geq$ 100 for adults (females 13-49)]. Additionally, the steady state post-application exposures from public health mosquitocide applications results in no combined risk estimates of concern for adults (females 13-49; dermal and inhalation exposures) and children 1 to < 2 years old (dermal, incidental oral, and inhalation exposures) (i.e., MOEs $\geq$ 40 for children 1 to < 2 years old and MOEs $\geq$ 100 for adults). If the FQPA SF is reduced to 1X, there are also no residential post-application risk estimates of concern for adults (females 13-49) or children/youths [MOEs > 4 for children 1 to < 2 years old, children 6 to < 11 years old, and children 11 to < 16 years old; and MOEs > 10 for adults (females 13-49 years old)].

The risk estimates are presented in Table 6.2.1 – Table 6.2.8.

Table 6.2.1. Steady State Residential Post-Application Exposure and Risk Estimates for Chlorpyrifos - Golf Course Uses.

Lifestage	Post-application Exposure Scenario		Application Rate[1]	State (TTR Data)	Dose (mg/kg/day)[2]	MOEs[3]
	Use Site	Route of Exposure				
Adult (Females 13-49 years old)	Golf Course Turf	Dermal	1.0 (Emulsifiable Concentrate)	CA	0.010	1,200
				IN	0.0069	1,700
				MS	0.012	1,000
				Mean	0.0095	1,200
Youths 11 to < 16 years old				CA	0.010	1,400
				IN	0.0069	2,000
				MS	0.012	1,200
				Mean	0.0096	1,500
Children 6 to < 11 years old				CA	0.012	1,900

Table 6.2.1. Steady State Residential Post-Application Exposure and Risk Estimates for Chlorpyrifos - Golf Course Uses.						
Lifestage	**Post-application Exposure Scenario**		**Application Rate[1]**	**State (TTR Data)**	**Dose (mg/kg/day)[2]**	**MOEs[3]**
	Use Site	**Route of Exposure**				
				IN	0.0082	2,800
				MS	0.014	1,600
				Mean	0.011	2,000
Adult (Females 13-49 years old)			1.0 (Granular)	CA	0.0088	1,400
Youths 11 to < 16 years old					0.0088	1,600
Children 6 to < 11 years old					0.010	2,200

1 Based on the maximum application rates registered for golf course turf.
2 Dose (mg/kg/day) equations for golfing applications are provided in Appendix B of the occupational and residential exposure assessment (W. Britton, D424484, 12/29/2014). For dose estimation from exposures to golfing on treated turf, the TTR data were used. Doses have been presented for all State sites, including the mean of all state sites.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). LOC = if the FQPA SF is retained at 10X, the total LOC for residential exposure assessment is 100X for adults (females 13-49) and 40X for all other subpopulations, including children. If the FQPA SF is reduced to 1X, the total LOC for residential exposure assessment is 10X for adults (females 13-49) and 4X for all other subpopulations, including children. See Table 4.2.2.1.2 for PODs.

Table 6.2.2. Residential Post-Application Inhalation Steady State Exposure Estimates from Chlorpyrifos ULV Aerial Mosquitocide Application - AgDISP Model.			
Application Parameters	**Population**	**Air Concentration Estimate (mg/m^3)[1]**	**MOE[2]**
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Adults	0.0047	1,300
	Children 1 to <2 years old		500
10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Adults	0.00070	8,800
	Children 1 to <2 years old		3,400

1 Air concentration estimate modeled using AGDISP v8.2.6 at breathing height of adults and children.
2 MOE = POD (mg/m^3) ÷ Dose (mg/m^3). See Table 4.2.2.1.2 for PODs.

Table 6.2.3. Residential Post-Application Inhalation Steady State Exposure Estimates from Chlorpyrifos ULV Ground Mosquitocide Application – Well Mixed Box (WMB) Model.		
Population	**Air Concentration Estimate (mg/m^3)[1]**	**MOE[2]**
Adults	0.0051	1,200
Children 1 to <2 years old		460

1 Air concentration estimate modeled using the well mixed box model. The inputs and algorithms used are presented in Appendix C of D424484 (W. Britton, 12/29/2014).
2 MOE = POD (mg/m^3) ÷ Dose (mg/m^3). See Table 4.2.2.1.2 for PODs.

Table 6.2.4. Residential Post-Application Dermal Steady State Exposure Estimates Resulting from Chlorpyrifos Aerial ULV Mosquitocide Application.

Application Parameters	Lifestage	Application Rate (lb ai/A)	AgDISP Deposition Fraction[1]	Adjusted TTR[2] (µg/cm^2)	Dermal Dose[3] (mg/kg/day)	MOE[4]
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Adults	0.010	1.0	0.00038	0.0015	16,000
	Children 1 to < 2 Years Old				0.0026	53,000
10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Adults	0.010	0.086	0.000033	0.00013	180,000
	Children 1 to < 2 Years Old				0.00022	610,000

1 The fraction of chlorpyrifos residue deposited following aerial mosquitocide application was determined with use of the AgDISP (v8.2.6) model.
2 TTR_t (µg/cm^2) = [(Day 0 Residue from MS TTR study (µg/cm^2) × Application Rate (0.010 lb ai/A)) ÷ Application Rate of MS TTR Study (3.83 lb ai/A))] × AgDISP Deposition Fraction. The MS TTR data was selected for use because it is the worst case and, as a result, most protective of human health.
3 Dermal Dose (mg/kg/day) = [(TTR_t (µg/cm^2) × CF1 (0.001 mg/µg) × Transfer Coefficient (180,000 cm^2/hr, adults; 49,000 cm^2/hr, children) * ET (1.5 hrs))] ÷ BW (kg).
4 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.5. Residential Post-Application Dermal Steady State Exposure Estimates Resulting from Chlorpyrifos ULV Ground Mosquitocide Application.

Lifestage	Application Rate (lb ai/A)	Deposition Fraction[1]	Adjusted TTR[2] (µg/cm^2)	Dermal Dose[3] (mg/kg/day)	MOE[4]
Adults	0.010	1.0	0.00038	0.00013	180,000
Children 1 to < 2 Years Old				0.00022	610,000

1 Ground fraction of mosquitocide application rate deposited on turf as determined using eight published studies on ground ULV application in which deposition was measured.
2 TTR_t (µg/cm^2) = [(Day 0 Residue from MS TTR study (µg/cm^2) × Application Rate (0.010 lb ai/A)) ÷ Application Rate of MS TTR Study (3.83 lb ai/A))] × AgDISP Deposition Fraction
3 Dermal Dose (mg/kg/day) = [(TTR_t (µg/cm^2) × CF1 (0.001 mg/µg) × Transfer Coefficient (cm^2/hr - 180,000, adults; 49,000, children) × ET (1.5 hrs))] ÷ BW (kg)
4 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.6. Residential Post-Application Steady State Incidental Oral Exposure Estimates Resulting from Chlorpyrifos ULV Aerial Mosquitocide Application.

Application Parameters	Lifestage	Application Rate (mg ai)	Dermal Exposure (mg/day)[1]	Incidental Oral Dose (mg/kg/day)[2]	MOE[3]
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Children 1 to < 2 Years Old	0.010	0.028	$5.2x10^{-5}$	1,900
10 mph Wind Speed			0.0022	$4.5x10^{-6}$	22,000

Dv 0.5 = 40 µm 300 Foot Release Height					

1 Dermal exposure (mg/day) as calculated for children's aerial based ULV applications using the algorithms as described in Appendix C of D424484 (W. Britton, 12/29/2014).
2 Incidental Oral Dose estimated using the algorithms as described below in Appendix C of the 2014 HHRA.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.7. Residential Post-Application Steady State Incidental Oral Exposure Estimates Resulting from Chlorpyrifos ULV Ground Mosquitocide Application.

Lifestage	Application Rate (mg ai)	Dermal Exposure (mg/day)[1]	Incidental Oral Dose (mg/kg/day)[2]	MOE[3]
Children 1 to < 2 Years Old	0.010	0.0024	$4.5x10^{-6}$	22,000

1 Dermal exposure (mg/day) as calculated for children's ground based ULV applications using the algorithms described in Table 6.2.5 above, and as described below in Appendix C of D424484 (W. Britton, 12/29/2014).
2 Incidental Oral Dose estimated using the algorithms as described in Appendix C of the 2014 HHRA.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.8. Combined Residential Post-Application Steady State Exposure Estimates from Chlorpyrifos Mosquitocide Applications.						
Population	**Application Parameter**	**Route of Exposure**	**Dermal or Incidental Oral Dose (mg/kg/day) or Air Concentration estimate (mg/m^3)[1]**	**MOE[2]**	**Combined Routes[3]**	**Combined MOEs[4]**
Adults (Females 13-49 years old)	Aerial ULV Mosquitocide Application 1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Inhalation	0.0047	1,300	X	1,200
		Dermal	0.0015	16,000		
	Aerial ULV Mosquitocide Application 10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Inhalation	0.00070	8,800	X	8,400
		Dermal	0.00013	180,000		
	Ground Mosquitocide Application – WMB	Inhalation	0.0051	1,200	X	1,200
		Dermal	0.00013	180,000		
Children 1 to < 2 years old	Aerial ULV Mosquitocide Application 1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Inhalation	0.0047	500	X	400
		Dermal	0.0026	53,000		
		Incidental Oral	$5.2x10^{-5}$	1,900		
	Aerial ULV Mosquitocide Application 10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Inhalation	0.00070	3,400	X	2,900
		Dermal	0.00022	610,000		
		Incidental Oral	$4.5x10^{-6}$	22,000		
	Ground Mosquitocide Application – WMB	Inhalation	0.0051	460	X	450
		Dermal	0.00022	610,000		
		Incidental Oral	$4.54x10^{-6}$	22,000		

1. See Tables 6.2.3 – 6.2.7 for route-specific exposure inputs and risk estimates.
2. MOE = POD (mg/m^3) ÷ Dose (mg/m^3). See Table 4.2.2.1.2 for PODs.
3. X indicates the exposure scenarios included in the combined MOE.

4. Combined MOE = 1 ÷ [(1/dermal MOE) + (1/inhalation MOE) + (1/incidental oral MOE)], where applicable.

6.3 Residential Risk Estimates for Use in Aggregate Assessment

Table 6.3 reflects the residential risk estimates that are recommended for use in the aggregate assessment for chlorpyrifos.

- Adults (females 13-49 years old): post-application dermal exposures from golfing on treated turf using MS TTR data.
- Children 11 to < 16 years old: post-application dermal exposures from golfing on treated turf using MS TTR data.
- Children 6 to < 11 years old: post-application dermal exposures from golfing on treated turf using MS TTR data.

Exposures to treated turf from mosquitocide applications are completed as stand-alone assessments since mosquitocide applications are typically only made as a result of/in response to a public health need, and require a risk mitigation/risk management determination significantly different from an assessment without a large public health benefit. Therefore, these exposures are not aggregated with exposures from food and drinking water.

Table 6.3. Recommendations for the Residential Exposures for the Chlorpyrifos Aggregate Assessment.

Lifestage	Exposure Scenario	Dose[1]			MOE[2]			
		Dermal (mg/kg/day)	Inhalation (mg/m^3)	Oral (mg/kg/day)	Dermal	Inhalation	Oral	Total
Adults (Females 13-49 Years Old)	Golf Course Turf – MS TTR Data	0.012	N/A	N/A	1,000	N/A	N/A	1,000
Children 11 to < 16 Years Old		0.012	N/A		1,200	N/A		1,200
Children 6 to < 11 Years Old		0.014	N/A		1,600	N/A		1,600

1 Dose = the highest dose for each applicable lifestage of all residential scenarios assessed. Total = dermal + incidental oral (where applicable).

2 MOE = the MOEs associated with the highest residential doses. Total = 1 ÷ [(1/Inhalation MOE) + (1/Dermal MOE) + (1/Incidental Oral MOE)], where applicable.

7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. The durations of exposure identified for chlorpyrifos uses are acute and steady state. The acute aggregate assessment includes food and drinking water only. The steady state aggregate assessment includes food, drinking water, and residential exposures.

A drinking water level of comparison (DWLOC) approach to aggregate risk was used to calculate the amount of exposure available in the total 'risk cup' for chlorpyrifos oxon in drinking water after accounting for any chloropyrifos exposures from food and/or residential uses. This DWLOC can then be compared to the EDWCs to determine if there is an aggregate risk of concern. EFED has provided an updated drinking water assessment (DWA) for chlorpyrifos which includes the EDWCs for aggregate risk assessment. For chlorpyrifos,

DWLOCs were calculated for both the acute and steady state aggregate assessments for infants, children, youths and adult females.

For complete details on the assumptions, results, and characterization of the drinking water analysis refer to EFED's DWA (R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

7.1 Acute Aggregate Risk – DWLOC Approach

The acute aggregate assessment includes only food and drinking water. Acute DWLOCs were calculated for infants, children, youths, and adults. The DWLOCs were calculated assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb. With the FQPA SF reduced to 1X, the lowest acute DWLOC calculated was for infants (<1 year old) at 230 ppb.

Table 7.1.1. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA 10X SF.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Drinking Water Exposure (chlorpyrifos oxon)[4]		Acute DWLOC with FQPA 10X[5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	2200	55	51	1.0	23
Children[1] (1-2 yrs)	1400	35	52	1.0	58
Youths[1] (6-12 yrs)	2800	70	51	1.0	150
Adults[2] (Females 13-49 yrs)	3100	31	103	1.0	51

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=50 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 40 with FQPA SF retained) exposures.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE=100 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 100 with 10X FQPA SF retained) exposures.
[3] **FOOD:** MOE_{food} = POD_{food} (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.4). ARI_{food} = [(MOE_{food})/(MOE_{target})].
[4] **WATER (ARI approach):** ARI_{water}= 1/[(1/ARI_{agg}) – ((1/ARI_{food}) + (1/ARI_{dermal}))]; Where ARI_{agg}=1 (Note:HED is generally concerned when calculated ARIs are less than 1).
MOE_{water} = ARI_{water} x MOE_{target}.
WATER (Reciprocal MOE approach): MOE_{water} = 1 ÷ [(1/MOE_{agg}) – ((1/MOE_{food}) + (1/MOE_{dermal}))]; Where MOE_{agg} =Target MOE.
[5] **DWLOC:** DWLOC ppb= POD_{water} (ppb; from Table 4.2.2.1.2) ÷ MOE_{water}

Table 7.1.2. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Drinking Water Exposure (chlorpyrifos oxon)[4]		Acute DWLOC with FQPA 1X[5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	2200	55	51	1.0	230

Table 7.1.2. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]					
Population	**Food Exposure (chlorpyrifos)[3]**		**Drinking Water Exposure (chlorpyrifos oxon)[4]**		**Acute DWLOC with FQPA 1X[5] (ppb chlorpyrifos oxon)**
	MOE	**ARI**	**MOE**	**ARI**	
Children[1] (1-2 yrs)	1400	35	52	1.0	600
Youths[1] (6-12 yrs)	2800	70	51	1.0	1,500
Adults[2] (Females 13-49 yrs)	3100	31	10	1.0	530

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE= 5 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 4 with FQPA SF reduced to 1X) exposures.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE= 10 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 10 with FQPA SF reduced to 1X) exposures.
[3] **FOOD:** MOE_{food} = POD_{food} (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.4).
ARI_{food} = [$(MOE_{food})/(MOE_{target})$].
[4] **WATER (ARI approach):** ARI_{water}= $1/[(1/ARI_{agg}) – ((1/ARI_{food}) + (1/ARI_{dermal}))]$; Where ARI_{agg}=1 (Note:HED is generally concerned when calculated ARIs are less than 1).
MOE_{water} = ARI_{water} x MOE_{target}.
WATER (Reciprocal MOE approach): $MOE_{water} = 1 ÷ [(1/MOE_{agg}) – ((1/MOE_{food}) + (1/MOE_{dermal}))]$; Where MOE_{agg} =Target MOE.
[5] **DWLOC:** DWLOC ppb= POD_{water} (ppb; from Table 4.2.1.2) ÷ MOE_{water}

7.2 Steady State Aggregate Risk – DWLOC Approach

The steady state aggregate assessment includes dietary exposures from food and drinking water and dermal exposures from residential uses. Treated golf course turf represent the highest residential dermal exposures. Aggregate DWLOCs are presented below for the population subgroups of infants (< 1 year old), children (1-2 years old), youths (6-12 years old), and adults (females 13-49 years old). The assessment of these index lifestages is protective for the other population subgroups, including youths 11 to < 16 years old. The DWLOCs were calculated assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. The lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb if the FQPA SF is retained at 10X and the lowest steady state DWLOC calculated was for infants (< 1 year old) at 43 ppb if the FQPA SF is reduced to 1X.

Table 7.2.1. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA 10X SF.[1,2]							
Population	**Food Exposure (chlorpyrifos)[3]**		**Residential Exposure (chlorpyrifos)[4]**		**Drinking Water Exposure (chlorpyrifos oxon)[5]**		**Steady State DWLOC with FQPA 10X[6] (ppb chlorpyrifos oxon)**
	MOE	**ARI**	**MOE**	**ARI**	**MOE**	**ARI**	
Infants[1] (<1 yr)	550	14	NA	NA	54	1.1	4.0
Children[1] (1-2 yrs)	410	10	NA	NA	55	1.1	9.9
Youths[1] (6-12 yrs)	700	18	1,600	40	44	1.1	21

Table 7.2.1. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA 10X SF.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Residential Exposure (chlorpyrifos)[4]		Drinking Water Exposure (chlorpyrifos oxon)[5]		Steady State DWLOC with FQPA 10X[6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Adults[2] (Females 13-49 yrs)	1040	10	1,000	10	124	1.2	7.5

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=50 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 40) exposure.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE=100 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 100 with 10X FQPA SF retained) exposure.
[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.5).
$ARI_{food} = [(MOE_{food})/(MOE_{target})]$.
[4] **RESIDENTIAL:** $MOE_{residential} = 1 \div (1/\text{Dermal MOE})$, (see Table 6.3).
[5] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) – ((1/ARI_{food}) + (1/ARI_{residential}))]$; Where ARI_{agg}=1 (Note:HED is generally concerned when calculated ARIs are less than 1).
$MOE_{water} = ARI_{water} \times MOE_{target}$.
WATER (Reciprocal MOE approach): $MOE_{water} = 1/ [(1/MOE_{agg}) – ((1/MOE_{food}) + (1/MOE_{residential}))]$; Where MOE_{agg} =Target MOE.
[6] **DWLOC:** DWLOC ppb= PoD_{water} (ppb; from Table 4.2.2.1.2) /MOE_{water}

Table 7.2.2. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Residential Exposure (chlorpyrifos)[4]		Drinking Water Exposure (chlorpyrifos oxon)[5]		Steady State DWLOC with FQPA 1X[6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	550	140	NA	NA	5.0	1.0	43
Children[1] (1-2 yrs)	410	102	NA	NA	5.0	1.0	110
Youths[1] (6-12 yrs)	700	180	1,600	400	4.0	1.0	230
Adults[2] (Females 13-49 yrs)	1040	104	1,000	100	10	1.0	91

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=5 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 4 with FQPA SF reduced to 1X) exposure.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE= 10 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 10 with FQPA SF reduced to 1X) exposure.
[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.5).
$ARI_{food} = [(MOE_{food})/(MOE_{target})]$.
[4] **RESIDENTIAL:** $MOE_{residential} = 1 \div (1/\text{Dermal MOE})$, (see Table 6.3).
[5] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) – ((1/ARI_{food}) + (1/ARI_{residential}))]$; Where ARI_{agg}=1 (Note:HED is generally concerned when calculated ARIs are less than 1).
$MOE_{water} = ARI_{water} \times MOE_{target}$.
WATER (Reciprocal MOE approach): $MOE_{water} = 1/ [(1/MOE_{agg}) – ((1/MOE_{food}) + (1/MOE_{residential}))]$; Where MOE_{agg} =Target MOE.
[6] **DWLOC:** DWLOC ppb= PoD_{water} (ppb; from Table 4.2.2.1.2) /MOE_{water}

8.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Spray drift is a potential source of exposure to those nearby pesticide applications. This is particularly the case with aerial application, but, to a lesser extent, spray drift can also be a potential source of exposure from the ground application methods (e.g., groundboom and airblast) employed for chlorpyrifos. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling coupled with methods employed for residential risk assessments for turf products.

In the 2011 occupational and residential exposure assessment, the potential risks to bystanders from spray drift and exposure from volatilization were identified as possible concerns. Spray drift is the movement of aerosols and volatile components away from the treated area during the application process. The potential risks from spray drift and the impact of potential risk reduction measures were assessed in July 2012 (J. Dawson *et al.,* D399483, 07/13/2012). This evaluation supplemented the 2011 assessment where limited monitoring data indicated risks to bystanders. To increase protection for children and other bystanders, chlorpyrifos technical registrants voluntarily agreed to lower application rates and to other spray drift mitigation measures (R. Keigwin, 2012). As of December 2012, spray drift mitigation measures and use restrictions appear on all chlorpyrifos agricultural product labels (including a restriction to nozzles and pressures that produce a medium to coarse droplet size). Spray drift risk estimates have been re-presented here for children and adults using endpoints based on 10% RBC AChE inhibition and PODs derived with a PBPK model; and assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X.

If the FQPA SF is retained at 10X, there were no dermal risk estimates of concern from indirect spray drift exposure to chlorpyrifos at the field edge for adults (females 13-49 years old) (MOEs $\geq$ 100). For children 1 to < 2 years old, there were no combined (dermal + incidental oral) risk estimates of concern from indirect spray drift exposure to chlorpyrifos (MOEs $\geq$ 40), except for two scenarios. For aerial applications at 2.3 lb ai/A, a distance of 10 feet results in MOEs not of concern. However, the 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of 80 feet for coarse or very coarse droplets and 100 feet for medium droplets for aerial applications are required for application rates $\geq$ 2.3 lb ai/A. For airblast applications > 3.76 lb ai/A, distances of 10 to 25 feet results in MOEs not of concern (LOC = 40). However, the 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of $\geq$ 25 feet and medium to coarse drops are required for airblast applications at rates >3.76 lb ai/A. Therefore, there are no risk estimates of concern incorporating the agreed-upon buffer distances and droplet sizes/nozzle types by the EPA and the technical registrants in 2012.

If the FQPA SF is reduced to 1X, there were no dermal risk estimates of concern from indirect spray drift exposure to chlorpyrifos at the field edge for adults (females 13-49 years old) (MOEs $\geq$ 10) and no combined (dermal + incidental oral) risks for children 1 to < 2 years old at the field edge (MOEs $\geq$ 4).

Table 8.1. Summary of Spray Drift Distances from the Field Edge for Chlorpyrifos MOEs to be > LOCs with 10X FQPA SF Retained.[1]

Application Rate (lb ai/A)	Nozzle Droplet Type/ Canopy Density	Adult Buffer Summary			Children 1 to < 2 Years Old Buffer Summary (Dermal + Incidental Oral)		
		Distance (Feet) from the Field Edge Needed For MOE > LOC of 100			Distance (Feet) from the Field Edge Needed for MOE > LOC of 40		
		Aerial[2]	Groundboom[2]	Airblast	Aerial[2]	Groundboom[2]	Airblast
6.0	Medium/ Coarse for Aerial and Ground-boom	NA	NA	0	NA	NA	25
4.3			0			0	10
4.0							10
3.76							10
3.0							0
2.3	Sparse for Airblast	0			10		
2.0					0		
1.5							
1.0							

1 Per December 2012 spray drift mitigation memorandum, aerial application of greater than 2 lb ai/A is only permitted for Asian Citrus Psylla control, up to 2.3 lb ai/A.
2 NA = not allowable.

Table 8.2. Summary of Spray Drift Distances from the Field Edge for Chlorpyrifos MOEs to be > LOCs with FQPA SF Reduced to 1X.[1]

Application Rate (lb ai/A)	Nozzle Droplet Type/ Canopy Density	Adult Buffer Summary			Children 1 to < 2 Years Old Buffer Summary (Dermal + Incidental Oral)		
		Distance (Feet) from Field Edge Needed for MOE > LOC of 10			Distance (Feet) From Field Edge Needed for MOE > LOC of 4		
		Aerial[2]	Groundboom[2]	Airblast	Aerial[2]	Groundboom[2]	Airblast
6.0	Medium/ Coarse for Aerial and Ground-boom	NA	NA	0	NA	NA	0
4.3			0			0	
4.0							
3.76							
3.0							
2.3	Sparse for Airblast	0			0		
2.0							
1.5							
1.0							

1 Per December 2012 spray drift mitigation memorandum, aerial application of greater than 2 lb ai/A is only permitted for Asian Citrus Psylla control, up to 2.3 lb ai/A.
2 NA = not allowable.

9.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

In January 2013, a preliminary assessment of the potential risks from volatilization was conducted.[18] The assessment evaluated the potential risks to bystanders, or those who live and/or work in proximity to treated fields, from inhalation exposure to vapor phase chlorpyrifos and chlorpyrifos-oxon emitted from fields following application of chlorpyrifos. The results of the January 2013 assessment indicated that offsite concentrations of chlorpyrifos and

[18] R. Bohaty, C. Peck, A. Lowit, W. Britton, N. Mallampalli, A. Grube. Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization. 1/31/13. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399484, D400781.

chlorpyrifos-oxon may exceed the target concentration based on the toxicological endpoints used at that time.[19]

One significant area of uncertainty described in the preliminary assessment was the use of the aerosolized chlorpyrifos inhalation toxicity study -- as opposed to chlorpyrifos vapor -- for evaluation of lung AChE resulting from field volatilization. Because field volatilization is the production and release of vapor into the atmosphere after sprays have settled on treated soils and plant canopies, the vapor, rather than the aerosol, is the relevant form for evaluation of bystander volatilization exposures. However, EPA lacked chlorpyrifos vapor toxicity data at the time it conducted the preliminary volatilization assessment in 2013. Following the release of the preliminary volatilization assessment, DAS conducted, high quality nose-only vapor phase inhalation toxicity studies for both chlorpyrifos and chlorpyrifos-oxon[20] to address this uncertainty.

In June 2014, a reevaluation of the 2013 preliminary volatilization assessment was conducted to present the results of the vapor studies and their impact. In the vapor studies, female rats were administered a saturated vapor, meaning that the test subjects received the highest possible concentration of chlorpyrifos or chlorpyrifos-oxon which can saturate the air in a closed system. At these saturated concentrations, no statistically significant inhibition of AChE activity was measured in RBC, plasma, lung, or brain at any time after the six-hour exposure period in either study. Under actual field conditions, indications are that exposures to vapor phase chlorpyrifos and its oxon would be much lower as discussed in the January 2013 preliminary volatilization assessment.

Because these new studies demonstrated that no toxicity occurred even at the saturation concentration, which is the highest physically achievable concentration, then there are no anticipated risks of concern from exposure to the volatilization of either chlorpyrifos or chlorpyrifos oxon. In June 2014, the January 2013 volatilization assessment was revised to reflect these findings.[21]

10.0 Cumulative Exposure/Risk Characterization

OPs, such as chlorpyrifos, share the ability to inhibit AChE through phosphorylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic

[19]EPA MRID# 48139303**:**Acute Inhalation Exposure of Adult Crl:CD(SD) Rates to Particulate Chlorpyrifos Aerosols: Kinetics of Concentration-Dependent Cholinesterase (ACHE) Inhibition in Red Blood Cells, Plasma, Brain and Lung; Authors: J. A. Hotchkiss, S. M. Krieger, K. A. Brzak, and D. L. Rick; Sponsor: Dow AgroSciences LLC.

[20]W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D411959. TXR# 0056694. EPA MRID# 49119501.

W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos-Oxon Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain, and Lung Cholinesterase Activity in Female CD(SD):Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D415447. TXR# 0056869. EPA MRID# 49210101.

[21] W. Britton. W. Irwin. J. Dawson. A. Lowit. E. Mendez. Chlorpyrifos:Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies. 6/25/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D417105.

neurotoxicity. This shared MOA/AOP is the basis for the OP common mechanism grouping per OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999). The 2002 and 2006 CRAs used brain AChE inhibition in female rats as the source of dose response data for the relative potency factors and PODs for each OP, including chlorpyrifos. Prior to the completion of Registration Review, OPP will update the OP CRA on AChE inhibition to incorporate new toxicity and exposure information available since 2006.

OPP has conducted the chlorpyrifos human health risk assessment both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X) due to uncertainties associated with neurodevelopmental effects in children and exposure to OPs. There is a lack of an established MOA/AOP for the neurodevelopment outcomes which precludes the Agency from formally establishing a common mechanism group per the *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999) based on that outcome. Moreover, the lack of a recognized MOA/AOP and other uncertainties with exposure assessment in the epidemiology studies prevent the Agency from establishing a causal relationship between OP exposure and neurodevelopmental outcomes. As part of an international effort, the ORD has been developing a battery of NAMs for evaluating developmental neurotoxicity. Information from these NAMs may be used in the future as part of the weight of evidence evaluation of neurodevelopmental toxicity potential for OPs. These NAMs will be presented, using the OPs as a case study, to the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Scientific Advisory Panel (SAP) in September 2020. The Agency will also continue to evaluate the epidemiology studies associated with neurodevelopmental outcomes and OP exposure prior to the release of the revised DRA. During this period, the Agency will determine whether or not it is appropriate to apply the guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* for the neurodevelopment outcomes.

11.0 Occupational Exposure/Risk Characterization

11.1 Occupational Handler Exposure and Risk Estimates

The term handlers is used to describe those individuals who are involved in the pesticide application process. There are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of a chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event. Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from chlorpyrifos use. For purpose of occupational handler assessment, the parent chlorpyrifos is the relevant compound.

Current labels generally require that handlers use normal work clothing (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. Also, some products are marketed in engineering controls such as water-soluble packets. In order to determine what level of personal protection is required to alleviate risk concerns and to ascertain if label modifications are needed, steady state exposure and risk estimates were updated

for occupational handlers of chlorpyrifos for a variety of scenarios at differing levels of personal protection including engineering controls.

The previously assessed occupational handler assessments have been updated to incorporate the approach applied for PBPK-derivation of PODs for adults based on 10% RBC AChE inhibition. The results have been summarized assuming both that the database uncertainty factor has been retained at 10X and has been reduced to 1X. If the database uncertainty factor is retained, the total LOC for occupational exposure assessment is 100X for adults (represented by females 13-49). If the database uncertainty SF is reduced to 1X, the total LOC for occupational exposure assessment is 10X for adults (represented by females 13-49). The occupational handler scenarios, exposure assumptions and inputs have not changed since the previous assessment[22].

Combining Exposures/Risk Estimates:

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological endpoint, RBC AChE inhibition, is the same for these exposure routes.

Summary of Occupational Handler Non-Cancer Exposures and Risk Estimates

Detailed result tables are provided in Appendix 10.

In this assessment for the non-seed treatment scenarios, a total of 288 occupational handler exposure scenarios were assessed. Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the database uncertainty 10X SF has been retained (LOC = 100), 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Risks of concern for 45 additional exposure scenarios could potentially be mitigated if engineering controls are used. If the database uncertainty 10X SF is reduced to 1X (LOC = 10), 19 scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 10). Risks of concern for 15 additional scenarios could potentially be mitigated if engineering controls are used.

For the seed treatment scenarios, a total of 93 scenarios were assessed (40 short-term primary handler scenarios + 40 intermediate-term primary handler scenarios + 13 short- and intermediate-term planting scenarios). Assuming the 10X database uncertainty factor has been retained (LOC = 100), 12 short-term exposure and 10 intermediate-term scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100) for primary handlers; there are no short- or intermediate scenarios of concern for seed planters. Assuming the 10X database uncertainty factor has been reduced to 1X (LOC = 10), there are no short- or intermediate-term risk estimates of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs > 10) for primary handlers or seed planters.

[22] Some occupational handler exposure inputs have changed since the previous ORE assessments were completed in 2011 (W. Britton, D388165, 06/27/2011), 2014 (W. Britton, D424484, 12/29/2014), and 2016 (W. Britton, D436317, 11/03/2016) (e.g., amount of seed treated per day, seed planted per day). The changes to the inputs are not expected to result in significant changes to the risk estimates and have not been updated at this time.

11.2 Occupational Post-Application Exposure and Risk Estimates

11.2.1 Dermal Post-Application Exposure and Risk Estimates

Detailed result tables are provided in Appendix 11.

A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessments; these assumptions and exposure factors remain unchanged from the previous assessment (W. Britton, D424484, 12/29/2014).

The 2011 and 2014 occupational and residential exposure assessments incorporated 7 Chemical-specific DFR studies. These studies used 5 different formulations and were conducted on 12 different crops. Specifically, the DFR studies examined the use of 1) emulsifiable concentrate formulations on sugarbeets, pecans, citrus, sweet corn, cotton, and turf; 2) wettable powder formulations on almonds, apples, pecans, cauliflower, tomato and turf; 3) granular formulations on sweet corn and turf; 4) a total release aerosol formulation on ornamentals; and 5) a microencapsulated liquid formulation on ornamentals. The submitted studies were reviewed by HED. Despite limitations, HED recommended the use of all or some of the data in the studies to assess post-application risks to chlorpyrifos except for the tomato DFR data. Summaries for all DFR studies can be referenced in Appendix I of D424484 (W. Britton, 12/29/2014).

The current assessment uses the same DFR data and crop pairings as the previous occupational and residential exposure assessments. For example, DFR data for an individual crop was applied to that specific crop, as well as to crops in the same crop grouping (e.g., cauliflower data was used for cauliflower and all other cole crops). For other crops in which no crop-specific or crop group-specific data are available, the DFR data for the crop deemed the closest match were used as surrogates to calculate potential exposure (e.g., cauliflower data were also used for strawberries, cranberries, and leafy vegetables). Additionally, whenever possible, a label use was assessed using DFR data for the same formulation type. A full description of the criteria for selection of DFR data for assessment of post-application exposures to individual crops/crop groupings can be referenced in Section 2.4.3 of D388165 (W. Britton, 06/27/2011).

Summary of Occupational Post-Application Dermal Exposure and Risk Estimates

Current labels require a Restricted Entry Interval (REI) of 24 hours from most crops and activities, but in some cases such as tree fruit, REIs are up to 5 days after application. Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} of 10X has been retained, the majority of the post-applications scenarios are not of concern 1 day after application (REI = 24 hours). However, for some activities such as irrigation, hand harvesting, scouting, and thinning result in risks of concern up to as many as 10 days following application for the non-microencapsulated formulations and > 35 days for the microencapsulated formulation.

Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} has been reduced to 1X, the majority of the post-application risk estimates are not of concern 1 day after application (REI = 24 hours).

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Berry: Low	Strawberry	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 - 4
	Cranberry	1.5			0	0 - 5
Field and Row Crops: Low to Medium	Clover (Grown for Seed)	1.9	MRID 44748102 (sugar beet EC)	MN	1	1
				OR	0	1
	Perennial Grass Seed Crops	1.0	MRID 44748102 (sugar beet EC)	MN	0	1
				OR	0	1
	Alfalfa	1.0	MRID 44748102 (cotton EC)	TX	0 – 1	1
	Cotton[1]	1.0	MRID 44748102 (cotton EC)	CA	0	0
				MS	0	0 – 1
				TX	0	0 – 1
	Peppermint/ Spearmint	2.0	MRID 44748102 (sugar beet EC)	MN	0 - 1	1
				OR	0	0 – 1
	Wheat	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 - 1
				MN	0	0 - 1
	Soybean	1.0	MRID 44748102 (cotton EC)	MS	0	0 – 1
	Sugar Beet	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 – 1
				MN	0	0 – 1
				OR	0	0 – 1
Field and Row Crops: Tall	Corn: Sweet; Corn: Field, Including Grown for Seed	1.5	MRID 44748102 (sweet corn EC)	IL	0 – 1	0 – 3
				MN	0 – 1	0 – 3
				OR	0 – 1	0 – 2
	Corn: Sweet; Corn: Field, Including Grown for Seed	1.0	MRID 44748102 (sweet corn EC)	IL	0 – 1	0 – 2
				MN	0 – 1	0 – 2
				OR	0 – 1	0 – 2
	Sorghum	1.0	MRID 44748102 (sweet corn EC)	IL	0	0 – 1
				MN	0	0 – 1
	Sunflowers	1.5	MRID 44748102 (sweet corn EC)	IL	0	1
				MN	0	1
Tree Fruit: Deciduous	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines	2.0	MRID 44748101 (apple WP)	CA	0	1
				WA	0	1 – 2
				NY	0	1 – 2

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
	(Dormant and Delayed Dormant)					
	Nectarine & Peaches (Dormant and Delayed Dormant)	3.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	2 - 3
	Cherries (Sour)	4.0	MRID 44748101 (apple WP)	CA	0 – 1	1 – 5
				WA	0 – 2	2 – 6
				NY	0 – 3	2 – 6
Tree Fruit: Evergreen	Conifer Trees and Christmas Tree Plantations	1.0	MRID 43062701 (citrus EC)	CA (scouting, harvesting seed cone, irrigation)	0	0 – 1
			MRID 44839601 (turf EC)	MS (harvesting/ seedling production)	0	0
	Citrus	6.0 (CA and AZ)	MRID 43062701 (citrus EC)	CA	0	0 – 2
		4.0	MRID 43062701 (citrus EC)	CA	0	0
Forestry	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant)	2.0	MRID 44748101 (apple WP)	WA	0 – 1	2 – 4
				NY	0 – 1	2 – 4
	Deciduous Trees (Plantations and Seed Orchards)	1.0	MRID 44748101 (apple WP)	CA	0	0 – 1
				WA	0	0 – 1
				NY	0	0 – 1
Tree Nuts[2]	Almonds	2.0	MRID 44748101 (almond WP)	CA (arid)	0	1
	Almonds (Dormant and Delayed Dormant)	4.0	MRID 44748101 (almond WP)	CA (arid)	0	1 – 3
	Filberts, Pecans, Walnuts	2.0	MRID 44748101 (pecan EC)	GA	0	0
				LA	0	0
				TX	0	0

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
	Filberts & Walnuts (Dormant and Delayed Dormant)[3]	2.0	MRID 44748101 (pecan EC)	GA	0	0
Ornamentals/ Nurseries (Outdoor Only)	Deciduous Trees in Nurseries and Orchards Except Apples (Dormant and Delayed Dormant) Non-bearing Apple Trees	1.0	MRID 44748101 (apple WP)	CA	0	0
				WA	0	1
				NY	0	0
Ornamentals/ Nurseries (Outdoor Only)	Non-bearing Fruit and Nut Trees (Almonds, Citrus, Filbert, Cherry, Pear, Plum/Prune)	4.0	MRID 43062701 (citrus EC)	CA	0	0
	Non-bearing Fruit Trees (Peach, Nectarine)	3.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	2
	Non-bearing Fruit Trees (Apple)	2.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	1
	Conifers in Nurseries	1.0	MRID 43062701 (citrus EC)	CA	0	0
Field and Row Crops: Low to Medium (Outdoor Only)	Ornamentals	2.0	MRID 44748102 (sugar beet EC)	CA	0 – 1	1 – 5
				MN	0 – 1	1 – 3
				OR	0 – 1	1 – 2
Vegetable: Root and Tuber	Carrot	0.94	MRID 44748102 (sugar beet EC)	CA	0	0 – 1
				MN	0 – 1	0 – 1
	Radish	1.0	MRID 44748102 (sugar beet EC)	MN	0 – 1	0 – 1
Vegetable: Fruiting	Pepper	1.0	MRID 44748102 (cotton EC)	CA	0	0 – 2
				MS	0 – 1	1
				TX	0 – 1	1
Vegetable: Head and Stem Brassica	Broccoli, Brussel Sprouts, Cabbage, and Cauliflower	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 – 10
Vegetable: Leafy	Bok Choy, Collards, Kale, Kohlrabi	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 – 6
	Asparagus	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 – 1

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Stalk and Stem: Vegetable				MN	0 – 1	1
				OR	0	0 – 1
	Non-bearing Pineapple	2.0	MRID 44748102 (cotton EC)	MS	0	1
Vine/ Trellis	Grapes (Dormant and Delayed Dormant) Grapes (Post-harvest and Prior to Budbreak)	2.0	MRID 43062701 (citrus EC)	CA	0	1
Turf	Turf for Sod and Seed	3.76	MRID 44829601 (turf EC and WP)	CA	0	1
				IN	0	1
				MS	0	1
	Turf for Golf Course	1.0	MRID 44829601 (turf EC and WP)	CA	0	0
				IN	0	0
				MS	0	0
Granular Applications						
Field and Row Crops: Low to Medium	Soybeans	1.0	MRID 44748102 (sweet corn G)	IL	0	0
	Sugar Beet	2.0	MRID 44748102 (sweet corn G)	IL	0	0
				OR	0	0 – 1
	Peanuts	4.0	MRID 44748102 (sweet corn G)	IL	0	0 – 1
Field and Row Crops: Tall	Corn, Sweet; Corn, Field; Corn, Grown for Seed	2.0	MRID 44748102 (sweet corn G)	IL	0	0 – 1
				OR	0 – 1	0 – 1
Nursery	Woody Ornamentals (In Container and Field Grown) – Preharvest	6.0 (Note: all other ornamental application rates are either 1.1 or 1.0 lb ai/A)	MRID 44748102 (sweet corn G)	IL	0	0
				OR	0	0
Turf	Turf for Sod or Seed	1.0	MRID 44829601 (turf G and fertilizer)	CA	0	0
	Golf Course				0	0
Microencapsulated Formulation Application						

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Nursery (Microencap. Formulations)	Ornamentals – Nurseries and Greenhouses	1.4	MRID 46722702 (smooth ornamentals ME)	Greenhouse	0 - 3	1 to > 35
Greenhouse						
Greenhouse (Total Release Fogger and. Liquid Concentrate Formulations)	Ornamentals – *Liquid Concentrates*	2	MRID 46722701 (hairy ornamentals ME)	Greenhouse	0 – 1	1 – 5
	Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers*	0.29	MRID 46722701 (hairy ornamentals ME)	Greenhouse	0	0 – 2

1. Mechanical harvesting (tramper) activities are not anticipated to result in significant chlorpyrifos exposures due to the 14-day pre-harvest interval (PHI).
2. Exposure during nut sweeping and windrowing results from contact with soil, for which transfer coefficients are currently unavailable. Assessment options include requesting exposure data or a qualitative comparison with a post- application exposure scenario assumed to result in higher exposure. Note that dislodgeable soil residue would be needed for an exposure assessment, as this would be the media contacted by worker's performing this activity. A study monitoring such exposure is available (Exposure of Workers During Reentry into Pecan Groves Treated with Super-Tim 80WP, Griffin Corporation, 1994; EPA MRID 43557401), however has yet to be evaluated for derivation of transfer coefficients.
2. Transfer coefficients for dormant pruning are unavailable. Assessment options include requesting exposure data or a qualitative comparison with a post-application exposure scenario assumed to result in higher exposure. Note that dislodgeable branch or bark residue would be needed for an exposure assessment, as this would be the surface contacted by workers performing this activity.

11.2.2 Dermal Post-Application Exposure and Risk Estimates: Chlorpyrifos Oxon

Chlorpyrifos is activated by desulfuration, reacting in bioactivation to the more toxic and potent AChE inhibitor, chlorpyrifos oxon. The oxon is highly unstable due to rapid deactivation through hydrolytic cleavage by a process called dearylation which releases TCP. Workers reentering an indoor environment (i.e., greenhouses) previously treated with chlorpyrifos could potentially be exposed to the oxon as chlorpyrifos degrades. Available exposure data indicate chlorpyrifos oxon may form in indoor environments.[23] Toxicity adjustment factors (TAFs) were used to estimate the potency of chlorpyrifos oxon relative to chlorpyrifos. HED determined the oxon to be between 11.9 (acute) and 18 (chronic) times more toxic than the parent.

Dermal exposure to the oxon on foliar surfaces from reentry into an outdoor environment (e.g., field crops and orchards) previously treated with chlorpyrifos is not anticipated and, therefore, has not been assessed. No occupational exposure studies (handler, post-application, or DFR) were identified that quantified the levels of oxon present in the environment. However, a search of open literature for the 2011 assessment resulted in 4 plant metabolism studies which measured surface residues. Three plant metabolism studies[24] measured leaf surface residues of the oxon in outdoor environments that were either well below the parent, not detectable, or detected at a level just above the level of detection (LOD). The potential for exposure to the oxon is further minimized due to rapid deactivation of the oxon to TCP. Further, the dietary exposure risk assessment[25] conducted in support of registration review concludes the following, "all residues in food are assumed to be parent chlorpyrifos since the chlorpyrifos oxon is not typically found in foods in monitoring data or crop field trials."

The 4th plant metabolism study, a tomato and green bean metabolism study conducted in a greenhouse, was less definitive than the other three plant metabolism studies regarding oxon presence; therefore, there is concern that the formation of the oxon may be greater and its deactivation to TCP slower in greenhouses when compared to the outdoor environment. The study results indicate that oxon residue is from 9 to 14X less than the parent from fruit analyzed on the day of application in flat and asymmetric roof greenhouses. The proportion of oxon to parent is less for all days which measurable levels were observed (all but 8 and 15 days after application). The oxon was detected until day 5 with levels between 5 and 6X below that of the parent. It should be noted that residues of chlorpyrifos and oxon were measured from analysis of whole fruit samples. HED typically assesses occupational post-application exposure and risk based upon the potential for transfer from surface residues. The whole fruit samples, which include surface residues, as well as residues which may have been contained within the fruit

[23] J.L. Martinez Vidal, et al. 1998. Diminution of Chlorpyrifos and Chlorpyrifos Oxon in Tomatoes and Green Beans Grown in Greenhouses. J. of Agric. and Food Chem. 46 (4), 1440–1444.

[24] Iwata, Y. et al. 1983. Chlorpyrifos Applied to California Citrus: Residue Levels on Foliage and On and In Fruit. J. Agric. Food Chem. 31(3), 603-610.

H. Jin and G.R. Webster. 1997. Persistence, Penetration, and Surface Availability of Chlorpyrifos, Its Oxon, and 3,5,6-Trichloro-2-pyridinol in Elm Bark. 45(12), 4871-4876.

R. Putnam, et al. 2003. The Persistence and Degradation of Chlorthalonil and Chlorpyrifos in a Cranberry Bog. J. Agric. Food Chem. 51(1), 170-176.

[25] D. Drew. Chlorpyrifos: Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review. 11/18/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D424486.

sample, may overestimate the amount of oxon on the fruit surface. Regardless, the 2011 occupational and residential exposure assessment recommended additional data to measure the chlorpyrifos and oxon residues on leaf surfaces following treatment with a liquid formulation in greenhouses in order to address these uncertainties and more accurately address the risk potential for exposure from occupational reentry into greenhouses treated with chlorpyrifos. To date, no data have been submitted to address these uncertainties. As a result, HED has assessed occupational dermal post-application exposures in greenhouses using conservative assumptions of oxon formation.

In order to account for the formation of and potential increased toxicity from exposure to chlorpyrifos oxon, a total toxic residue approach was applied which combines chlorpyrifos and chlorpyrifos oxon (expressed as toxicity equivalents). The total toxic residue approach[26] estimates the chlorpyrifos oxon equivalent residues by 1) assuming a specific fraction of the measured chlorpyrifos dislodgeable foliar residues are available as the oxon and 2) factoring in the relative potency of chlorpyrifos oxon with use of a TAF. It was conservatively assumed that 5% (0.05) of the total chlorpyrifos present as DFR in greenhouses is available for worker contact during post-application activities. This assumption is based on a review of available TTR and DFR data for other OPs where both the parent and metabolite were measured in residue samples. Five percent was found to be the high-end value for the percent of parent that metabolized during the course of the residue studies. The chronic TAF (which is appropriate for steady state assessment) of 18 was derived from BMD analysis of inhibition of RBC AChE in adult female rats (adult male rats not examined) observed in the repeated phase of the CCA study. Once predicted, these total toxic (dislodgeable foliar) residues are used to estimate exposures from post-application activities in greenhouse and risks are estimated with used of the steady state POD for occupational exposures, 3.63 mg/kg/day.

Summary of Occupational Post-Application Dermal Exposure and Risk Estimates with Use of Total Toxic Residue Approach

Due to uncertainty regarding the formation of chlorpyrifos oxon in greenhouses, HED also estimated risks for reentry into treated greenhouses (all 4 formulations) for the parent chlorpyrifos plus chlorpyrifos oxon using a total toxic residue approach. When the total toxic residue approach is used and with the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X UF_{DB} has been retained, MOEs are not of concern 0 to 6 days after treatment for non-microencapsulated formulations. For the microencapsulated formulation, MOEs are not of concern 3 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

When the total toxic residue approach is used and with the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the 10X UF_{DB} has been reduced to 1X, there are no risk estimates of concern with the current labeled REI (24 hours), except for the microencapsulated formulation. For the microencapsulated formulation, MOEs are of concern 0 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

[26] Total DFR (µg/cm^2) = [Chlorpyrifos DFR (µg/cm^2) * TAF] + [Chlorpyrifos DFR (µg/cm^2)]

Table 11.2.2.1. All Formulations - Summary of Post-Application Risk Assessment for Total Toxic Residue (Chlorpyrifos + Chlorpyrifos Oxon) Using Chlorpyrifos -Specific DFR Data.						
Crop Group	**Crop**	**App Rates (lbs. ai/ acre)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Nursery	Ornamentals – Nurseries and Greenhouses	0.0070 lb ai/gal 1.4 lb ai/A	MRID 46722702 (smooth ornamentals ME)	Greenhouse	0 to >35	3 to > 35
Field and Row Crops – Low to Medium	Ornamentals – Nurseries and Greenhouses	2.0	MRID 44748102 (sugar beet EC)	CA	0 – 1	1 – 6
				OR	0 – 1	1 – 2
				MN	0 – 1	1 – 5
Nursery	Ornamentals - Greenhouse	0.29	DFR: MRID 46722701 (hairy ornamentals -aerosol)	Greenhouse	0 – 1	0 – 5

Restricted Entry Interval

Chlorpyrifos is classified as Toxicity Category II via the dermal route and Toxicity Category IV for skin irritation potential. It is not a skin sensitizer. There were some risk estimates of concern related to contacting chlorpyrifos treated foliage both outdoors and in greenhouses; therefore, HED is recommending that the REI be revised on the label to address those concerns.

Table 11.2.2.2. Acute Toxicity Profile: Chlorpyrifos.				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute Oral (rat)	44209101	LD_{50} = 223 mg/kg (M & F)	II
870.1200	Acute Dermal (rabbit)	44209102	$LD_{50} \geq$ 5000 mg/kg (M & F)	IV
870.1300	Acute Inhalation (rat)	00146507	LC_{50} > 0.2 mg/L (M & F)	II[1,2]
870.2400	Primary Eye Irritation (rabbit)	44209103	Minimum to mild irritant	IV
870.2500	Primary Skin Irritation (rabbit)	44209104	Mild irritant	IV
870.2600	Dermal Sensitization (guinea pig)	44209105	Non-Sensitizing (Buehler Method)	N/A

[1] Study classified as Supplementary (TXR 0004633, S. Saunders, 08/26/1985)
[2] Study requirement waived and Toxicity Category II assigned (TXR 5001957, M. Hashim, 12/20/1997)

11.2.3 Inhalation Post-Application Exposure and Risk Estimates

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of

pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037). The Agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219). During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for chlorpyrifos.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments.

The Worker Protection Standard for Agricultural Pesticides contains requirements for protecting workers from inhalation exposures during and after greenhouse applications through the use of ventilation requirements. [40 CFR 170.110, (3) (Restrictions associated with pesticide applications)].

A post-application inhalation exposure assessment is not required as exposure is expected to be negligible. Seed treatment assessments provide quantitative inhalation exposure assessments for seed treaters and secondary handlers (i.e., planters). It is expected that these exposure estimates would be protective of any potential low-level post-application inhalation exposure that could result from these types of applications. As described in Section 4, a quantitative occupational post-application inhalation risk assessment is not required for chlorpyrifos or chlorpyrifos oxon due to the lack of toxicity from the vapor phase of these chemicals, even at the saturation concentration.

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13.0 List of Appendices

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Appendix 1: Summary of OPP's ChE Policy and Use of BMD Modeling

OPP's ChE policy (USEPA, 2000[27]) describes the way ChE data are used in human health risk assessment. The following text provides a brief summary of that document to provide context to points of departure selected.

AChE inhibition can be inhibited in the central or peripheral nervous tissue. Measurements of AChE or cholinesterase (ChE) inhibition in peripheral tissues (e.g., liver, diaphragm, heart, lung etc) are rare. As such, experimental laboratory studies generally measure brain (central) and blood (plasma and red blood cell, RBC) ChE. Blood measures do not represent the target tissue, per se, but are instead used as surrogate measures for peripheral toxicity in studies with laboratory animals or for peripheral and/or central toxicity in humans. In addition, RBC measures represent AChE, whereas plasma measures are predominately BuChE. Thus, RBC AChE data may provide a better representation of the inhibition in target tissues. As part of the dose response assessment, evaluations of neurobehavior and clinical signs are performed to consider the dose response linkage between AChE inhibition and apical outcomes.

Refinements to OPP's use of ChE data have come in the implementation of BMD approaches in dose response assessment. Beginning with the OP CRA, OPP has increased its use of BMD modeling to derive PODs for AChE inhibiting compounds. Most often the decreasing exponential empirical model has been used.

OPP does not have a defined benchmark response (BMR) for OPs. However, the 10% level has been used in the majority of dose response analyses conducted to date. This 10% level represents a 10% reduction in AChE activity (i.e., inhibition) compared to background (i.e., controls). Specifically, the BMD_{10} is the estimated dose where ChE is inhibited by 10% compared to background. The $BMDL_{10}$ is the lower confidence bound on the BMD_{10}.

The use of the 10% BMR is derived from a combination of statistical and biological considerations. A power analysis was conducted by the Office of Research and Development (ORD) on over 100 brain AChE datasets across more than 25 OPs as part of the OP CRA (USEPA, 2002). This analysis demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies. In addition, the 10% level is generally at or near the limit of sensitivity for discerning a statistically significant decrease in ChE activity in the brain compartment and is a response level close to the background brain ChE level. With respect to biological considerations, a change in 10% brain AChE inhibition is protective for downstream cholinergic clinical signs and apical neurotoxic outcomes. With respect to RBC AChE inhibition, these data tend to be more variable than brain AChE data. OPP begins its BMD analyses using the 10% BMR for RBC AChE inhibition but BMRs up to 20% could be considered on a case by case basis as long as such PODs are protective for brain AChE inhibition, potential peripheral inhibition, and clinical signs of cholinergic toxicity.

[27] USEPA (2000) Office of Pesticide Programs, US Environmental Protection Agency, Washington DC 20460. August 18, 2000 Office of Pesticide Programs Science Policy of The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides.

Appendix 2: Summary of Regulatory and Scientific Activities to Address Uncertainty Around Neurodevelopmental Effects

1. Regulatory Context & History:

Historically, data on the AChE inhibition has been the critical effect used to derive points of departure (PODs) for OPs, including chlorpyrifos. The Registration Eligibility Decision (RED) for chlorpyrifos was completed in 2006 and relied on AChE inhibition results from laboratory animals to derive PODs but retained the FQPA 10X Safety Factor due to concerns over age-related sensitivity and uncertainty associated with potential neurodevelopmental effects observed in laboratory animals. Since that time, numerous epidemiology, laboratory animal, and mechanistic studies have evaluated the hypothesis that chlorpyrifos exposure results in adverse effects on the developing brain. This body of studies has raised concerns that EPA's historical practice of using AChE inhibition as the critical effect for deriving PODs may not be protective of neurodevelopmental outcomes.

EPA-OPP initiated a science evaluation of the potential effects on neurodevelopment in 2007 following the receipt of a petition from Pesticide Action Network of North America (PANNA) and Natural Resources Defense Council (NRDC) seeking revocation of all tolerances and cancellation of all FIFRA registrations of products containing chlorpyrifos. EPA has three times presented approaches and proposals to the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP)[28] for evaluating epidemiologic, laboratory animal, and mechanistic data exploring the possible connection between *in utero* and early childhood exposure to chlorpyrifos and adverse neurodevelopmental effects. The SAP's reports have rendered numerous recommendations for additional study and sometimes conflicting advice for how EPA should consider (or not consider) the epidemiology data in conducting EPA's registration review human health risk assessment for chlorpyrifos. For over a decade, EPA has evaluated the scientific evidence surrounding the different health effects associated with chlorpyrifos. Despite these efforts, unresolved scientific questions remain. EPA has continued to pursue some aspects of these uncertainties but has not found resolution.

2. Previous Risk Assessments, Peer Review & Public Process:

The public process surrounding science issues on chlorpyrifos and in the PANNA/NRDC petition has been extensive and began with the September 2008 FIFRA SAP. The 2008 SAP evaluated the Agency's preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action (USEPA, 2008). The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the PODs but noted that despite some uncertainties, the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies were "indeed quite strong and provided extremely valuable information (p. 35, FIFRA SAP, 2008)" and "concluded that the Columbia

[28] FIFRA SAP is a federal advisory committee created by Congress through FIFRA and is the primary venue for external, independent scientific advice to the EPA on major health and safety issues related to pesticides:

study is epidemiologically sound and that there is minimal selection and information bias (p. 32, FIFRA SAP, 2008)."

In 2010, EPA developed the Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which describes the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. The draft epidemiology framework was reviewed favorably by the FIFRA SAP in 2010. As suggested by the FIFRA SAP, EPA did not immediately finalize the draft epidemiology framework but instead used the document in several pesticide evaluations prior to making revisions and finalizing. OPP's epidemiology framework was finalized in December 2016.[29] (USEPA, 2016).

In 2011, EPA released the preliminary human health risk assessment for chlorpyrifos.[30]. The preliminary assessment used red blood cell (RBC) AChE inhibition from laboratory rats as the critical effect for extrapolating risk. The preliminary assessment also used the standard 10X factors for inter- and intra-species extrapolation. The 10X FQPA SF was removed with a note to the public that a weight of evidence (WOE) as described in the Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" evaluation would be forthcoming.

In 2011, EPA convened a meeting of the FIFRA SAP to review the PBPK-PD model for chlorpyrifos. The panel made numerous recommendations for the improvement of the model for use in regulatory risk assessment, including the inclusion of dermal and inhalation routes. From 2011-2014, Dow AgroSciences, in consultation with EPA, refined the PBPK-PD model for use in the revised human health risk assessment.

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the U.S., including those from the CCCEH, Mt. Sinai and CHAMACOS. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies. The 2012 Panel described the Agency's epidemiology review as "very clearly written, accurate" and "very thorough review". The 2012 Panel went further to note that "The Panel believes that the [Agency's] epidemiology review *appropriately concludes* that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age….." [*italics added*]. Although the 2012 Panel noted that the RBC AChE inhibition remained the most robust dose-response data, the 2012 Panel expressed significant concerns about the degree to which 10% AChE inhibition is protective for neurodevelopmental effects pointing to evidence from epidemiology, *in vivo* animal studies, and

[29] https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf
[30] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025

in vitro mechanistic studies, and urged the EPA to find ways to use the CCCEH cord blood data (pp. 50-52, FIFRA SAP, 2012).

In 2014, EPA released the revised human health risk assessment. The revised assessment used the chlorpyrifos PBPK-PD model for deriving human PODs for RBC AChE inhibition, thus obviating the need for the inter-species extrapolation factor and providing highly refined PODs which accounted for gender, age, duration and route specific exposure considerations. The PBPK-PD model was also used to develop data derived intra-species factors for some lifestages. The 10X FQPA SF was retained based on the outcome of the 2012 FIFRA SAP and development of a WOE analysis on potential for neurodevelopmental outcomes according to OPP's *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*.

Based on the aggregate human health risks identified in 2014, a proposed rule (PR) for revoking all tolerances of chlorpyrifos was published in the Federal Register on November 6, 2015 (80 FR 69079). The 2014 human health risk assessment (HHRA), which used the 10% RBC AChE inhibition endpoint, was the basis for the proposed tolerance revocation for chlorpyrifos since a determination of 'reasonable certainty of no harm' could not be met due to risks identified from drinking water using a national-scale assessment.

In 2015, EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood reported by the CCCEH study investigators. The Agency convened another meeting of the FIFRA SAP in April 2016 to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for PODs. The 2016 SAP did not support the "direct use" of the cord blood and working memory data for deriving the regulatory endpoint due in part to lack of raw data from the epidemiology study, insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, and lack of a second laboratory to reproduce the analytical blood concentrations.

Despite their critiques regarding uncertainties in the CCCEH studies, the 2016 SAP expresses concern throughout the report that 10% RBC AChE inhibition is not sufficiently protective of human health. Specifically, the Panel stated that it "agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell (RBC) acetylcholinesterase (AChE) inhibition (i.e., toxicity at lower doses) (p. 18, FIFRA SAP, 2016)." This statement is repeated multiple times throughout the 2016 SAP report (e.g., pp. 22, 25, 39-40, and 53, FIFRA SAP, 2016).

The 2016 SAP was supportive of the EPA's use of the PBPK model as a tool for assessing internal dosimetry from typical OPP exposure scenarios using peer reviewed exposure assessment approaches (e.g., food, water, residential, occupational). The 2016 SAP recommended the use of a time weighted average (TWA) blood concentration of chlorpyrifos for the CCCEH study cohort as the PoD for risk assessment (p. 36, 42, 45, FIFRA SAP, 2016) and EPA's 2016 chlorpyrifos HHRA followed this approach.

3. Regulatory and Scientific Activities Since 2016

In March 2017, EPA denied the NRDC/PANNA petition to revoke all tolerances and cancel all FIFRA registrations of products containing chlorpyrifos. In the 2017 denial, EPA noted that "further evaluation of the science is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos." The denial went on to state that EPA "will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution on those issues." Since that time, EPA has continued to pursue acquisition of the raw data from new laboratory animal studies and the epidemiology studies conducted by Columbia University; evaluated the new laboratory animal studies with results suggesting effects on the developing brain occur at doses lower than does that cause AChE inhibition; and evaluated whether or not additional statistical analysis, including bias analysis, would be useful in characterizing the epidemiology results.

3.1 Transparency in Regulatory Decision Making: Availability of Raw Data

For conventional pesticides, like chlorpyrifos, EPA receives numerous toxicology studies in laboratory animals conducted according to OCSPP[1] and OECD[2] guidelines to comply with pesticide registration data requirements listed in the 40CFR Part 158. Most of these studies are conducted in accordance with Good Laboratory Practice (GLP), as set forth in 40 CFR Part 160. In accordance with GLP regulations, registrants certifying compliance with Good Laboratory Practice are required to retain the raw data from these toxicology studies. Raw data must also be retained by pesticide producers pursuant to EPA's Books and Records regulations (40 CFR section 169.2(k)) and EPA must, upon request, be furnished with (or given access to) such records (see sections 160.15 and 169.3). These toxicology studies (including the raw data, if it is in EPA's possession) used by EPA in human health risk assessment can, in turn, be obtained through a Freedom of Information Act request as long as the person affirms under FIFRA section 10(g) that he or she will not provide the data to a multinational pesticide producer. As such, EPA and stakeholders interested in pesticide risk assessment have high expectations with regard to the transparency of data used to develop hazard assessment and characterization. Although for most conventional pesticides, EPA uses the guideline studies submitted by pesticide registrants, there are some cases where studies from the open scientific literature are used. In those situations, in line with EPA's commitment to transparency, EPA often makes an effort to obtain the raw data from the investigators. EPA will often, but not always, receive such requested information.

- With regard to the new laboratory animal studies (reviewed by Mendez, 2020, D457378), EPA contacted the primary investigators in July-August 2018. Dr. Russell Carr from Mississippi State University kindly provided the requested information. However, none of the others provided EPA with the raw data.

- With regard to the raw data from CCCEH, EPA has a history of requesting this information as detailed on EPA's website (https://www.epa.gov/ingredients-used-

[1] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances
[2] http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm

pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data). Throughout 2018, EPA continued to pursue the raw data from CCCEH but to no avail. See Attachment 1.

3.2 Review of New Laboratory Animal Studies

Chlorpyrifos has numerous studies in laboratory animals evaluating effects on behavior and learning in young animals exposed during gestation and/or post-natal period. Beginning with the 2008 preliminary evaluation, EPA evaluated the open literature studies in 2008 in a preliminary evaluation, in 2012 in a comprehensive systematic review of the literature, and again in 2016 with additional studies. EPA has consistently concluded, with support from the FIFRA SAP, that these studies provide evidence of the potential effects on the developing brain from exposure to chlorpyrifos but that they lack robustness for using as PODs for extrapolating human health risk. Moreover, until recently, the dose levels used in these animal behavior studies typically were only high enough to elicit AChE inhibition. The newest studies have used lower doses, including some below doses required to elicit 10% AChE inhibition.

In 2018, the California Department of Pesticide Regulation (CDPR) proposed to adopt a regulation designating chlorpyrifos as a toxic air contaminant (TAC) in California[31]. As part of this determination, CDPR developed its "Final Toxic Air Contaminant Evaluation of Chlorpyrifos Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders[32]." The CDPR risk characterization document cites five new laboratory animal studies not previously reviewed by EPA (Gomez-Gimenez *et al.,* 2017, 2018; Silva *et al*., 2017; Lee *et al.,* 2015; Carr *et al.,* 2017). CDPR is using these studies as the main source of information for their new POD for acute oral exposure (Table 23 in CDPR, 2018). EPA-OPP in consultation with the Office of Research and Development, has reviewed these five studies (Mendez, 2020, D457378) in accordance with OPP's Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment.[33]
In short, EPA concludes that the Gomez-Gimenez et al (2017, 2018) and Silva et al (2017) papers are of unacceptable quality due to a number of deficiencies described in Mendez, 2020, D457378. Lee et al (2015) is considered acceptable but only for use qualitatively as some key deficiencies surrounding the assignment of pups from litters were noted. EPA finds the Carr et al (2017) study to be of high quality and provides strong support for the conclusion that effects on the developing brain may occur below a dose eliciting 10% AChE inhibition. Using the raw data provided by Dr. Carr, EPA conducted an independent statistical analysis of these results[34]. EPA's statistical analysis confirms the conclusions of Carr et al (2017) that young rats exposed to chlorpyrifos, at doses lower than those eliciting brain AChE inhibition, spent significantly less time in the dark container prior to emerging as compared to the control group.

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[31] https://www.cdpr.ca.gov/docs/emon/pubs/tac/tacpdfs/chlorpyrifos/proposed_determination_chlorpyrifos.pdf

[32] https://www.cdpr.ca.gov/docs/emon/pubs/tac/tacpdfs/chlorpyrifos/final_eval_chlorpyrifos_tac.pdf

[33] https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf

[34] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939

EPA-OPP continues to view the laboratory animal studies as part of the weight of the evidence surrounding the effects on the developing brain. Despite the strength of the new Carr paper, EPA continues to conclude these studies are not robust enough for deriving a POD.

3.3 Potential for Additional Statistical Analysis of CCCEH Studies

One of the areas of additional evaluation by EPA was a consideration of whether additional statistical analyses would be useful in characterizing the epidemiology results.

As described by Lash et al (2014[35]), quantitative bias analysis (QBA) evaluates nonrandom errors that may affect the results and interpretation of epidemiological studies. The purpose is to estimate the potential magnitude and direction of biases and to quantify the uncertainty about these biases. EPA held a series of conference calls with Dr. Timothy Lash at Emory University about the CCCEH studies. Dr. Lash is a recognized expert in this area. These conference calls and associated activities are described in the docket[36]. Some stakeholders have identified the limited blood lead testing in the CCCEH cohort to be an area of uncertainty and potential unresolved confounder in the epidemiology results. Dr. Lash noted that given that lead abatement was conducted by New York City prior to the start of the CCCEH study that this was not a major concern for him. Dr. Lash initially identified potential selection bias in the interpretation of working memory IQ from Rauh et al (2011) as a possible area for QBA. Upon further evaluation of this issue, it was determined that a QBA would not be useful or possible since working memory was only evaluated in children at age 7 but not at other ages.

EPA has recently pursued some additional questions about the statistical analysis conducted in CCCEH papers[37]. In Rauh et al (2011), CCCEH investigators log-transformed the working memory composite score but not log-transforming the chlorpyrifos exposure in the data analysis. EPA asked the investigators why this was done. The researchers explained that the natural log-transformation was applied to the outcome variables to stabilize the variance and improve the linear model fit. EPA inquired about further sensitivity analysis and if any model-fit diagnostics were available. CCCEH investigators responded that they did perform various transformations of the data in an exploratory mode but did not publish or further detail these results or share the results of these exploratory analyses with EPA.

EPA also recently asked CCCEH investigators about the impact of including/excluding extremely high exposure data points. The CCCEH investigators noted that there are three subjects with non-missing data had chlorpyrifos levels above 25 pg/g. These three subjects were not included in the final model because one subject with 63 pg/mg was a highly influential observation (outlier) and drastically impacted inference and the data from the two other subjects were too sparse and the splines too unstable in this region. The CCCEH investigators did not share the results of these exploratory analyses with EPA.
Although EPA does not have a specific reason to believe that CCCEH have inappropriately handled the data or statistical analysis, without the availability of the raw data, EPA remains

[35] Lash TL, Fox MP, MacLehose RF, Maldonado G, McCandless LC, Greenland S. 2014. Good practices for quantitative bias analysis. Int J Epidemiol. 2014 Dec;43(6):1969-85. doi: 10.1093/ije/dyu149. Epub 2014 Jul 30.
[36] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939
[37] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939

unable to verify the reported findings of the CCCEH papers. Moreover, EPA and interested stakeholders are unable to conduct alternative statistical analyses to evaluate the robustness and appropriateness of the approaches used by the investigators.

4. FQPA 10X Safety Factor for the 2020 Human Health Risk Assessment

The Food Quality Protection Act (FQPA, 1996) requires EPA in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, *an additional tenfold margin of safety* for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account *potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children*." The statute goes on to state that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Over the last decade, EPA has used several different approaches for assessing the human health risk to chlorpyrifos. EPA began registration review with a 2011 preliminary assessment using a traditional risk assessment based on laboratory animal data with standard 10X inter- and inter-species extrapolation factors but without the FQPA 10X SF. The 2014 revised human health risk assessment applied the PBPK-PD model to derive PODs for 10% RBC AChE inhibition which obviated the need for the inter-species factor and applied the FQPA 10X SF based on uncertainty identified regarding the potential for chlorpyrifos to effect neurodevelopment. In 2016, EPA used the PBPK model to derive an internal human POD based on the TWA for blood concentrations to women potentially exposed to chlorpyrifos from residential uses voluntarily cancelled in 2000. Despite the distinct differences in approach, EPA's acute and chronic population adjusted doses (PADs) in the 2011 and 2014 risk assessments are quite similar. Specifically, in the 2011 preliminary assessment, the acute and chronic PADs were 0.0036 mg/kg/day and 0.0003 mg/kg/day respectively, whereas in the 2014 revised assessment, the acute and chronic PADs are 0.005 mg/kg/day and 0.0008 mg/kg/day for females ages 13-49, respectively. In the 2016 assessment and using a PBPK model to derive a TWA for blood concentrations to women potentially exposed to chlorpyrifos from residential uses voluntarily cancelled, a PAD of 0.00005 mg/kg/day was calculated which is approximately an order of magnitude lower than the 2011 and 2014 assessments.

In conclusion, despite several years of study, peer review, and public process, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X UF_{DB}.

Appendix 2 Attachment 1: Summary of Regulatory and Scientific Activities to Address Uncertainty Around Neurodevelopmental Effects

Despite a stated public commitment to "share all data gathered," CCCEH has not provided EPA with the data used in the CCCEH epidemiology studies. In the summer of 2015, Dr. Dana Barr of Emory University (formerly of CDC) provided the EPA with limited raw urine and blood data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful for the EPA's current purpose of assessing risk to chlorpyrifos. The EPA does not have any of the other measurements of the children in the cohort (e.g., chlorpyrifos blood data, interviews, test or IQ scores). CCCEH researchers have asserted that the pesticide component of the cohort study was privately funded, not federally funded, and therefore disclosure of underlying data is not required. EPA has described its efforts to acquire the CCCEH data on its website (https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data).

Some recent requests include[38].

- April 19, 2016: EPA letter to Linda P. Fried, Dean, Mailman School of Public Health
- May 18, 2016: Linda P. Fried, Dean, Mailman School of Public Health letter to EPA
- June 27, 2016: EPA letter to Linda P. Fried, Mailman School of Public Health
- January 17, 2017: USDA letter to EPA citing Scientific Integrity Policy
- January 2, 2018: EPA letter to Linda Fried, once again requesting dataset
- January 8, 2018: Email from Linda Fried saying EPA needs to "clarify the information requests"

Throughout 2018, EPA continued to request the raw data from Columbia University:

- February 1, 2018: Teleconference and email to Howard Andrews regarding continued interest in reviewing the raw data and questions regarding statistical analysis of the Columbia dataset[39]
- February 6, 2018: Email from Howard Andrews requesting additional details on EPA's questions regarding the statistical analysis of the Columbia dataset
- March 26, 2018: Email to Howard Andrews with additional questions regarding statistical analysis of the Columbia dataset
- May 31, 2018: Teleconference with Howard Andrews regarding statistical analysis of Columbia dataset and reiterated request for the raw dataset
- June 27, 2018: Teleconference with Howard Andrews regarding raw dataset and CCCEH concern about the identification of study participants[40]

Following the June 2018 conference call with CCCEH, EPA contacted the CDC in July 2018 to discuss HIPAA and data de-identification issues as it relates to the CCCEH. The CDC

[38] Links to each letter can be found on https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data.
[39] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939
[40] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0937

representative noted that even after taking out personally identifiable information (PII) from the dataset, the data that remain can still pose identification issues because of the possibility of linking it with information currently in the public domain. The CDC representative further noted there are some datasets that cannot be deidentified given the nature of the data and specified that geographic location is one of the variables that makes something highly identifiable. In the case of CCCEH, the study participants live within a small geographical range with New York City. The CDC representative noted that for those cases, there is the possibility of allowing the data to be viewed in a secure data center[41].

Since June 2018, EPA has not made further attempts at obtaining or viewing the raw data from CCCEH.

[41] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0936

Appendix 3: Physical/Chemical Properties

Physical/Chemical Properties of Chlorpyrifos.		
Parameter	Value	Reference
Melting point/range	41.5-42.5 ºC	Chlorpyrifos IRED
pH	NR	
Density (21ºC)	1.51 g/mL	
Water solubility (25°C)	1.05 mg/L	
Solvent solubility (20°C)	Acetone >400 g/L Dichloromethane >400 g/L Methanol 250 g/L Ethyl acetate >400 g/L Toluene >400 g/L n-hexane >400 g/L	
Vapor pressure, (25°C)	1.87×10^{-5} torr[1]	
Dissociation constant, pK_a	NR	
Octanol/water partition coefficient, Log(K_{OW})	4.7	
UV/visible absorption spectrum	NR	

NR – not reported.

[1] R. Bohaty, June 2011, D368388 and D389480, *Chlorpyrifos Drinking Water Assessment for Registration Review* (CRF assessment, Oct. 16, 2009 product chemistry BC 2062713)

Appendix 4: Current U.S. Tolerances and International Residue Limits for Chlorpyrifos

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico[2]**	**Codex[3]**
40CFR180.342 chlorpyrifos *per se* (*O,O* -diethyl *O* -(3,5,6-trichloro-2-pyridyl) phosphorothioate	*O,O*-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate (apples, grapes, tomatoes) *O,O*-diethyl-*O*-(3,5,6- trichloro-2-pyridyl) phosphorothioate, including the metabolite 3,5,6-trichloro-2-pyridinol (citrus fruits; fat, kidney, and liver of cattle; kiwifruit; peppers; rutabagas; green onion subgroup (crop subgroup 3-07B); meat and meat byproducts of cattle (calculated on the fat content))			Chlorpyrifos. The residue is fat soluble.
Commodity[1,]	Tolerance (ppm) /Maximum Residue Limit (mg/kg)			
	US	Canada	Mexico[2]	Codex[3]
Alfalfa, forage	3.0			
Alfalfa, hay	13			5 alfalfa fodder
Almond	0.2			0.05
Almond, hulls	12			
Apple	0.01	0.01		1 pome fruits
Apple, wet pomace	0.02			
Banana	0.1			2
Beet, sugar, dried pulp	5.0			
Beet, sugar, molasses	15			
Beet, sugar, roots	1.0			0.05
Beet, sugar, tops	8.0			
Cattle, fat	0.3	1		
Cattle, meat	0.05	1		1 (fat)
Cattle, meat byproducts	0.05	1		0.01 cattle, kidney and liver
Cherry, sweet	1.0			
Cherry, tart	1.0			
Citrus, dried pulp	5.0			
Citrus, oil	20			
Corn, field, forage	8.0			
Corn, field, grain	0.05	0.05		0.05 maize
Corn, field, refined oil	0.25			0.2 maize oil, edible
Corn, field, stover	8.0			10 maize fodder (dry)
Corn, sweet, forage	8.0			

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico[2]**	**Codex[3]**
Corn, sweet, kernel plus cob with husk removed	0.05	0.05		0.01 sweet corn (corn-on-the-cob)
Corn, sweet, stover	8.0			
Cotton, undelinted seed	0.2			0.3 cotton seed
Cranberry	1.0			1
Cucumber	0.05	0.05		
Egg	0.01			0.01 (*)
Fig	0.01			
Fruit, citrus, group 10	1.0	1		1
Goat, fat	0.2			
Goat, meat	0.05			
Goat, meat byproducts	0.05			
Hazelnut	0.2			
Hog, fat	0.2			
Hog, meat	0.05			0.02 (fat)
Hog, meat byproducts	0.05			0.01 (*) pig, edible offal
Horse, fat	0.25			
Horse, meat	0.25			
Horse, meat byproducts	0.25			
Kiwifruit	2.0	2		
Milk, fat (Reflecting 0.01 ppm in whole milk)	0.25			0.02 milk
Nectarine	0.05	0.05		
Onion, bulb	0.5	0.2		0.2
Peach	0.05	0.05		0.5
Peanut	0.2			
Peanut, refined oil	0.2			
Pear	0.05			1 pome fruits
Pecan	0.2			0.05 (*)
Pepper	1.0	1		2 peppers sweet including pimento or pimiento); 20 peppers chili, dried
Peppermint, tops	0.8			
Peppermint, oil	8.0			
Plum, prune, fresh	0.05			0.5 plums (including prunes)
Poultry, fat	0.1			
Poultry, meat	0.1			0.01 (fat)
Poultry, meat byproducts	0.1			0.01 (*) poultry, edible offal
Pumpkin	0.05			
Radish	2.0			
Rutabaga	0.5	0.5		
Sheep, fat	0.2			

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico[2]**	**Codex[3]**
Sheep, meat	0.05			1 (fat)
Sheep, meat byproducts	0.05			0.01 sheep, edible offal
Spearmint, tops	0.8			
Spearmint, oil	8.0			
Sorghum, grain, forage	0.5			
Sorghum, grain, grain	0.5			0.5
Sorghum, grain, stover	2.0			2 sorghum straw and fodder, dry
Soybean, seed	0.3			0.1 soya bean (dry)
Strawberry	0.2			0.3
Sunflower, seed	0.1	0.1		
Sweet potato, roots	0.05			
Turnip, roots	1.0			
Turnip, tops	0.3			
Vegetable, brassica, leafy, group 5	1.0			2 Broccoli 1 Cabbages, head 0.05 Cauliflower 1 Chinese cabbage (type pe-tsai)
Vegetable, legume, group 6 except soybean	0.05	0.05 lentils		0.01 common bean (pods and/or immature seeds); peas (pods and succulent=immature seeds)
Walnut	0.2			0.05 (*)
Wheat, forage	3.0			
Wheat, grain	0.5			0.5
Wheat, straw	6.0			5 wheat straw and fodder, dry
Prepared 05/19/2020 D. Drew				

[1] Includes commodities listed in the CFR as of 5/19/2020. The 40CFR 180.342 (a) (3) also stipulates that "a tolerance of 0.1 part per million is established for residues of chlorpyrifos, per se, in or on food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food service establishments where food and food products are prepared and served, as a result of the application of chlorpyrifos in microencapsulated form."
[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.
[3] * = absent at the limit of quantitation. (fat) = to be measured on the fat portion of the sample.

Tolerances with regional registrations

Commodity	Parts per million	Canada	Codex
Asparagus	5.0		
Grape	0.01	0.01	0.5

Appendix 5: Master Use Summary Document

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
AGRICULT-URAL FARM PREMISES Livestock housing and holding areas (such as hog barns, empty chicken houses, dairy areas, milkrooms, calf hutches, calving pens and parlors).		✓		Indoor general surface spray	backpack sprayer; high and low sprayer (pressure or volume)	0.075 lb a.i./ 1000 ft sq 1.2 EC, ME	[14.4] NS	NA	12	NA	NA	NS	NS		Only permitted for use in poultry houses
ALFALFA		✓		At plant	groundboom	1.0 G	1.0	1.0	[1] NS	1	21	24	[10] NS	Missouri only	Lower PHI permitted for EC rates 0.33 lb a.i./A (7 d) and 0.67 lb a.i./A (14 d) e.g. Reg. No. 62719-591 Stand is in production 3-5 years. Planted ¼" to ½" deep.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Foliar	aerial or ground/ broadcast, chemigation	1.0 EC	[4.0] NS	4.0	[4] NS	4	21	24	10		Lower PHI permitted for EC rates 0.33 lb a.i./A (7 d) and 0.67 lb a.i./A (14 d) *e.g.*, Reg. No. 62719-591 Multiple harvests (or cuttings) per year when used for feed/fodder and 1 harvest per year when grown for seed. Cuttings occur about every 30 days. Only 1 crop cycle per year but up to 9 cuttings, varies by geography.
				Total		**1.0**	**5.0**	**5.0**	**[5] NS**	**5**	**21**	**24**	**[10] NS**		Represents Missouri scenario otherwise 4.0 lb a.i./A per is max.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
ALMOND		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WDG, WP	2.0	NA	1	NA	NA		10	Restricted use in California.	
		✓		**foliar**; broadcast	aircraft, airblast	2.0 WDG,WP	6.0	NA	3	NA	14		10		
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) WDG	2.5	NA	1	NA	14	24	NS		
		✓		Dormant/ delayed dormant; foliar; **orchard floors** broadcast	ground boom, handgun, chemigation	4.0 EC*	4.0	NA	2	NA	14		10	Restricted use in California. Only one dormant application can be made.	
				Total	**--**	**4.0**	**14.5**	**NA**	**7**	**NA**	**14**		**NS**		Excludes nursery applications (See general "Fruits" listing)
APPLE		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 EC 2.0 WDG 1.5 WP	2	2.0	1	1	NA	24/ 4 d	10d		Reflects spray drift mitigation measures.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**; ground	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	1.5 (1.5 lb ai/100 gal) WDG	1.5	NA	1	1	28	4d	NS	Use permitted in states east of the Rockies except Mississippi.	
				Total		**2.0**	**3.5**		**2**						
ASPARAGUS		✓		Foliar, pre-harvest; broadcast	aircraft, ground boom	1.0 EC, WDG	1.0	1.0	1	1	1	24	10		
		✓		Postharvest, broadcast	aircraft, ground boom	1.0 EC, WDG	2.0	2.0	2	1	1	24	10		
					granular soil band treatment ground boom	1.5 G	3.0	3.0	2	2	180	24	[10] NS	Permitted in California, the Midwest, and the Pacific Northwest 19713-505, 19713-521, 5481-525, 62719-34, 83222-34	Do not apply more than 3.0 lb a.i./A between harvests.
				Total		**1.5 G**	**3.0 G 2.0**	**3.0 G 2.0**	3	3	1	24	10		

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
BEANS		✓		Preplant; Seed treatment	Seed Treatment	*0.016-0.348* 0.000798 lb ai/lb seed ME *0.013-0.272* 0.000625 lb ai/lb seed WP *0.012-0.253* 0.00058 lb ai/lb seed EC	NS	[0.348] NS	NS	[1] NS	NS	NS	NS	ME is SLN only for ID	Italics highlight the range of application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding rate information provide by BEAD.[4]
BEEF/RANGE/ FEEDER CATTLE (MEAT)/ DAIRY CATTLE (NON-LACTATING)				Summer, late fall, spring; impregnated collar/tag	Animal treatment (ear tag)	0.0066 lb/animal	[0.0099] NS	NA	3	NA	NS	NS	NS		Reg. No. 39039-6 Cattle ear tags are assumed to last 4-6 months Two tags per animal at 0.0033 lb a.i./tag in the summer and one tag per animal at 0.0033 lb a.i./A.
BEETS (UNSPECIFIED; TABLE OR SUGAR)		✓		At plant, soil band treatment	Ground boom	1.0 EC	NS	1	NS	1		24		Allowed in Oregon Court ordered	Minimum Incorporation: 2 inches

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
"grown for seed"														buffer of 60 ft for ground chlorpyrifos application is required for "affected waterways".	
		✓		Preplant, soil incorporated treatment	Broadcast/ ground boom	1.9 EC	NS (2.8 ID)	NS	1	NS				Allowed in Oregon and Idaho	OR-09007; 62719-591 ID-090002; 62719-591
				Total		**1.9**	**NS**	**NS**	**NS**	**NS**		**24**			One or the other type of application.
SUGAR BEETS		✓		Preplant, soil incorporated treatment	Broadcast/ ground boom	1.0 EC 2.0 G	3.0	2.0	1	1	NA	24	10		Minimum Incorporation: 1 inch
		✓		At plant, soil band treatment	Broadcast/ ground boom	1.0 EC, WDG 2.0 G	3.0	2.0	1	1	30	24	10		
		✓		Post plant, soil band	Broadcast/ ground boom	2.0 G	3.0	2.0	1	1	30	24	10		
		✓		Post-emergence band treatment; broadcast	Broadcast/ ground boom	1.0 EC, WDG	3.0	1.0	3	1	30	24	10		

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		broadcast	Aircraft, ground boom, chemigation	1.0 EC, WDG	3.0	1.0	3	1	30	24	10		EC is not for use in MS
				Total		**1.0 EC 2.0 G**	**4.0**	**[4.0] NS**	**3**	**[3] NS**	**30**	**24**	**10**		One granular application at 2.0 a.i./A and two liquid applications at 1.0 a.i./A per year. Also assumed per crop cycle.
CARROT Grown for Seed (INCLUDING TOPS)		✓		Foliar pre-bloom broadcast	aircraft, ground boom	0.94 EC	0.94	1	1	1	7	24	NA	Oregon and Washington Court ordered buffer of 60 ft for ground and 300 ft for aerial application is required for "affected waterways".	OR090011 SLN Expires: 12/31/2018 WA090011 SNL Expires: 12/31/2016 Carrots take two years to produce seed. All commercial production of the carrot (vegetable) takes place in the first year when the plant

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															is nowhere near blooming.
CHERRIES		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WDG, EC 1.5 WP	2.0	NA	1	NA	NS	24	10		
		✓		**foliar**; broadcast	airblast	4.0 EC	10.0	NA	5	NA	14	24	10		Tart cherry only
					aircraft	2.0									Reflects spray drift mitigation
		✓		Foliar, post-harvest; **trunk spray/drench**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) WDG, EC	2.5	NA	1	NA	2	24	[10] NS		Only some labels specify a 10 d MRI.
				Total	**--**	**4.0**	**4.5 (sweet)** **14.5 (tart only)**		**6**						Excludes nursery applications (See general "Fruits" listing) The foliar applications only apply to tart cherries, thus, sweet cherry scenarios (*e.g.*, Pacific NW) annual

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															application rate would be 4.5 lb total a.i./year.
CHRISTMAS TREE PLANTATIONS		✓		**foliar**; broadcast	helicopter, orchard blast	1.0 EC, WDG, WP	3.0	NA	3	NA	[0] NS	24	7	Aerial applications via helicopter are only permitted in Washington and Oregon.	
		✓		post-harvest; **Stump Treatment**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) EC, WDG	2.5	NA	1	NA	NA		7		
				Total		**2.5**	**5.5**		**4**						
CITRUS		✓		**foliar**; broadcast	airblast, ground boom	6.0 WP, WSP, EC	7.5	NA	2	NA	35 (21 for low rates)	5d	30 (10 for low rates)	6.0 lb a.i. /A is only permitted in California and Arizona. The max single rate in other states is restricted to 4 lb a.i./A.	
		✓			aircraft	2.3 WP, WSP, EC					21	5	10	Florida, California,	Aerial application used

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
														and potentially Texas	to control psyllid, the vector for citrus greening. Reflects spray drift mitigation
		✓		foliar; **orchard floors broadcast**	ground boom, chemigation, handheld, backpack, drench/dip, handgun, and low-pressure hand wand	1.0 G*, WSP, EC	3.0	NA	3	NA	28	24/ 5 d	10		
				Total	**--**	**6.0**	**10.5**		**5**						Registered labels permit both foliar and soil applications in the same orchard. Total excludes nursery applications (See general "Fruits" listing)
CLOVER (GROWN FOR SEED)		✓		Preplant	Ground boom	1.9 EC	1.9	1.9	1	1	NS	24	NA	Use only permitted in Oregon.	OR-0900100; master label: 62719-591

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Post-Plant Foliar	aircraft and ground boom										Either a preplant or post plant application is allowed.
COLE CROPS (EXCLUDES CAULIFLOWER AND BRUSSELS SPROUTS)		✓		Preplant, soil incorporated treatment	Ground boom	2.0 EC, WDG, G	4.0	2.0	2	1	30	24	10		Min. incorporation: 2 inches
		✓		At plant, soil band treatment	Ground boom					1					One granular application permitted per year.
		✓		Post plant	Ground boom					1					
		✓		Foliar Established Plantings, soil sidedress treatment	Ground boom					1					
		✓		Foliar, broadcast	Aircraft, ground boom, chemigation	1.0 EC, WDG, WP	4.0	3.0	4	3	21		10		Multiple crops per year are possible in some locations.
				Total			**8.0**	**5**	**6**	**4**					Some labels restrict the yearly application rate to 3 lb a.i./A.

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															The maximum number of crops per year is 2.
BRUSSELS SPROUTS		✓		At plant, soil band treatment	Ground boom	2.0 EC; G	2.0	[2.0] NS	2	1	21	24	10		
		✓		Preplant, soil incorporated treatment	Ground boom										Minimum incorporation is 2 inches
		✓		Post plant, soil application	Ground boom	2.25 EC, G	2.25	[2.25] NS							
		✓		Foliar broadcast	Aircraft, Ground boom	1.0 EC	[5.3] NS	3.0	NS	3			10		83222-20, 84930-7, 86363-3 specify a 7-day MRI. All other labels specify a 10-day MRI. The PHI stated 84930-7 is conflicting [p. 4 (21 days and p. 19 (30 days)]
				Total		**2.3**	**5.3**		**NS**		**21**	**24**	**7**		Assume one application of either at plant, preplant, or post plant followed with additional

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															foliar applications.
CAULI-FLOWER		✓		At plant, soil band treatment	Ground boom	2.0 EC 2.3 G	2.0 EC 2.25 G	NS	[1] NS	1	21	3d	10		Only one granular application.
		✓		Preplant, soil incorporated treatment	Ground boom	2.3 G 2.0 EC	2.3	NS	[1] NS	1	30, EC, 21 G				Minimum incorporation is 2 inches
		✓		Post plant, soil application	Ground boom										
		✓		Foliar broadcast	aircraft, ground boom	1.0 EC	[5.3] NS	3.0	NS	3	21		10		
				Total		**2.3**	**5.3**	**[5.3] NS**	**NS**	**[4] NS**	**21**	**24**	**10**		Assume one application at either plant, preplant, or post plant followed with additional foliar applications.
COMMERCIAL /INSTITUTION-AL/ INDUSTRIAL PREMISES/ EQUIP. (INDOOR)				Broadcast	Product Container	0.4373 lb a.i./100 sq ft 190.5 G	NS	NA	NS	NA	NA	NS	NS		For treatment of fire ants
				Crack and Crevice/Void	Sprayer/ Injection	0.0625 lb a.i./1000 sq ft	NS	NA	NS	NA	NA	NS	NS		499-419

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
Non-food areas of manufacturing, industrial, and food processing plants; warehouses; ship holds; railroad boxcars.						2.7 ME									
				Crack and Crevice/Spot	Sprayer/ Injection	0.0424 lb/gal ME	NS	NA	NS	NA	NA	NS	7		
COMMERCIAL /INSTITUTIONAL /INDUSTRIAL PREMISES/EQUIP. (OUTDOOR) Outdoor commercial use around non-food areas of manufact-uring, industrial, and food processing plants; warehouses; ship holds; railroad boxcars				Soil broadcast	Low and High Pressure, Backpack, Handgun Sprayers	0.0247 lb a.i./1000 sq ft 1.1 ME	NS	NA	NS	NA	NA	NS	NS		
				Directed spray		0.1132 lb a.i./1000 sq ft 4.9 ME	NS	NA	NS	NA	NA	NS	NS		Specific to: Inside and outside dumpsters and other trash holding containers, trash corrals and other trash storage areas.
				Crack and Crevice/void/ general outdoor		0.0424 lb/gal ME	NS	NA	NS	NA	NA	NS	7		
CONIFERS AND DECIDUOUS TREES;		✓	?	**foliar**; broadcast	Ground boom	1.0 EC	3	NA	6	NA	7	24	7		

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
PLANTATION, NURSERY		✓	?	foliar; **stump treatment**	backpack, drencher, low pressure hand wand	0.3 EC	0.3	NA	1	NA	7	24	7		
				Total		**1.0**	**3**	**NA**	**6**	**NA**	**7**	**24**	**7**		The total number of applications assumed is either 3 foliar applications or 2 foliar applications with one stump treatment.
CORN (ALL)		✓		Preplant	ground/ **soil incorporated** conservation tillage, in furrow, broadcast, chemigation, soil band	3.0 EC 2.0 G	3.0	3.0	NS	3	NA	24/ 5 EC	10		19713-520, 19713-599, 33658-26, 34704-857, 72693-11, 83222-20 The minimum incorporation depth is 2 inches.
					soil incorporated aerial conservation tillage	2.0 EC, G									

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓			ground/ conservation tillage, in furrow, broadcast, chemigation, soil band	1.0 EC 2.0 G	3.0	3.0	NS	3	21		10		19713-520
		✓		Storage or preplant seed treatment	Seed treatment	*0.001-0.021* 0.000625 lb a.i./ lb seed WP *0.1-1.9* 0.058 lb a.i./ lb seed FC	[?] NS	[1.9] NS	[?] NS	1	NS	NS	NS		Italics highlight the range of application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding rate information provide by BEAD.[4]
		✓		At plant	soil incorporated, conservation tillage	2.0 G	[?] NS	3.0	[?] NS	3	21	24	10		
		✓		Post emergence	Aerial or ground, broadcast, chemigation	1.5 EC 1.0 WDG	NS	3.0	NS	3	21	24/ 5d (EC	10		A brush on max single rate is permitted at 1.0 lb ai/a (72693-11)

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Foliar	Aerial or ground/ broadcast, granule, seed and chemigation	1.5 EC	3.0	3.0	NS	3	21		10		
				Total		**3.0**	**8.1**	**8.1**	**NS**	**4**	**21**		**10**		Two granular applications are allowed with a maximum single rate of 1.0 lb a.i./A or one granular application at 2 lb a.i./A. Total with seed treatment PHI: 21 d except Delaware and Florida (7 d)
COTTON		✓		Storage or preplant seed treatment	Seed treatment	*0.8-2.2* 0.00116 lb/lb seed EC	[2.2] NS	[2.2] NS	[1] NS	1	NS	NS	NS		264-932 Rates in italics highlight the potential range of application rates depending on the number of seeds per lb and the number

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															of seeds planted per acre. Seeding rate information provide by BEAD.[2]
		✓		Foliar	aerial, chemigation, ground boom	1.0 EC, WDGP	3	3.0	3	3	14	24	10		Except MS
				Total		**1.0**	**3.2**	**3.2**	**3**	**3**	**14**	**24**	**10**		1.6 lb a.i./A is max single rate (seed treatment) **Total with seed treatment** 1 crop cycle per year assumed
CRANBERRY		✓		Foliar	aircraft, ground boom/ broadcast and chemigation	1.5 EC, WDG	3.0	NA	2	NA	60	24	10	Not for use in Mississippi.	Do not apply to bogs when flooded.
CUCUMBER		✓		Storage or preplant seed treatment	Commercial seed treatment	*0.4* 0.00058 lb/lb seed EC	NS	0.1	2	1	NS	NS	NS		Seeding rate information provide by BEAD.[2] 264-932, 62719-221, CA040004 Per registrant 2 CCs per year

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
FIGS		✓		**dormant/ delayed dormant**; soil application	ground boom	2.0 WDG, EC	2.0	NA	1	NA	217	4 d	NS	Use is restricted to California only.	Incorporation to 3 inches is suggested but not required following application.
FILBERTS/ HAZELNUT		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WP	2.0	NA	1	NA	14	24	10		
		✓		**foliar**; broadcast	aircraft, airblast	2.0 WDG, WP, EC	6.0	NA	3	NA	14		10		Some labels specify a retreatment interval of 10 days.
				Total		**2.0**	**6.0**	**NS**	**3.0**	**NA**	**14**	**24**	**10**		Excludes nursery applications (See general "Fruits" listing)
FOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT)				When needed, crack and crevice treatment, spot treatment		0.0424 lb/ gal ME	NS	NA	NS	NA	NA	NS	7		53883-264, 84575-3 Spot Treatment: Do not exceed two square feet per individual spot.
FOREST PLANTINGS (REFORESTAT			✓	Foliar, broadcast	ground boom	1.0 EC	6.0	NA	6	NA		24	7		

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
ION PROGRAMS) (TREE FARMS, TREE PLANTATION, ETC.)															
			✓	Foliar, stump treatment	direct spray, drencher	0.34 EC	6.0	NA	[18] NS	NA			7		
FOREST TREES (SOFTWOODS, CONIFERS)			✓	Foliar, broadcast	ground boom, drencher	0.61 EC	3.6	NA	NS	NA	24		7		
			✓	Foliar, stump treatment	direct spray	[3.6] 2.4 lb a.i./100 gal EC	3.6	NA	NS	NA			7		Application rate is provided as a dilution factor.
FRUITS & NUTS Non-bearing (not to bear fruit within 1 year) fruit trees in nurseries (includes: almonds, citrus, filbert, apple, cherry, nectarine, peach, pear, plum, prune).		✓		Foliar-Non-bearing nursery broadcast	High/low volume spay/ handheld sprayer/power sprayer	4.0 EC	4.0	NA	NS	NA	14	NS	7		For nectarines and peaches, the use is restricted to one application of no more than 3 lb a.i./A per cc. For apples, the max rate is 2 lb a.i./A per crop cycle and the use is restricted to 1 application (either canopy or trunk drench) per year.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															Example label, 62719-254
		✓		Foliar-Non-bearing nursery trunk drench	drencher, high- and low-pressure sprayer	2.0 WDG	2.0	NA	NS	1	14		7		
				Total		**4.0**	**6.0**								Maximum Single Rates: 3.0 (nectarines and peaches) 2.0 (apples) Maximum Yearly Rates: 3.0 (nectarines and peaches) 2.0 (apples)
GINSENG (MEDCINAL)		✓		Preplant, post-emergence	Ground, soil broadcast	2.0 G	2.0	NA	1	NA	365	24	NA	Permitted in Michigan and Wisconsin	MI110006,WI110003) Minimum incorporation: 4 inches Application should be followed by rainfall or overhead watering. Valid until June 29, 2016.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
GOLF COURSE TURF				When needed, soil broadcast/ spot treatment	Ground, low pressure	1.0 EC	2.0	NA	2	NA		24	NS		
				Foliar, broadcast,	Ground boom, handgun, low pressure and backpack	1.0 EC, G, B	2.0	NA	2	NA		24	NS		Chemigation not allowed for the EC formulation.
					Tractor drawn spreader, push type spreader, belly grinder	1.0 G						[24] NS	7		
				Mound treatment	Granule applicator	1.0 G	2.0	NS	2	NS		NS	7		
				Total		**2.0**	**2.0**	**NA**	**2**	**NA**	**NS**		**NS**		
GRAPES		✓		Dormant/ Delayed Dormant (pre-bloom)	Ground boom, broadcast, drench high/low spray volume	1.0 WDG, EC	1.0	1	1	NA	35	24	NS	East of the continental divide only.	Do not use in conjunction with soil surface applications for grape borer control.
		✓				2.0 EC	2.0	1	1	NA	35			Permitted in Colorado, Idaho, and Washington	CO080008, ID090004, WA090002 Master label: 62719-591

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Foliar	Ground/ broadcast, basal spray and drench (soil treatment)	2.25 EC	2.25	1	1	NA	35		NS	Permitted east of the continental divide.	
		✓				1.0 EC	3.0	3	3	NA	35		NS	California	CA080010
		✓		Postharvest, dormant/ delayed dormant	Ground boom, broadcast	2.0 EC	2.0	1	1	NA	NS		NS	California	CA080009
				Total		**2.25**	**2.25**	**1**			**35**	**24**	**NS**	Permitted east of the continental divide.	
						2.0	**5.0**	**4**			**NS**		**NS**	California	
GRASS FORAGE/ FODDER/HAY		✓		Foliar, broadcast	Aircraft, ground boom, chemigation	1.0 EC	3.0	NA	3	NA	NS	24		Permitted in Nevada, Oregon, Washington, and Idaho	NV080004, NV940002, OR090009, WA090010, ID090003
GREENHOUSE		✓		early evening, aerosol, fog or fumigation	Total release fogger	0.029 0.0066 lb a.i./1000 sq. ft PL	NS	NA	NS	NA	NS	NS	2		
HOUSEHOLD/ DOMESTIC DWELLINGS INDOOR PREMISES	✓			When needed	Bait station	0.0003 lb/bait station	NS	NA	NS	NA	NA	NS	NS		9688-67

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
HYBRID COTTONWOOD/ POPLAR PLANTATIONS		✓		Foliar, dormant, delayed dormant; broadcast	High volume (dilute) Low volume (concentrate)	1.9 EC	[2.0] NS	6.0	[1] NS	3		24	7	Washington	WA090004 Energy wood plantations may be harvested as often as every 2-3 years; pulpwood 5-10 years; and saw timber 15-20 years. (Arkansas production guide). In Washington the crop takes 2-8 years
LEGUME VEGETABLES		✓		Preplant, soil treatment	Ground boom	1.0 EC, WDG	1.0	NA	1	NA	NS	24	NA		No MRI because application only once a year
		✓		At planting, soil treatment	Ground boom	1.0 EC, WDG	1.0	NA	1	NA	NS		NA		
				Total		**1.0**	**1.0**	**NA**	**1**	**NA**	**NS**	**24**	**NS**		Assumed either a preplant or an at plant treatment.
MINT/ PEPPERMINT/ SPEARMINT		✓		Preplant soil incorporated	Aerial or ground/ broadcast	2.0 EC, WDG	[2.0] NS	2.0	[1] NS	1	90	24	NA	No use in Mississippi.	19713-599, 33658-26, 34704-857, 67760-28, 84229-25,

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															84930-7, OR940027 MRI NA due to once per crop cycle application
		✓		Post-emergence, Postharvest, Foliar	Chemigation, ground/ airblast	2.0 EC	2.0	2.0	[1] NS	2	90		NS	No use in Mississippi.	Postharvest application retreatment not specified on some labels.
				Total		**2.0**	**4.0**	**4.0**	**2.0**	**3**	**90**	**24**	**NS**		Labels allow one growing season application including pre-plant and one post-harvest application per season.
MOSQUITO CONTROL; HOUSEHOLD/ DOMESTIC DWELLINGS OUTDOOR PREMISES; RECREATIONAL AREAS	✓			When needed; broadcast	Ultra-low volume air and ground	0.01 EC	0.26	NA	26	NS	NA	NS	24 h	In Florida: Do not apply by aircraft unless approved by the Florida Dept of Ag.	Aerial applications may be made at altitudes ranging from 75-300 ft (see labels for specifics).

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															For use by federal, state, tribal or local government officials or by persons certified in the appropriate category or authorized by the state or tribal lead regulatory agency.
NECTARINE		✓		**dormant/ delayed dormant** broadcast	airblast, handgun	3.0 WDG, EC	3.0	NA	1	NA	NS	24/ 4d	10		83222-20 others at 2 lb a.i./a
					Aircraft	2.0 WDG, EC									Updated to reflect spray drift mitigation.
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**	Handgun, low pressure backpack, dip	2.5 (3.0/100 gal) WDG, EC	2.5	NA	1	NA	14		5		There is no application retreatment interval specified on some of the label. The application rate is provided as a dilution factor.

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				Total		**3.0**	**5.5**	**NA**	**2**	**NA**					Some labels limit the amount a.i./A per year. Multiple types of applications can occur such as preplant, trunk drench and dormant, delayed dormant applications. Excludes nursery applications (See general "Fruits" listing)
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES to and around outside surfaces of nonresidential buildings and structures. Permitted areas of use include				Outdoor general surface/ Band (may be better if called perimeter)	Ground sprayer/ band sprayer	1.0 EC	NS	NA	NS	NA	NA	NS	NS		

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
fences, pre-construction foundations, refuse dumps, outside of walls, and other areas where pests congregate or have been seen															
NURSERY-STOCK: : Ornamental nursery stock annuals, perennials and woody plants being grown in the field, in ball and burlap or in containers outdoor and in greenhouses				Dormant/ Delayed Dormant	high spray	3.0 EC	3.0	NA	1	NA		24	NS		
				Preplant	Ground boom, soil incorporated	4.0 EC, WP	NS	NA	NS	NA					
				foliar, soil directed	Tractor drawn spreader, push type spreader, belly grinder, gravity fed	1.1 G									

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
					backpack, spoon										
				Total		**4.0**	**CBD**		**3**						
ONIONS		✓		Post plant (seeding) Broadcast	Ground boom	1.0 EC	1.0	NS	2	NS	60	24	NS		
		✓		At plant, soil drench or basal spray	Ground boom	1.0 EC, WDG, G	1.0		1						2-inch incorporation
				Total		2.0	2.0		2		60	24	NS		
ORNAMENTAL AND/OR SHADE TREES, HERBACEOUS PLANTS		✓		Foliar broadcast	Ground boom, air blast, handgun, low- and high-pressure hand wands	2.0 EC, WP 1.0 G, B	2.0	NA	[2] NS	NA	NS	24	NS		Some labels include an MRI of 7 days.
		✓		Dormant /Delayed Dormant	Handgun, low pressure and backpack	3.0 EC	3.0	NA	1	NA	NS		7		Low volume spray permitted for concentrated solutions and lower rates.
ORNAMENTAL LAWNS AND TURF, SOD FARMS (TURF)		✓		When needed, broadcast, soil or spot treatment	ground boom (WP only), high pressure hand wand	3.76 EC, WP	7.52	NA	2	NA	NS	24	NS		
		✓		NS	Tractor drawn spreader, push type spreader, belly grinder	1.0 B	2.0	NA	2	NA	NS	24	NS		Bait is used for fire ant control.

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
ORNAMENTAL NON-FLOWERING PLANTS		✓		Foliar, broadcast, soil drench	Chemigation, ground boom, low and high pressure handwand, handgun, backpack sprayer, sprinkling can	0.007/gal ME	NS	NA	12	NA	NA	24	NS		Application rate provided as a dilution factor. Restricted use—occupational only
ORNAMENTAL WOODY SHRUBS AND VINES				Foliar broadcast	Ground boom, air blast, handgun, low- and high-pressure sprayer, backpack	2.0 EC, WDG 0.01 lb/gal EC	2.0 0.01 lb/gal	NA	[1] NS	NA	NS	24	NS		Several labels do not restrict the application rate in lb a.i./A. Examples include 16.5 lb/100 gal (228-625) and 1.0 lb/100 gal (829-280).
				Dormant/ delayed dormant		1.0 EC 0.005 lb/gal EC	1.0	NA	[1] NS	NA					
				Preharvest	Tractor drawn spreader, push type spreader, belly grinder	6.0 G	6.0	NA	[1] NS	NA					
				Preplant, potted, bailed-and	groundboom, handgun, low- and high-	1.0 EC	NS	1	NS	1					

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				burlapped, containerized	pressure sprayer, backpack, drench										
				Pretransplant	groundboom	4.0 WP	[48.0] NS	4	12	4					
				Total		**6.0 G 4.0 WP**	**CBD**		**CBD**						
PEACH		✓		**dormant/ delayed dormant** broadcast	airblast	3.0 EC 2.0 WDG	3.0	NA	1	NA	10	24/ 4d	NS		83222-20 (all other labels restrict to 2 lb ai/a)
					aircraft,	2.0 EC 2.0 WDG							NS		Updated to reflect spray drift mitigation.
		✓		**Post-harvest** broadcast	airblast	2.5 (3.0/100 gal) EC	2.5	NA	1	NA	NA		NS	Permitted in Georgia and South Carolina	GA0400001, SC040001 SLN Expires:
					aircraft	2.0 (3.0/100 gal) EC	2.0								GA0400001, SC040001 SLN Expires: Updated to reflect spray drift mitigation
		✓		pre-plant, foliar;	handheld, backpack, drench/dip,	2.5 (3.0/100 gal) WDG	2.5	NA	1	NA	14	5	NS		Some labels do not specify minimum

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				trunk spray/drench or pre-plant dip; ground	handgun, and low-pressure hand wand										retreatment interval.
						3.0	**5.5**	**NA**	**3**	**NA**	**NA**	**24**	**NS**		It is possible that multiple types of applications can occur such as soil, foliar and/or post-harvest and dormant/ delayed dormant applications. Excludes nursery applications (See general "Fruits" listing)
				Total		**3.0**	**8.0**	**NA**	**3**	**NA**	**NA**	**24**	**NS**	Permitted in Georgia and South Carolina	
PEANUT		✓		Preplant	Aerial or ground/ broadcast	2.0 EC, WDG	[4.0] NS	4.0	[2] NS	2	NA	24	10	Do not apply aerial in Mississippi	Assumes one crop cycle per year.
		✓		At plant, post plant		4.0 G	[4.0] NS	4.0	2	2	21	24	10		
		✓		At pegging		2.0 G EC, WDG	[4.0] NS	4.0	2	[2] NS	21	24	10		

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				Total		**4.0 G 2.0 EC, WDG**	**4.0**	**4.0**	**2**	**2**	**10**	**24**	**10**		
PEAR		✓		**dormant/ delayed dormant** broadcast	aircraft, airblast	2.0 WDG, EC	2.0	NA	1	NA	NA	24	NA	Restricted use in California.	83222-20 allows 3.0 lb a.i./ A; however, this does not match the 2001 RED.
		✓		**Post-harvest** broadcast	aircraft, airblast	2.0 WDG, EC	2.0	NA	1	NA	NA	24	NS	Permitted in California, Oregon and Washington.	
				Total		**2.0 WDG, EC**	**4.0**	**NA**	**2**	**NA**	**NA**	**24**	**NS**		Multiple types of applications may occur in within a year in California, Oregon and Washington such as a post-harvest application and a dormant, delayed dormant. Excludes nursery applications

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															(See general "Fruits" listing)
PEAS		✓		Preplant Seed treatment	Seed Treatment	0.30 0.000625 lb/lb seed WP 0.28 0.00058 lb/lb seed EC	NS	NS	NS	NS	NS	NS	NS		There is a range of potential application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding information provide by BEAD.[2]
PECANS		✓		**dormant/ delayed dormant** broadcast	aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	14		10		66222-19 and 66222-233
		✓		**foliar**; broadcast	airblast	4.3 EC, WDG	6.3	NA	3	NA	14	24	10		Some labels require a 28 d PHI
					aircraft	2.0 EC, WDG									Updated to reflect spray drift mitigation.
		✓		foliar; **orchard floors broadcast**	Ground boom, chemigation	4.3 EC, WDG	4.3	NA	2	NA	14		10		

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				Total		**4.3**	**12.6**	**NA**	**6**	**NA**	**14**	**24**	**10**		Considers multiple type of applications (*e.g.*, dormant, foliar broadcast, and orchard floor) but excluding nursery For nursery applications (See general "Fruits" listing)
PEPPER		✓		Foliar	Ground broadcast	1.0 WDG	[8] NS	8.0	[8] NS	8	7	24	10	Permitted in Florida	FL040005; 1 crop cycle per year.
PINEAPPLE		✓		Post plant	Ground boom, broadcast	2.0 EC	6.0	6.0	3	NA	365	24	30	Permitted in Hawaii	HI090001 SNL Expires: March 29, 2014. Do not make applications beyond three months after planting.
PLUM/ PRUNE		✓		**dormant/ delayed dormant**; broadcast	Aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	NA	24/ 4d	10		

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		foliar; **trunk spray/drench**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 3.0/100 gal WDG	2.5	NA	1	NA	NA		10		
				Total		**2.5**	**4.5**	NA	2	NA					Excludes nursery applications (See general "Fruits" listing)
POULTRY LITTER		✓		When needed, animal bedding/litter treatment.	Sprayer	0.07126 a.i./1000 sq ft 3.1 ME	NS	NA	NS	NA	NA		NS		53883-264, 84575-3
PUMPKIN		✓		Preplant Seed treatment	Seed treatment	0.3 0.00058 lb /lb seed WP	[0.3] NS	[1] NS	[1] NS	1	NS	NS	NS	California maximum single rate 0.000625 lb a.i./lb.	There is a range of potential application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding information provide by BEAD.[4]

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
RADISH		✓		Foliar	Broadcast ground	1.0 EC	NS	1	NS	1	NS	24	NS	permitted in Oregon	OR090012 on radish grown for seed. Label valid until December 31, 2012. (per registrant SLN still valid)
		✓		Preplant	Soil incorporation ground	3.0 EC	12.0	3	4	1	NS	NS	10		
		✓		At plant/post-plant	In furrow drench/ treatment	3.0 EC 2.8 G	[15.0] NS	3	[5] NS	1	30, EC, 7, G	24	10		Only one granular application permitted.
				Total		**3.0**	**[22.0] NS**	**2**	**[9] NS**						Only one preplant or at plant application is assumed.
RIGHTS OF WAY, ROAD MEDIANS				When needed, soil broadcast	Granular or low-pressure wand	1.0 EC, G, Bait	[2.0] NS	NA	2	NA	NA	NS	7		Apply when needed
RUTABAGA		✓		Preplant	Chemigation, Groundboom	2.4 EC, WDG	[4.8] NS	2.4	[2] NS	1	30	24	10		
					Aerial	2.0 EC, WDG		2.0							Updated to reflect spray drift mitigation.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		At plant/post-plant	In furrow drench/ treatment	2.4 EC, G WDG	4.8	2.4	[2] NS	1	7	24	10	Disallowed in California and Arizona.	Two crop cycles per year
				Total		**2.4**	**[9.6] NS**	**4.8**	**[4] NS**	**2**		**24**	**10**		
SEWER MANHOLE COVERS AND WALLS				When needed	Low pressure	0.31 lb/manhole RTU	NS	NA	NS	NA	NA	NA	NS		3 pints product/ manhole
SEED ORCHARD TREES		✓		**foliar**; broadcast	Ground boom	1.0 EC	3.0	3.0	NS	NA	30	24	7		62719-575, 62719-615
		✓			High volume sprayer	2.5 0.01 a.i./tree 0.02 EC	2.5	NS	[1] NS	NA	30	24	7		Cone worm treatment (62719-575 and 62719-615) Treatment of 1000 trees per acre would results in a single application rate of 10 lb a.i./a. DAS: 1000 is a bit high, typically for orchards 312 trees per acre
		✓		foliar; **stump treatment**	backpack, drencher, low	0.3 EC	0.3	1.0	NS	NA	30	24	7		62719-575, 62719-615

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
					pressure hand wand,										
				Total		**1.0**	**5.8**	**3**	**NS**	**NA**	**30**	**24**	**7**		The total number of applications assumed is either three foliar applications or two foliar applications with one stump treatment.
SORGHUM GRAIN		✓		Seed Treatment	Seed treatment	[0.0009] 0.01-0.0024 lb ai/ 100 lbs seed EC	0.01	0.01	[1] NS	1	NA	NS	NS		264-932
		✓		Preplant Soil Directed	Ground Spreader/T Band	1.5 G	1.5	1.5	[1] NS	1	60	24	10		
		✓		Foliar/Post emergent	Ground, Aerial, Chemigation	1.0 EC, WDG	1.5	[1.5] NS	[1] NS	3	30	24	10		PHI varies across labels
				Total		**3.3 G 1.0 EC, WDG**	**3.01**	**3.01**	**[3] CBD**	**3**	30	24	10		One crop cycle per year.
SOYBEAN		✓		foliar , post-emergence soil broadcast	broadcast ground, aerial, chemigation	1.0 EC, WDG	3.0	3.0	3	3	28	24	14		One crop cycle per year.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		At plant/post plant treatment; soil band	ground boom	2.2 G 1.0 EC	3.0	3.0	1 (G), 3 (EC)	1 (G), 3 (EC)	28	24	10		
				Total		**1.0 EC, WDG 2.2 G**	**3.0**	**3.0**	**3**	**3**					One crop cycle per year.
STRAW-BERRIES		✓		Pre-plant	Aerial or ground/ broadcast	2.0 EC	2.0	**NS**	1	NS	NA	24	10	No use in Mississippi	33658-26
		✓		Foliar	Aerial or ground/ broadcast, foliar spray	1.0 EC, WDG	2.0	**NS**	2	**NS**	21	24	10		Two applications (2 lb ai) for all products per cc.
		✓		Post-harvest	Ground directed spray	1.0 EC, WDG	2.0	**NS**	2	**NS**	21		14		
				Total		**2.0**	**4.0**		**3**						One preplant application and two foliar and/or postharvest application permitted per year.
SUNFLOWER		✓		At plant	Aerial/ground	2.0 G	3.0	3.0	[1] NS	1	42	24	10		Per registrant 1 cc per year

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Preplant		2.0 EC, WDG	3.0	3.0	[1] NS	1	42		10		2 inches min incorporation
		✓		Post emergent or foliar		1.5 EC, WDG	3.0	3.0	[2] NS	2	42		10		
				Total		**2.0**	**5.0**	**5.0**	**3**	**3**					Assumed either an at plant or preplant application followed with two foliar applications. One crop cycle per year
SWEET POTATO		✓		Preplant, soil broadcast	Aircraft, ground boom	2.1 G, EC, WDG	2.1	NS	1	1	125	24		LA090002, MS080007, NC090001 permits 60 PHI	
					Aircraft	2.0 G, EC, WDG									Updated to reflect spray drift mitigation.
TOBACCO		✓		Preplant	Aircraft, ground boom	2.0 EC, G, WDG	2.0	NS	1	1	7	24	NA		
TRITICALE		✓		Storage Commercial Slurry Seed Treatment	Seed treatment	0.003 0.0024 lb ai/ 100 lbs seed EC	[0.003] NS	[1] NS	[1] NS	[1] NS	NA	[10] NS	[10] NS		264-932 Seeding information provide by BEAD.[4] One crop cycle per year.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
TURNIP		✓		Preplant	soil incorporation/ ground boom, handgun	2.3 G, WDG	[4.6] NS	2.3	[2] NS	1	30	24	10		Minimum incorporation: 2 inches.
		✓		Post plant	Soil incorporation/ ground boom, handgun	2.3 G, WDGP	[4.6] NS	2.3	[2] NS	1	30	24	10		Minimum incorporation: 2 inches.
				Total		**2.3**	**4.6**	**2.3**	**2**	**1**	**30**	**24**	**10**		Assumed either a preplant or post plant application. Two crop cycles per year
UTILITIES For use in and around telecommunications, power, utilities and railroad systems equipment: Buried cables, cable television pedestals, cables, pad-mounted electric power transformers, telephone cables, underground				When needed, broadcast	Product container	190.5 G 0.44 lb ai./100 sq ft (see comments)	NS	NS	NS	NS	NS	NS	NS		Applications permitted as needed. Reg. Nos. 13283-14, 13283-17 Broadcast product onto the ground covering the area of the pad location, plus a two-foot perimeter around the outside of the pad location.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
vaults, telecommunications equipment, power and utilities equipment															
WALNUTS		✓		**dormant/ delayed dormant**; broadcast	Aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	14		10		62719-301 (12 lb a.i./A)
		✓		**foliar**; broadcast	aircraft, airblast, chemigation	2.0 EC, WDG	4.0	NA	2	NA	14	24	10		Some labels do not specify retreatment interval.
		✓		foliar; **orchard floors broadcast**	Ground boom, chemigation	4.0 EC, WDG	4.0	NA	1	NA	14		10		
				Total		**4.0**	**10.0**		**4**						Excluding nursery applications; includes dormant, foliar broadcast, and orchard floor. For nursery applications (See general "Fruits" listing)

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
WIDE AREA/ GENERAL OUTDOOR TREATMENT For ants and other misc. pests.	✓	✓		when needed, Broadcast	Ground sprayer	0.5084 lb ai/100 gal EC	[1.02] NS	NA	2	NA	NA	NS	NS		66222-19
				when needed, Drench	Drench	1	NS	NA	NS	NA	NA		NS		228-624
						[1] 8.2 lb a.i/100 gal EC	NS	NA	NS	NA	NA		NS		228-625
				Total		[1]	NS	NA	NS	NA	NA				
WHEAT		✓		Slurry Seed Treatment	Seed treatment	0.003 0.0024 lb ai/ 100 lbs seed EC	[0.006] NS	1	[2] NS	1	NA	NA	NA	Only for use in AZ, CA, CO, ID, KS, MN, MO, NE, NM, NV, ND, OK, OR, SD, TX, UT, WA and WY	Seeding information provide by BEAD.[4]
		✓		Foliar, soil treatment	Ground, broadcast	0.5 EC	[8.0] NS	4.0	[2] NS	1	14/ 28	24	14		PHI: 14 forage or hay, 28 grain or straw
		✓		Post-emergence foliar	Ground, Aerial, Chemigation	1.0 EC	[4.0] NS	2.0	[4] NS	2	14/ 28		NS		Label states 1.0 lb ai/A for cereal leaf beetles and then state max rate 0.5 lb ai/A in restriction). Some labels restrict no more than 2 applications per crop/season PHI 14 forage or hay, 28 grain or straw

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				Total		**[1] 4.0 EC**	[12.006]	**[6.003] 5.0**	[8] NS	[4] 2					MO otherwise 2.0 plus seed treatment
WOOD PROTECTION TREATMENT TO BUILDINGS/ PRODUCTS OUTDOOR				When needed, Wood surface treatment	Low pressure handwand, backback sprayer, paintbrush	16.65 lb/10,000 sq ft 0.17 lb a.i./gal EC	NS	NA	NS	NA	NS	NS	NS		
						0.08 lb ai/gal EC, RTU EC, ME	NS	NA	NS	NA	NS	NS	NS		Apply 1 gal per 100 sq ft of wood

1. EC - emulsifiable concentrate; WDG – water dispersible granular in water soluble packet; WP – wettable power in water soluble packet; B – bait (granular), G – granular; ME – microencapsulated; RTU – ready to use.
2. Reported as per crop cycle or per season
3. PHI – Preharvest interval; REI – reentry interval; MRI – Minimum retreatment interval
4. Becker, J.; Ratnayake, S. Acres Planted per Day and Seeding Rates of Crops Grown in the United States, U.S. EPA OPP/BEAD, 2011; example calculations provided below:
   Beans: 0.00058 lb a.i./lb seed / 960 seeds/lb seed x 418,176 seeds/A [pgs. 19, 81 (beans, succulent)]
   Corn: 0.000625 lb a.i./lb seed / 1,800 seeds/lb seed x 59,739 seeds/A [pgs. 24, 81 (corn, sweet)]
   Cotton: 0.00116 lb a.i./lb seed / 4,500 seeds/lb seed x 85,00 seeds/A [pgs. 13, 81]
   Cucumber: 0.00058 lb a.i./lb seed / 12,000 seeds/lb seed x 80,418 seeds/A [pgs. 25, 81]
   Peas: 0.000625 lb a.i./lb seed / 1,361 seeds/lb seed x 653,400 seeds/A [pgs. 34, 82]
   Pumpkin: 0.00058 lb a.i./lb seed / 1,600 seeds/lb seed x 7,260 seeds/A [pgs. 37, 82]
   Sorghum: 0.001 lb a.i./lb seed / 11,000 seeds/lb seed x 100,000 seeds/A [pgs. 16, 39]
   Triticale: 0.003 lb a.i./100 lb seed / 109 lb seed/A [pg.16]
   Wheat: 0.003 lb a.i./100 lb seed /116 lb seed/A [pg. 16]
   [ ] indicate assumptions that are made when the information is not specified but can be inferred

Appendix 6: Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1; the AHETF database; the Outdoor Residential Exposure Task Force (ORETF) database; the ARTF database; ExpoSAC Policy 14 (SOPs for Seed Treatment); the 2012 Residential SOPs: Lawns/Turf, Outdoor Fogging/Misting Systems; registrant-submitted exposure monitoring studies MRIDs 44180401, 44301301, 44793301, 44829601, 42974501, 43062701, 44748101, 44748102, 46722701, and 46722702; and published literature studies are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency.

Appendix 7: Residential Mosquito ULV Spreadsheets

See attached spreadsheets:

- Appendix 7_1_Adult Worst Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_2_Adult Best Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_3_Child Worst Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_4_Child Best Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_5_Adult Ground Mosquito ULV applications.xlsx
- Appendix 7_6_Child Ground Mosquito ULV applications.xlsx

Appendix 8: Residential Post-Application Golfing Spreadsheet

See attached spreadsheet:

- Appendix 8_Chlorpyrifos Residential Golfer Postapp.xlsx

Appendix 9: Spray Drift Spreadsheets

See attached spreadsheets:

- Appendix 9_1_Adult Drift with MS TTR Data _ 6 lb ai through 3.xlsx
- Appendix 9_2_Adult Drift with MS TTR Data _ 2 lb ai and below.xlsx
- Appendix 9_3_Child Drift with MS TTR Data _ 6 lb ai through 3.xlsx
- Appendix 9_4_Child Drift with MS TTR Data _ 2_3 lb ai through 1_0.xlsx

Appendix 10: Occupational Handler Spreadsheets

See attached spreadsheets:

- Appendix 10_1_Chlorpyrifos Occup Handler Risk Estimates.xlsx
- Appendix 10_2_Occ Seed Treatment.xlsx

Appendix 11: Occupational Post-Application Spreadsheets

See attached spreadsheet:

- Appendix 11_Occupational Postapp.xlsx

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

PC Code : 059101
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September 15, 2020

MEMORANDUM

SUBJECT: Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review

TO: Patricia Biggio, Chemical Review Manager
Matthew Manupella, Acting Team Leader
Dana Friedman, Branch Chief
Risk Management and Implementation Branch 1
Pesticide Re-Evaluation Division (7508P)

THROUGH: Dana Spatz, M.S., Chief
Environmental Risk Branch 3
Environmental Fate and Effects Division (7507P)

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FROM: Rochelle F. H. Bohaty, Ph.D., Senior Chemist
Sarah C. Hafner, Ph.D., Chemist
Environmental Risk Branch 3
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This memorandum transmits an update to the refined chlorpyrifos drinking water assessment completed in 2016 for registration review, as well as supporting documents and files. This update builds upon the 2016 DWA and focuses on a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. These uses were identified as being high benefit crops to growers by the Biological and Economic Analysis Division in OPP, or the most important of all the currently registered uses by Corteva Agriscience. As in past assessments, this refined assessment considers usage data, upper bound, and average application rates. Furthermore, this update uses updated scenarios (i.e., uses new soil, weather, and crop data), applies new methods for considering the entire distribution of community water systems percent cropped area adjustment factors, integrates state level percent crop treated data, and includes quantitative use of surface water monitoring data.

The exposure estimates reported in this assessment and associated conclusions drawn are solely for those uses listed above. Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).

Chlorpyrifos

Drinking Water Assessment for Registration Review: Update

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September 15, 2020

Abstract

This refined drinking water assessment provides an update to the 2016 drinking water assessment for the registration review of chlorpyrifos. This assessment only evaluates a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. This subset of uses was identified as being the most important of all the currently registered uses of chlorpyrifos.

This assessment utilizes new surface water model scenarios (i.e., soil, weather, and crop data), integrates the entire distribution of community water system percent cropped area adjustment factors, integrates state-level percent crop treated data, and considers the quantitative use of available surface water monitoring data. These methods have recently undergone external peer and public review.

Concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are not likely to exceed the drinking water level of comparison (DWLOC) with or without the retention of the FQPA safety factor for the subset of uses considered. This conclusion is based on upper bound application rates determined from usage data.

Analysis of monitoring data shows that there are several monitoring sites across the United States that could have concentrations higher than the DWLOCs. However, the contribution of other currently registered uses of chlorpyrifos (i.e., uses not considered in this assessment), could not be ruled out, nor could a definitive conclusion be made that the measured concentration data correlated to one of the specific uses evaluated in this assessment.

Executive Summary

This drinking water assessment (DWA) updates and builds upon the 2016 drinking water assessment for chlorpyrifos (USEPA, 2016) completed as part of the registration review process. The focus of this assessment is surface water, as groundwater was determined to not be a potential route of exposure concern in prior assessments. The estimated concentrations from the 2016 DWA for the specific uses considered in this update were used as a gauge for determining the need for refinement.

Exposure estimates for chlorpyrifos and chlorpyrifos-oxon in drinking water sourced from surface water are provided for upper bound and average application rates and typical application timing for a subset of currently registered uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in defined areas of the country (i.e., Hydrologic Unit Code (HUC)-2 regions). These uses encompass a large portion of the total amount of chlorpyrifos applied per year on a national basis, but there is also a lot of chlorpyrifos use that is not captured by these crops, including use on corn, almonds, grapes, peanuts, pecans, and walnuts, for example.

This subset of uses was selected based on discussion of critical uses with the registrant, Corteva Agriscience, and high benefit crops determined by the Biological and Economic Analysis Division (BEAD). As California is in the process of canceling most chlorpyrifos uses, this DWA does not consider use in California (HUC-18), except with respect to an evaluation of the monitoring data. Monitoring data from California reflects historical usage of chlorpyrifos that may also represent uses and environmental conditions relevant to the uses considered in this assessment.

This drinking water assessment integrates three recently developed and externally peer reviewed method improvements for conducting drinking water assessments.

1) ***New surface water model scenarios (i.e., soil, weather, and crop data):*** The Pesticide in Water Calculator (PWC) is a model that uses soil, hydrology, land cover/land use, weather, and waterbody properties to simulate environmental conditions to estimate pesticide concentrations for risk assessment purposes. The development of new PWC scenarios described in the methods document titled, *"Creating New Scenarios for Use in Pesticide Surface Water Exposure Assessments"* (USEPA, 2020) provides an opportunity to clearly and consistently identify field scenario inputs, and to rank the millions of new scenarios by vulnerability, thus providing a better understanding of estimated concentrations relative to environmental conditions and use.

2) ***Use of community water system percent cropped area (PCA) adjustment factors and state level percent crop treated (PCT) data:*** The recently completed methods document titled *"Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment"* (USEPA, 2020) provides an approach to apply use and usage data to further refine estimated drinking water concentration (EDWCs) in higher-tier assessments for agricultural and non-agricultural uses individually or in combinations. The goal of the PCA and PCT refinements is to generate EDWCs that are appropriate for human health risk assessment, but more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations.

3) ***Quantitative use of surface water monitoring data:*** EPA recently evaluated the extent to which existing monitoring data can describe the range of possible pesticide concentrations, using updated tools for monitoring data analysis. The seasonal wave with streamflow adjustment and extended capability (SEAWAVE-QEX) model and sampling bias factors (SBFs) were evaluated for short-term and long-term exposure durations of interest and described in the White Paper titled *"Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments"* and presented to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in November 2019. The goal of this work is to use surface water monitoring data at higher tiers to confidently estimate pesticide concentrations in surface water that may be sourced by community water systems.

A description of how these methods fit into the overall tiered drinking water assessment process can be found in the Framework for Conducting Pesticide Drinking Water Assessments for Surface Water (DWA Framework) (USEPA, 2020).

Both chlorpyrifos and chlorpyrifos-oxon are considered residues of toxicological concern in drinking water in this assessment. Chlorpyrifos-oxon forms from the treatment, e.g., chlorination, of source water containing chlorpyrifos. While chlorination is the primary method of disinfection used in the United States, other methods are used such as chloramines. Generally, alternatives to chlorination are used by systems serving larger populations.

To address the multitude of water treatment possibilities across the country, a bounding approach is used in this assessment to capture the range of potential exposures to chlorpyrifos or chlorpyrifos-oxon in drinking water. To represent those facilities that use disinfectant processes not including free chlorine, 100 percent of the chlorpyrifos entering the facility was assumed to be unchanged in the finished drinking water. Alternatively, to represent those facilities that employ chlorine as a disinfectant, 100 percent of the chlorpyrifos entering the facility was assumed to convert to chlorpyrifos-oxon, which is persistent over typical drinking water treatment distribution times.

The drinking water estimates are compared with four different DWLOCs. The Health Effects Division (HED) provided EFED with drinking water levels of comparison based on 10% red blood cell acetylcholinesterase inhibition for both acute (1-day) and steady state (21-day) exposure. For each of these exposure durations, two DWLOCs are considered, one with, and one without retention of the 10X FQPA safety factor.

Acute DWLOCs were calculated by HED for infants, children, youths, and adult females both with and without the 10X FQPA SF. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb chlorpyrifos-oxon. With the FQPA SF removed (FQPA SF of 1X) the lowest acute DWLOC calculated was for infants (<1 year old) at 240 ppb chlorpyrifos-oxon. Steady state DWLOCs were calculated by HED for infants, children, youths, and adult females both with and without the 10X FQPA SF. With the 10X FQPA SF retained, the lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb chlorpyrifos-oxon. With the FQPA SF removed (FQPA SF of 1X) the lowest steady state DWLOC calculated was for infants (<1 year old) at 43 ppb chlorpyrifos-oxon.

While this drinking water assessment is more refined than the 2016 assessment, it continues to demonstrate that exposure is sporadic, both temporally and spatially. This is supported by both model-

estimated concentrations, as well as measured chlorpyrifos concentrations in surface water across the United States.

Modeling results suggest EDWCs of either chlorpyrifos or chlorpyrifos-oxon in raw water (i.e., source water) or finished drinking water are not likely to exceed the DWLOCs for the 11 critical/high benefit uses included in this assessment, with or without the 10x FQPA safety factor. This conclusion only applies to these specific 11 uses in the areas of the country specified. It would be necessary to conduct a new DWA if additional uses were considered. Of note, this assessment does not account for potential residues in drinking water that may result from application on high usage crops such as corn, almonds, grapes, peanuts, pecans, and walnuts, as these crops were not identified by Corteva as critical uses or by BEAD as having high benefit to growers. This assessment also does not account for exposure from non-agricultural uses. If additional crops or non-agricultural use sites are considered, it is expected that model estimated concentration could be above the 10x DWLOC in some areas of the country, primarily driven by the increase in percent cropped area. It is possible with refinement that additional crops or non-agricultural use sites may result in concentrations below the 1x DWLOC; however, additional work would be necessary.

Evaluation of available surface water monitoring data and the application of SEAWAVE-QEX and sampling bias factors suggests chlorpyrifos-oxon concentrations may be above both the 1-day and 21-day DWLOCs with or without the FQPA safety factor. Additional analyses were completed as part of a weight-of-evidence to better understand what uses and environmental conditions are associated with these concentrations, however, the available monitoring data could not be specifically linked to the uses considered in this assessment.

Our analysis shows that the concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are expected to vary across the country with the highest potential for exposure in high use areas in vulnerable (*i.e.*, runoff prone) watersheds. Whether exposure is to chlorpyrifos or chlorpyrifos-oxon is highly dependent on local drinking water treatment processes.

a. Modeling Summary

A summary of the chlorpyrifos-oxon EDWCs resulting from upper bound (descriptions are provided by crop in supporting document provided in **ATTACHMENT 2**) application rates for each refinement step are presented in **Table 1** by 2-digit HUC region. Only chlorpyrifos-oxon EDWCs are provided here as the exposure and risk assessment conclusions are driven by exposure to chlorpyrifos-oxon.

Table 1. Surface Water Sourced Estimated Drinking Water Concentrations Resulting from Different Refinements for a Subset of Upper Bound Application of Chlorpyrifos Uses

2-digit HUC Name Overlapping States[1]	2-digit HUC Uses	Maximum 1-in-10 Year Estimated Chlorpyrifos-oxon Concentrations in Source Surface Water (µg/L)			
		Maximum 2-digit HUC Use Site-Specific Percent Cropped Area[2]		Percent Cropped Area Aggregation[3]	Percent Cropped Area-Percent Crop Treated Aggregation[4]
		1-day Average	21-day Average	21-day Average	21-day Average
Mid-Atlantic VT, NY, PA, NJ, MD, DE, WV, DC, VA	HUC-02 Apple and Peach	1.0	0.8	-	-
South Atlantic-Gulf VA, NC, SC, GA, FL, TN, MS	HUC-03 Cotton, Citrus, Peach, and Soybean	3.1	1.8	-	-
Great Lakes WI, MN, MI, IL, IN, OH, PA, NY	HUC-04 Alfalfa, Sugar beet, Apple, Cherry, Peach, Soybean, and Asparagus	22.8	19.6	3.4	-
Ohio IL, IN, OH, PA, WV, VA, KY, TN	HUC-05 Apple and Soybean	5.3	4.0	-	-
Tennessee VA, KY, TN, NC, GA, AL, MS	HUC-06 Apple	0.4	0.2	-	-
Upper Mississippi MN, WI, SD, IA, IL, MO, IN	HUC-07 Alfalfa, Sugar beet, and Soybean	9.9	7.2	5.4	3.2
Souris-Red-Rainy ND, MN, SD	HUC-09 Alfalfa, Sugar beet, Soybean, Spring Wheat, and Winter Wheat	8.3	5.6	5.2[4]	3.3
Missouri MT, ND, WY, SD, MN, NE, IA, CO, IA, KS, MO	HUC-10 Alfalfa, Soybean, Spring Wheat, and Winter Wheat	5.7	3.6	-	-
Arkansas-White-Red CO, KS, MO, NM, TX, OK, AR, LA	HUC-11 Alfalfa, Soybean, and Winter Wheat	3.9	3.9	-	-
Texas-Gulf NM, TX, LA	HUC-12 Citrus, Peach, and Winter Wheat	1.1	0.7	-	-
Pacific Northwest WA, ID, MT, OR, WY, UT, NV	HUC-17 Alfalfa, Sugar beet, Apple, and Strawberry	8.5	6.1	2.5	-

Green shading indicates concentrations are below the 10x DWLOC (1-day = 43 µg/L and 21-day = 4.0 µg/L) while red shading indicates concentrations are above the 10x DWLOC.
- indicates values are not calculated because the concentrations in the prior step were below the 10x DWLOC.
[1] Sites are listed that include any overlap with the HUC-2 region.
[2] Use site-specific PCA refers to the use of a percent cropped area adjustment factor to adjust EDWCs to account only for the potential use sites (e.g., for example for HUC-03 the PCA is the summation of individual percent cropped area for orchard, cotton, and soybean) within each individual community water system where chlorpyrifos is being considered (see column "2-digit HUC Uses").
[3] PCA aggregation refers to the use of individual percent cropped area adjustment factors to proportionally allocate pesticide residue contribution in the development of EDWCs based on potential chlorpyrifos use sites (i.e., land use data) for individual watersheds. This analysis was done using the model output 1-in-10 year values and does not account for temporal residue contributions.
[4] PCA-PCT aggregation refers to the use of individual percent cropped area adjustment factors to proportionally allocate pesticide residue contribution in the development of EDWCs based on known chlorpyrifos use for individual watersheds. This analysis was done using the model output 1-in-10 year values and does not account for temporal residue contributions.
[5] The use pattern specific PCA is higher (i.e., >1) than all-ag PCA (0.95). Therefore, the use pattern specific PCA is capped at all-ag value and the use pattern PCA should not exceed the all-agricultural PCA. However, when aggregating the individual use residue contributions results, this capping cannot be completed.

In summary, after the first refinement of applying use (usage rates, application dates and retreatment interval) data along with 2-digiti HUC maximum use site-specific percent cropped area (PCA), the EDWCs for upper bound application rates are below both the 1-day and 21-day 1x DWLOCs. However, EDWCs are above the 21-day 10x DWLOC in HUC-04 (considering use only on alfalfa, sugar beet, apple, cherry, peach, soybean, asparagus), HUC-07 (considering use only on alfalfa, sugar beet, soybean), HUC-09 (considering use only on alfalfa, sugar beet, soybean, and spring and winter wheat), and HUC-17 (considering use only on alfalfa, sugar beet, apple, and strawberry). These regions were further refined.

After the second refinement, which includes aggregation of the 1-in-10 year 21-day average concentrations (i.e., portioning the residue contribution from each use), only HUC-07 and HUC-09 have EDWCs greater than the 10x DWLOC. HUC-04 and HUC-17 are no longer considered for further refinement.

The third refinement, which utilized the application of percent crop treated data based on state level usage data in HUC-07 and HUC-09, suggests that concentrations are below the DWLOCs.

The exposure estimates reported in Table 1 and associated conclusions drawn are solely for those uses listed above. Consideration of fewer uses reduces the footprint (i.e., percent cropped area) where chlorpyrifos may be applied. Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).

It should be noted that in some cases the states included (or listed) in a region, as described in Table 1, may not entirely fall within one region. Therefore, the regional conclusions should not be assumed to occur across the entire state, but only part of the state with overlap.

b. Monitoring Summary

SEAWAVE-QEX analysis was completed for 11 sites across the country. SEAWAVE-QEX permits the estimation of pesticide concentrations between sampling events. Estimated chlorpyrifos and chlorpyrifos-oxon concentrations from SEAWAVE-QEX do not exceed the 1- or 21-day 1x or 10x DWLOCs.

Application of SBFs to sites with enough data to support a high confidence analysis indicate that concentrations may be higher than the DWLOCs in HUC-17. Sites with less data suggest concentrations could be higher than the DWLOCs in several HUCs for both the 1- and 21-day and 1x and 10x DWLOC. It should be noted that most available monitoring data for chlorpyrifos do not meet data quantity criteria for use in SEAWAVE-QEX or for the quantitative application of SBFs. Generally, the highest quality and quantity of chlorpyrifos data would be considered historical. The detection frequency for chlorpyrifos has generally gone down in recent years; however, often this is concurrently observed with a reduction in sample frequency, so it cannot be determined if occurrence frequency of chlorpyrifos is going down.

Problem Formulation

a. Background

Over the past 15 years, there have been four assessments of potential chlorpyrifos exposure in drinking water. In the 2001 Interim Reregistration Eligibility Decision (IRED), OPP considered exposure to chlorpyrifos in drinking water[1,2] and recommended the quantitative use of monitoring data to estimate exposure in groundwater. At the time of the IRED, measured chlorpyrifos concentrations in groundwater from termiticide uses (greater than 2000 µg/L) were the primary focus of drinking water exposure. The model groundwater concentrations were orders of magnitude lower than the measured concentrations. The termiticide use was canceled after the IRED.

In 2011, a preliminary drinking water assessment derived EDWCs for several agricultural uses of chlorpyrifos on a national basis and examined available monitoring data (USEPA, 2011). That assessment recommended the use of surface water EDWCs derived from modeling and concluded that a range of agricultural uses could lead to high levels (peak concentrations greater than 100 µg/L) of chlorpyrifos in surface water that could potentially be used by community water systems to supply drinking water. The 2011 assessment also discussed the effects of drinking water treatment on chlorpyrifos. It concluded that once it reaches a drinking water treatment facility, chlorpyrifos can be readily converted to chlorpyrifos-oxon during disinfection processes, primarily through oxidative treatment methods such as chlorination. Therefore, chlorpyrifos and chlorpyrifos-oxon were considered residues of concern in the preliminary assessment to account for the variation of drinking water treatment methods used by community water systems around the country.

The updated 2014 drinking water assessment (USEPA, 2014) considered public comments received following release of the 2011 drinking water assessment. The 2014 assessment presented an approach for deriving more regionally specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos-oxon for two 2-digit HUC regions (**Figure 1**).[3] A 2-digit HUC region is a hydrologically-based area that delineates contiguous drainage areas. There are 18 regions in the lower 48 states, plus 1 additional each for Alaska, Hawaii, and the Caribbean (21 regions total in the U.S.). It also provided several additional analyses that focused on 1) clarifying labeled uses, 2) evaluating volatility and spray drift, 3) revising aquatic modeling input values following updated guidance documents, 4) comparing aquatic modeling and monitoring data, 5) summarizing the effects of drinking water treatment, 6) updating model simulations using current exposure tools, and 7) proposing a strategy to refine the

[1] U.S. Environmental Protection Agency, Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides, September 28, 2001

[2] Barrett, M, Nelson, H, Rabert, W., Spatz, D. Reregistration Eligibility Science Chapter for Chlorpyrifos Fate and Environmental Risk Assessment Chapter, June 2000

[3] Hydrologic Units Codes are a hierarchical system developed by United States Geological Survey to catalogue hydrological units within the United States. In this system, there are 18 individual HUC-02 regions in the contiguous drainage areas in the United States with an average size of 177,560 mi^2. The U.S. is divided and sub-divided into smaller hydrologic units. These units are arranged within each other and identified by a unique code consisting of two to eight digits based on the levels of classification in the hydrologic unit system. Additional information can be found at https://water.usgs.gov/GIS/huc.html.
Seaber P.R., Kapino, F. P., Knapp, G. L., 1997 Hydrological Unit Maps. W. S. P. United States Geological Survey. March 2007. Available at http://pubs.usgs.gov/wsp/wsp2294/ (Accessed March 5, 2016)

assessment using the drinking water intake percent cropped area adjustment factors. The additional analyses did not change the overall exposure assessment conclusions previously reported in the 2011 DWA.

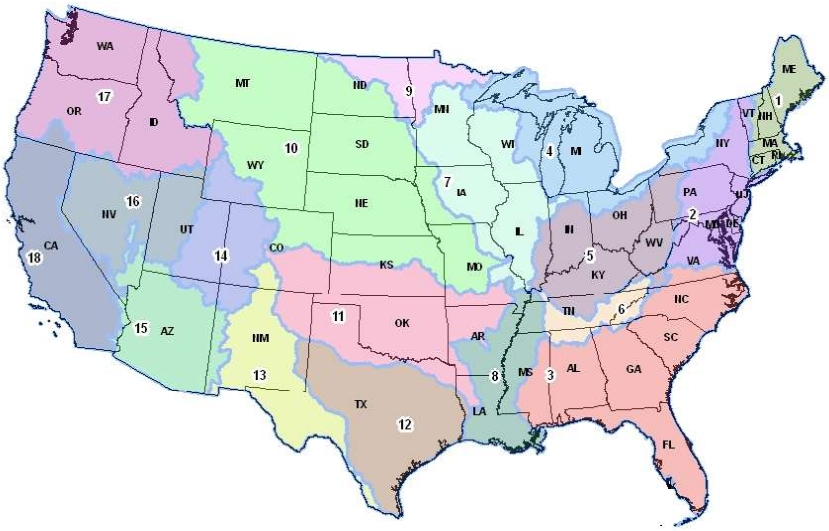


Figure 1. Spatial Distribution of HUC-02 Regions and U.S. State Boundaries

The 2016 DWA (USEPA, 2016) served to combine, update, and complete analysis for all 2-digit HUCs (or regions) presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. The document specifically focused on the exposure estimates for surface water. Urban uses, that had not previously been assessed due to label ambiguities and challenges interpreting the label, were also included. PWC-modeled estimated concentrations indicated that chlorpyrifos and chlorpyrifos-oxon concentrations in drinking water vary over the landscape with potential for localized concentrations to be >100 µg/L for the 21-day average concentration based on maximum use rates provided on the Master Use Summary Table (see **ATTACHMENT 1**). Results were also provided for application rates reflective of typical usage practices, resulting in lower concentrations, though many concentrations are above the current DWLOCs (see **Residues of Concern and Drinking Water Level of Comparison** section beginning on **page 22**).

In addition, a robust statistical analysis of all available surface water monitoring data for chlorpyrifos and chlorpyrifos-oxon was completed as part of the 2016 drinking water assessment. This included data from federal, state, and local agencies, universities, and the registrant.[4] The challenges and uncertainties in evaluating the chlorpyrifos and chlorpyrifos-oxon monitoring data were explained in detail. In summary, the data were determined to be inadequate to characterize the potential short-term exposure to chlorpyrifos and chlorpyrifos-oxon across the landscape. Though the model SEAWAVE-Q and SBFs were used to quantify the potential temporal uncertainty in the available monitoring data (i.e.,

[4] Surface water monitoring programs considered as part of 2016 DWA include Dow Agrosciences California Monitoring Program (DACMP), California Department of Regulation Surface Water Database (SURF), California Environmental Data Exchange Network (CEDEN), Central Coast Water Quality Preservation (CCWQP), Central Valley Irrigated Land Program (ILRP_5) , Central Valley Regional Water Control Board (CV_DNC_BPA), Oregon ELEM (OR ELEM), Registrants Organophosphate Monitoring Study, US EPA Storage and Retrieval Warehouse (STORET), USDA Pesticide Data Program (PDP), USGS National Water Information System (NWIS), USGS National Water Quality Assessment (NAWQA), USGS_EPA Stream Quality Index (USGS_MSQI), USGS State Data, USGS-EPA Pilot Monitoring Program (USGS-EPA reservoir), and Washington State Department of Agriculture (WSDA).

from non-daily sampling) on a site-specific basis, the assessment concluded that concentrations in aquatic systems likely fall within the range of PWC model-estimated concentrations reported in the assessment and could be above the DWLOC discussed in this assessment (see **Residues of Concern and Drinking Water Level of Comparison** section beginning on **page 22**).

b. Assessment Scope

This document provides an update to the refined drinking water assessment completed in 2016. This update integrates three new methods for advancing how EFED conducts drinking water assessments. The three methods include:

1) incorporation of new PWC surface water model scenarios (i.e., soil, weather, and crop data);
2) presentation of the entire distribution of community water systems percent cropped area adjustment factors and integration of state level percent crop treated area data; and
3) quantitative use of surface water monitoring data.

This assessment focuses on a subset of currently registered chlorpyrifos uses. Specifically, this assessment focuses on critical and high benefit uses of chlorpyrifos on alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, wheat, and strawberry in specific 2-digit HUC regions except for HUC-18, -19, -20, and -21. HUC-18 is not considered because California which makes up most of the region is canceling most chlorpyrifos uses. The other HUCs are not typically considered in drinking water assessments. HUCs in the contiguous states are expected to cover these regions -19, -20, and -21 are not expected to have the same agricultural intensity as areas within the contiguous states.

This assessment builds upon prior assessments and begins at the Tier 3 assessment level and proceeds through a Tier 4 assessment level, the most highly refined assessment tier. Based on prior monitoring data analysis conducted as part of the 2016 DWA and preliminary analyses completed as part of this assessment, it was decided that a Tier 4 monitoring data analysis would be beneficial to the assessment and could be informative if additional crops were evaluated. EDWCs are compared to the DWLOC (for more information on the DWLOC see the Residues of Concern and Drinking Water Level of Comparison section on **page 22** on this document).

c. Use Characterization

Chlorpyrifos is an organophosphate used as an insecticide on a wide variety of terrestrial food and feed crops, terrestrial non-food crops, greenhouse food/non-food, and non-agricultural indoor and outdoor sites. Based on an Office of Pesticide Programs Information Network (OPPIN) query (conducted July 2020), there are currently 112 active product labels (76 Section 3s and 36 Special Local Needs), which include formulated products (some with multiple active ingredients) and technical grade chlorpyrifos.

Several updates have been made to the chlorpyrifos registration over the years. For example, in the early 2000s, the registrants voluntarily agreed to eliminate and phase out some uses including eliminating most homeowner uses, as well as use on tomatoes, and restricting use on apples to pre-bloom and dormant applications. In addition, in 2002 label changes were made to include buffer zones to protect water quality as well as several reductions in application rates per season on a variety of crops including citrus and corn. More recent label updates have included spray drift buffers for sensitive sites (e.g., schools) to protect human health. In addition, in the early 2010s a master use summary table

was developed in consultation with the technical registrants to ensure consistency across labels and further define the intended use of chlorpyrifos.

1. Master Use Summary Table

The Environmental Fate and Effects Division (EFED) in consultation with the Pesticide Re-evaluation Division (PRD), the Biological and Economic Analysis Division (BEAD), and the Health Effects Division (HED) developed a list of all chlorpyrifos registered uses (see Master Use Summary Table provided in **ATTACHMENT 1**). This summary reflects all currently registered labels and any agreed-upon changes to these labels from the registrants that have not been made to the labels to date.

While the current labels may not reflect all the agreed-upon changes, the registrants agreed to update the chlorpyrifos labels to be reflective of the attached Master Use Summary. Commitment letters from the chlorpyrifos registrants are available online as part of the Biological Evaluation Chapters for Chlorpyrifos ESA Assessment.[5] In general, current single maximum chlorpyrifos application rates do not exceed 4 lb a.i./A nationwide; however, a single chlorpyrifos application of 6 lb a.i./A is permitted on citrus in a limited number of counties in California. Aerial applications are not permitted at rates higher than 2.0 lb a.i./A except for treatment of Asian citrus psyllid (citrus use areas including California, Arizona, Texas, and Florida). In this situation, chlorpyrifos may be applied at a rate of up to 2.3 lb a.i./A by aerial equipment. The maximum annual rate of chlorpyrifos that may be applied to a crop site is 14.5 lb a.i./A for tart cherries.

Chlorpyrifos can be applied in a liquid, granular, or encapsulated form, or as a cattle ear tag or seed treatment. Aerial and ground application methods (including broadcast, soil incorporation, orchard air blast, and chemigation) are allowed. Registered labels for liquid applications (i.e., flowable products) require 25-foot (ground boom and chemigation), 50-foot (orchard air blast), or 150-foot (aerial) no-spray buffer zones adjacent to waterbodies.

Agricultural Use Sites

Currently registered agricultural use sites include: agricultural farm premises (such as, barns, empty chicken houses, dairy areas, calving pens), poultry litter, cattle (impregnated collars/ear tags), alfalfa, orchards [including, almonds, apple, cherries, citrus, figs, filberts, non-bearing fruit and nuts (nursery), grapes, nectarine, peach, pear, pecan, plum/prune, seed orchard trees, and walnut], asparagus, beans, beets (grown for seed), sugar beets, carrots (grown for seed), clover (grown for seed), cole crops, corn (all), cotton, cranberry, cucumber, ginseng (medicinal), grass (forage/fodder/hay), legumes, mint, nursery stock, peanut, peas, pepper, pineapple, pumpkin, radish, rutabaga, sod farms, onions, sorghum, soybean, strawberry, sunflower, sweet potato, tobacco, triticale, turnip, wheat, and tree plantations [including Christmas trees, nursery plantations (conifer and deciduous trees), reforestation programs, conifers, and hybrid cottonwood/poplar].

[5] https://www3.epa.gov/pesticides/nas/final/chlorpyrifos/appendix-1-5.pdf

Non-agricultural Use Sites

Currently registered non-agricultural use sites include: commercial/institutional/industrial (indoor and outdoor – e.g., warehouses, food processing plants, ship holds, railroad cars), golf course turf, greenhouse, households (indoor), mosquito control (outdoor), nonagricultural buildings (outdoor – e.g., fences, construction foundations, dumps), ornamental plants, ornamental lawns, rights-of-way (including road medians), sewer manhole covers and walls, utilities (e.g., power lines, railroad systems, telecommunication equipment), wide area general outdoor use (e.g., for ants and other misc. pests), and wood protection treatment (for outdoor building products).

2. *Usage Data*

Based on usage data provided by BEAD, approximately 7.2 million pounds of chlorpyrifos are used each year for agricultural purposes in the United States (based on yearly averages from 2004 to 2013). Use on corn and soybean make up 20% of the total volume of chlorpyrifos used in the United States each year. However, both crops have low percent (≤5%) crop treated. Crops with relatively high usage of chlorpyrifos (at least 100,000 lbs/year) include alfalfa, almonds, apples, apricots, cotton, grapes, oranges, peanuts, pecans, sugar beets, walnuts and wheat. A large fraction, at least 40%, of the total acreage planted with apples, asparagus, broccoli, onions, and walnuts, is treated with chlorpyrifos. Considering agricultural uses, there has been a general trend of decreased usage per year as shown in **Figure 2**.

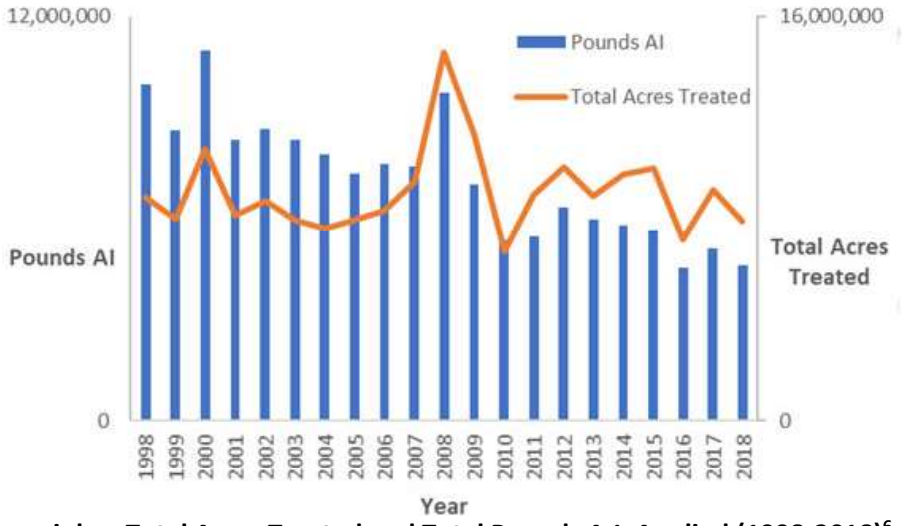


Figure 2. Chlorpyriphos Total Acres Treated and Total Pounds A.I. Applied (1998-2018)[6]

Limited national level chlorpyrifos usage data are available for registered non-crop use sites. These data not summarized here.

Critical Uses

In discussions with Corteva Agriscience, several crops were identified where chlorpyrifos is a critical pest management tool. This includes use of chlorpyrifos to combat alfalfa weevil in alfalfa, scale in citrus, cut

[6] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 1998-2018

worms and lygus bug in cotton, two spotted spider mites in soybean, sugar beet root maggot in sugar beet and Russian wheat aphid in wheat. These uses have been cross walked with 2-digit HUC regions with BEAD's help. A summary of each critical use is provided in **APPENDIX A** and briefly summarized in **Table 2**, while more detailed information from BEAD is provided in **ATTACHMENT 2**. This table notes the only regions identified where the chlorpyrifos use is critical. It is noted that use of chlorpyrifos in California (HUC-18) is not considered in this assessment given the recent regulatory actions the State has taken regarding chlorpyrifos use.

Table 2. Critical (according to Corteva Agriscience) Chlorpyrifos Use Summary

Use	2-digit HUC	Maximum Single Rate (lb a.i./A)	Maximum Annual Rate (lb a.i./A)	Maximum of Average Surveyed Single Application Rate (lb a.i./A)[a]	Maximum of Surveyed Single Application Rate (lb a.i./A)[a]	Average Annual Pounds Chlorpyrifos Applied
Alfalfa	04, 07, 09, 10, 11, 13, 14, 15, 16, and 17	1.0 (l)	5.0	0.6	1.3	600,000
Citrus[b]	03, and 12	6.0 (l)	10.5	2.7	3.0	450,000
Cotton	03	1.0 (l)	3.2	0.2	1.0	70,000
Soybean	03, 04, 05, 07, 09, 10, and 11	2.2 (g)[b]	3.0	0.5	1.0	1,200,000
Sugar beet	04, 07, 09, and 17	2.0 (g)[b]	4.0	1.2	1.5	100,000
Wheat	09, 10, 11, and 12	4.0 (l)	12.0	0.4	0.8	600,000

a. Maximum across the noted 2-digit HUCs. Values for the individual HUCs are provided in **ATTACHEMNT 2**.
b. Includes data for all citrus crops including orange, lemon, and grapefruit.

Data summarized in this table are taken from **ATTACHMENT 2**.
(g) granular
(l) liquid application
1.0 for liquid applications

High Benefit Uses

In addition to the uses that Corteva Agriscience identified as critical, BEAD identified several uses where chlorpyrifos is a high benefit to growers. A high benefit signifies that there are no alternative pesticides available or the alternatives are expensive or not as efficacious for a pest on a specific crop. This includes apple, asparagus, tart cherry, peach, and strawberry. A summary of each critical use is provided **APPENDIX A** and briefly summarized in **Table 3,** while more detailed information from BEAD is provided in **ATTACHMENT 2**. This table notes the only regions identified where the chlorpyrifos use is high benefit to a subset of uses.

Table 3. High Benefit Chlorpyrifos Use Summary

Use	2-digit HUC	Maximum Single Rate lb a.i./A	Maximum Annual Rate lb a.i./A	Maximum of Average Observed Single Application Rate lb a.i./A[a]	Maximum of Observed Single Application Rate lb a.i./A[a]	Average Annual Pounds Chlorpyrifos Applied
Apple	02, 04, 05, 06, 17	2.0 (l)	2.0	1.5	2.8[b]	300,000
Asparagus	04	1.5 (g)	3.0	0.96	1.0	70,000
Tart Cherry	04	4.0 (l)	14.5	1.1[e]	3.0[d,e]	60,000[d]
Peach	02, 03, 04, 12	3.0 (l)	8.0[c]	1.3	3.0	30,000
Strawberry	17	2.0 (l)	4.0	1.24	2.0	<500

a. Maximum across the noted 2-digit HUCs. Values for the individual HUCs are provided in **ATTACHEMNT 2**.
b. 2.0 lb a.i./A is the 90th percentile application rate
c. 8.0 lb a.i./A per year is permitted in Georgia and South Carolina; however, the annual max application rate is 5.5 lb a.i./A in other areas of the county.
d. The maximum rate observed is 3.0 lb a.i./A with the 90th percentile at 2.0 lb/A.
e. Both sweet and tart cherry

Data summarized in this table are taken from **ATTACHMENT 2**.
(l) liquid application, (g) granular

d. Exposure Characterization

1. Conceptual Exposure Model

Chlorpyrifos will initially enter the environment via direct application (e.g., liquid spray and granular) to use sites. It may move off-site via spray drift, volatilization (primarily following foliar applications), and runoff (generally by soil erosion and to a lesser extent dissolution in runoff water). Degradation of chlorpyrifos begins with cleavage of the phosphorus ester bond to yield 3,5,6-trichloro-2-pyridinol (TCP) or oxidative desulfurization to form chlorpyrifos-oxon as shown in **Figure 3.** TCP may be converted to 3,5,6-trichloro-2-methoxypyridine (TMP) also shown in **Figure 3**. Most environmental fate studies (except field volatility and air photolysis studies) submitted to EPA do not identify chlorpyrifos-oxon as a transformation product, yet organophosphates that contain a phosphothionate group, phosphorus-sulfur double bond (P=S), such as chlorpyrifos, are known to transform to the corresponding oxon analogue containing a phosphorus-oxygen double bond (P=O) instead. This transformation occurs via oxidative desulfurization and can occur through photolysis and aerobic metabolism, as well as other oxidative processes. Chlorpyrifos-oxon is considered less persistent than chlorpyrifos and may be present in air, soil, water, and sediment.

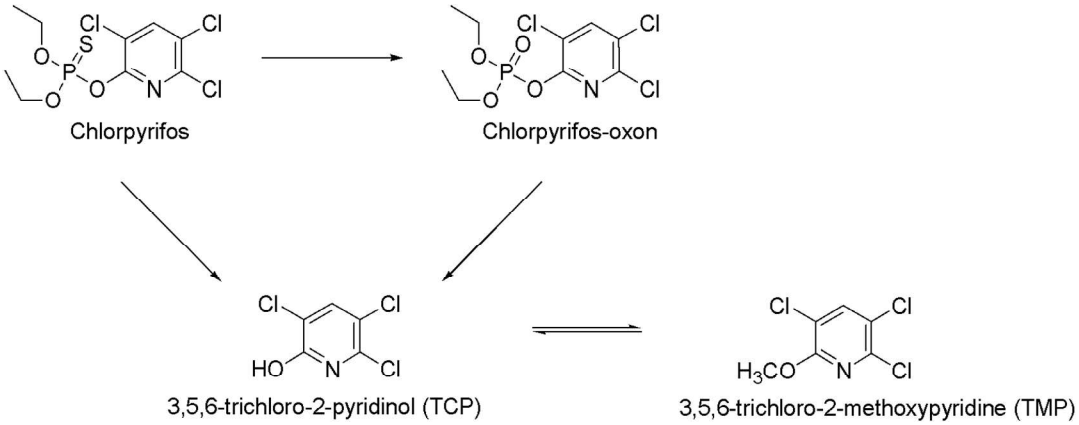


Figure 3. Environmental Transformation of Chlorpyrifos

2. Residues of Concern and Drinking Water Level of Comparison

Chlorpyrifos and chlorpyrifos-oxon are considered residues of toxicological concern for dietary exposure, including drinking water.[7] For this assessment, HED provided four different DWLOCs for both chlorpyrifos and chlorpyrifos-oxon based on 10% red blood cell acetylcholinesterase inhibition for both acute (1-day) and steady state (21-day) exposure. For each of these exposure durations, two DWLOCs are consider one with and one without retention of the 10X FQPA safety factor. This was done because the science addressing neurodevelopmental effects remains unresolved. The DWLOCs for chlorpyrifos are provided in **Table 4.** The DWLOCs for chlorpyrifos-oxon are provided in **Table 5**.[8] The DWLOCs may not be exactly 10-fold apart because the food and residential components of the aggregate exposure assessment completed by HED make up a different percentage of the risk cup depending on whether the 10x FQPA safety is retained or removed.

Table 4. Chlorpyrifos Drinking Water Level of Comparison

Safety Factor	Acute (1-day) µg/L	Steady State (21-day) µg/L
Retained (10x DWLOC)	180	17
Removed (1x DWLOC)	1000	100

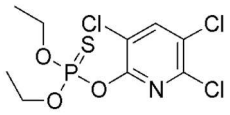
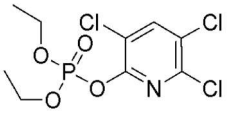
Table 5. Chlorpyrifos-oxon Drinking Water Level of Comparison

FQPA 10x Safety Factor	Acute (1-day) µg/L	Steady State (21-day) µg/L
Retained (10x DWLOC)	23	4.0
Removed (1x DWLOC)	230	43

Physical chemical properties for chlorpyrifos and chlorpyrifos-oxon are provided in **Table 6** (USEPA, 2016). TCP and TMP are not considered residues of toxicological concern based on analysis by HED and, therefore, are not discussed in detail in the remaining sections of this document.

[7] Email from Danette Drew (EPA/HED) to Rochelle Bohaty (EPA/EFED), September 21, 2010.
[8] Email from Kristin Rickard (EPA/HED) to Rochelle Bohaty (EPA/EFED), June 3, 2020.

Table 6. Physical/Chemical Properties of Chlorpyrifos and the Transformation Product of Concern, Chlorpyrifos-oxon

Parameter	Chlorpyrifos	Chlorpyrifos-oxon
IUPAC Name	*O,O*-diethyl o-(3,5,6-trichloro-2-pyridyl phosphorothioate	*O,O*-diethyl O-3,5,6-trichloropyridin-2-yl phosphate Diethyl 3,5,6-trichloro-2,6-pyridin-2-yl phosphate
Chemical Abstracts Service (CAS) Registry Number	2921-88-2	5598-15-2
Chemical Formula	$C_9H_{11}Cl_3NO_3PS$	$C_9H_{11}Cl_3NO_4P$
Smiles	S=P(OC1=NC(=C(C=C1Cl)Cl)Cl)(OCC)OCC	O=P(Oc1nc(c(cc1Cl)Cl)Cl)(OCC)OCC
Chemical Structure		
Molecular Mass (g/mol)	350.57	334.52
Vapor Pressure (Torr, 25°C)	1.87×10^{-5}	6.65×10^{-6}
Henry's Law Constant (atm – m^3/mol)	6.2×10^{-6}	5.5×10^{-9}
Solubility (20°C) (ppm)	1.4	26.0
Octanol-water partition coefficient (Log K_{ow})	4.7	2.89
Table is taken directly from the 2016 DWA (USEPA, 2016)		

It should be noted that an individual would not be exposed to both chlorpyrifos and chlorpyrifos-oxon at the same time at 100 percent of the EDWCs; however, both chemicals could be present in finished drinking water. Moreover, the conversion of chlorpyrifos to chlorpyrifos-oxon in the presence of chlorine may not always be 100 percent. Therefore, an individual would be exposed to both chlorpyrifos and chlorpyrifos-oxon to some degree. For example, an individual could be exposed to 10 percent chlorpyrifos and 90 percent chlorpyrifos-oxon. More discussion is provided in **Drinking Water Treatment Effects** subsection of this document (pg. 26).

3. Environmental Fate

A detailed discussion of the fate and transport of chlorpyrifos and chlorpyrifos-oxon in the environment is provided in the 2016 drinking water assessment. This includes data submitted to the U.S. EPA, as well as open literature data obtained prior to the assessment. Environmental fate parameters for chlorpyrifos are provided in **Table 7** and **Table 8**, respectively. No additional environmental fate data were submitted since the completion of the 2016 drinking water assessment. In summary, chlorpyrifos is expected to be persistent for several months in the environment, with aerobic soil and aerobic aquatic metabolism being the primary routes of transformation. Major routes of dissipation include spray drift, volatilization and runoff via dissolved phase and eroded sediment. Chlorpyrifos-oxon is expected to be more mobile but far less persistent in the environment than chlorpyrifos.

Table 7. Summary of Environmental Fate and Transport Characteristics of Chlorpyrifos

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a] days	Study ID	Study Classification
Laboratory Data				
Hydrolysis half-life (days)	pH 5, 25°C	73	MRID 00155577	Acceptable
	pH 7, 25°C	72		
	pH 9, 25°C	16		
	pH 7, 25°C	81	MRID 40840901	Acceptable
Aqueous photolysis half-life (days)	pH 7	29.6	MRID 41747206	Acceptable
Soil photolysis half-life (days)	--	Stable	MRID 42495403	Supplemental
Air photolysis half-life (hours)	Indirect	2	MRID 48789701	Acceptable
	Direct	6		
Aerobic Soil Metabolism half-life (days) 25 ˚C	Commerce Loam pH 7.4, 0.68% OC	19 (IORE)	Acc. 241547 MRID 00025619	Acceptable
	Barnes Loam, pH 7.1, 3.6% OC	36.7 (IORE)		
	Miami Silt Loam, pH 6.6, 1.12% OC	31.1 (IORE)		
	Catlin Silty Clay Loam, pH 6.1, 0.01% OC	33.4 (SFO)		
	Norfolk Loamy Sand, pH 6.6, 0.29% OC	156 (DFOP)		
	Stockton Clay pH 5.9, 1.01% OC	297 (IORE)		
	German Sandy Loam, pH 5.4, 1.01% OC	193 (IORE)		
	Sandy loam, pH 6.5, 0.8% OC	185 (DFOP)	MRID 42144911	Acceptable
Aerobic Aquatic Metabolism half-life (days) at 25 ˚C	Water, pH 8.1 Sediment, pH 7.7	30.4 (SFO)	MRID 44083401	Supplemental
Anaerobic Soil Metabolism half-life (days) 25 ˚C	Commerce, loam	78 (IORE)	MRID 00025619	Acceptable
	Stockton, clay	171 (SFO) Values represent only anaerobic phase		
Anaerobic Aquatic Metabolism half-life (days) 25 ˚C	Commerce pH 7.4	50.2 (IORE)	MRID 00025619	Supplemental
	Stockton pH 5.9	125 (SFO)		
Field Data				
Terrestrial Field Dissipation half-life (days)	Geneseo, Illinois Silt loam; pH 5.7, 3.1% OC	56	MRID 40395201	Supplemental
	Midland, Michigan Sandy clay loam; pH 7.7, 1.6% OC	33		
	Davis, California Loam; 0.91% OC pH 7.8	46		
Mobility Data				

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a] days	Study ID	Study Classification
Test System Name or Characteristics	**K_d**	**K_{oc}**	**Study ID**	**Study Classification**
Commerce loam	49.9	7300	Acc. 260794	Acceptable
Tracy sandy loam	95.6	5860		
Catlin silt loam	99.7	4960		

a. SFO = Single First Order; IORE = Indeterminate order rate equation; DFOP = Double first-order in parallel; The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the 2nd DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*, Health Canada, U.S. Environmental Protection Agency, December 21, 2012. The same model used to estimate the value used to derive a model input, is used to describe the DT_{50} and DT_{90} results.

An **acceptable** study is defined as a study that provides scientifically valid information that is fully documented, and which clearly addresses the study objectives as outlined in the guidelines.
A **supplemental** study provides scientifically valid information that address the study objectives as outlined in the guidelines but deviates from guideline recommendations and/or is missing certain critical data necessary for a complete evaluation-verification.
K_d = adsorption coefficient (mL/g)
Koc = organic carbon normalized adsorption coefficient (mL/g_{OC})

Table 8. Summary of Environmental Fate and Transport Characteristics of Chlorpyrifos-oxon

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a]	Study ID	Study Classification
Laboratory Data				
Hydrolysis half-life (days)	pH 4, 20°C	38	MRID 48355201	Supplemental
	pH 7, 20°C	5		
	pH 9, 20°C	2		
Air photolysis half-life (hours)	Indirect	11	MRID 48789701	Acceptable
	direct	6		
Aerobic Soil Metabolism half-life (days) 25 ˚C	Missouri Silty clay loam soil (20°C, pH 5.9-6.2)	0.03 (IORE)	MRID 48931501	Supplemental
	Georgia Loamy sand soil (20°C, pH 5.3-5.6)	0.1 (IORE)		
	Texas Sandy clay loam soil (20°C, pH 7.6-7.9)	0.02 (SFO)		
	California Loam soil (20°C, pH 6.1-6.3)	0.06 (IORE)		

Test System Name or Characteristics	K_f (regressed)	K_{foc} µg/g	1/n	Study ID	Study Status
Tift Sand pH 4.8, 0.61% OC	1.3	270	0.85	MRID 48602601	Supplemental
Hagen Loamy sand pH 5.2, 1.1% OC	2.1	245	0.84		
Ebbinghof Loam pH 5.2, 1.5% OC	4.0	191	0.89		

Tehama Loam pH 5.7, 4.4% OC	4.2	301	0.89		
Chelmorton Silt loam pH 5.9, 2.9% OC	4.3	146	0.88		

a. SFO = Single First Order; IORE = Indeterminate order rate equation; DFOP = Double first-order in parallel; The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the 2nd DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*, Health Canada, U.S. Environmental Protection Agency, December 21, 2012. The same model used to estimate the value used to derive a model input, is used to describe the DT_{50} and DT_{90} results.

An **acceptable** study is defined as a study that provides scientifically valid information that is fully documented, and which clearly addresses the study objectives as outlined in the guidelines.

A **supplemental** study provides scientifically valid information that address the study objectives as outlined in the guidelines but deviates from guideline recommendations and/or is missing certain critical data necessary for a complete evaluation-verification.

%OC = percent organic carbon in the soil K_f = Freundlich adsorption coefficient $(\mu g/g)/(\mu g/mL)^{1/n}$

K_{Foc} = organic carbon normalized Freundlich adsorption coefficient $(\mu g/g$ organic carbon$)(\mu g/mL)^{1/n}$

1/n = Freundlich exponent

4. Drinking Water Treatment Effects

Because drinking water for a large percentage of the population is derived from community water systems that treat raw water (USEPA, 1989) prior to consumption, the impact of water treatment on pesticide removal and transformation are considered, when possible, in estimating drinking water exposure (USEPA, 2000, 2001, 2011). Community water systems across the national use a wide range of water treatment processes including disinfection, coagulation/flocculation, sedimentation, and filtration (USEPA, 2006). The effect of various processes has been investigated for several pesticides (USEPA, 2011) including chlorpyrifos. These results are detailed in the 2016 DWA.

In summary, in the presence of free chlorine, the most common disinfection process utilized by community water systems, chlorpyrifos transforms to chlorpyrifos-oxon via rapid oxidation by the oxychlorine species. This transformation can yield almost 100% oxon. Reduction of chlorpyrifos in the presence of monochloramines, often used as an alternative to chlorine to avoid transformation biproducts, is low (<10%). Use of monochloramines is more common by community water systems serving larger (>100,001) populations. Once formed as a disinfection by-product, chlorpyrifos-oxon is expected to be relatively stable to drinking water distribution conditions and times (few hours to a few days) with a half-life of 12 days under typical water purification conditions (pH 8) due to stabilization .[9] Very limited data on physical removal processes such as coagulation/flocculation, sedimentation, and filtration are available for chlorpyrifos or chlorpyrifos-oxon. However, such processes, except for granular activated carbon,[10] have been shown to be ineffective for select organic pesticides (USEPA, 2001). Based on the physical-chemical properties of chlorpyrifos and chlorpyrifos-oxon, granular activated carbon likely reduces the amount of both chemicals to some extent. However, data are not available on the removal efficiency for either compound. Use of activated carbon is not a common treatment practice for treatment facilities.

Therefore, to address the multitude of water treatment possibilities, a bounding approach is used in this assessment. That is, to represent those facilities that use disinfectant processes other than free chlorine,

[9] pH 8 and residual chlorine concentration of 1 ppm.

[10] U.S. Environmental Protection Agency. 1998. Small System Compliance Technology List for the Non-Microbial Contaminants Regulated Before 1996. EPA 815-R-98-002.

100 percent of the chlorpyrifos entering the facility was assumed to be unchanged in the finished drinking water. Alternatively, to represent those facilities that employ chlorine as a disinfectant, 100 percent of the chlorpyrifos entering the facility was assumed to convert to chlorpyrifos-oxon.

Analysis

a. Approach

This document provides EDWCs by 2-digit HUC using a bounding approach to address the multitude of drinking water treatment possibilities across the country and potential exposures to chlorpyrifos and chlorpyrifos-oxon in drinking water. This assessment begins at Tier 3 and only considered those uses previously described as being a critical use (CU) or high benefit (HB) and are summarized by 2-digit HUC in **Table 9**. Empty cells indicate that the use is not assessed in the respective HUC. Alfalfa use in HUC-13, 14, 15, and 16 are not modeled in this update because prior estimated concentrations indicate that for usage rates provided by BEAD for this assessment, the estimated concentrations would be below the DWLOCs.

Table 9. Chlorpyrifos Use and 2-digit HUC Region Crosswalk

Name of 2-digit HUC Overlapping States	2-digit HUC	Alfalfa	Apple	Asparagus	Tart Cherry	Cotton	Citrus	Peach	Soybean	Sugar Beet	Wheat, Spring	Strawberry	Wheat, Winter
Mid-Atlantic VT, NY, PA, NJ, MD, DE, WV, DC, VA	02	-	HB	-	-	-	-	HB	-	-	-	-	-
South Atlantic-Gulf VA, NC, SC, GA, FL, TN, MS	03	-	-	-	-	CU	CU	HB	CU	-	-	-	-
Great Lakes WI, MN, MI, IL, IN, OH, PA, NY	04	CU	HB	HB	HB	-	-	HB	CU	CU	-	-	-
Ohio IL, IN, OH, PA, WV, VA, KY, TN	05	-	HB	-	-	-	-	-	CU	-	-	-	-
Tennessee VA, KY, TN, NC, GA, AL, MS	06	-	HB	-	-	-	-	-	-	-	-	-	-
Upper Mississippi MN, WI, SD, IA, IL, MO, IN	07	CU	-	-	-	-	-	-	CU	CU	-	-	-
Souris-Red-Rainy ND, MN, SD	09	CU	-	-	-	-	-	-	CU	CU	CU	-	CU
Missouri MT, ND, WY, SD, MN, NE, IA, CO, IA, KS, MO	10	CU	-	-	-	-	-	-	CU	-	CU	-	CU
Arkansas-White-Red	11	CU	-	-	-	-	-	-	CU	-	-	-	CU

Name of 2-digit HUC Overlapping States	2-digit HUC	Alfalfa	Apple	Asparagus	Tart Cherry	Cotton	Citrus	Peach	Soybean	Sugar Beet	Wheat, Spring	Strawberry	Wheat, Winter
CO, KS, MO, NM, TX, OK, AR, LA													
Texas-Gulf NM, TX, LA	12	-	-	-	-	-	CU	HB	-	-	-	-	CU
Rio Grande CO, NM, TX	13	<[a,b]	-	-	-	-	-	-	-	-	-	-	-
Upper Colorado WY, UT, CO, AZ, NM	14	<[a,c]	-	-	-	-	-	-	-	-	-	-	-
Lower Colorado NV, UT, AZ, NM, CA	15	<[a,d]	-	-	-	-	-	-	-	-	-	-	-
Great Basin CA, OR, ID, WY, NV, UT	16	<[a,e]	-	-	-	-	-	-	-	-	-	-	-
Pacific Northwest WA, ID, MT, OR, WY, UT, NV	17	CU	HB	-	-	-	-	-	-	HB	-	HB	-

a. 2016 drinking water assessment indicates EDWCs will be below the DWLOC.
b. HUC-13: 1.0 lb a.i./A (upper-bound); 2.3 µg/L (no PCA adjustment) chlorpyrifos concentration
c. HUC-14: 1.0 lb a.i./A (upper-bound); 1.6 µg/L (no PCA adjustment) chlorpyrifos concentration
d. HUC-15: 0.75 lb a.i./A (upper-bound) 2.5 µg/L (no PCA adjustment) chlorpyrifos concentration
e. HUC-16: 1.0 lb a.i./A (upper-bound) 1.8 µg/L (no PCA adjustment) chlorpyrifos concentration
\- Use not assessed

Critical use (CU)
High benefit (HB)
< Indicates where concentrations are expected to be below the 10xDWLOC
Empty cells with - indicate that the use is not assessed the respective HUC

The 2-digit HUCs considered in this assessment are shown in **Figure 4**. Regions considered in this assessment are shown in green shading while those not considered are shown in gray shading in **Figure 4**.

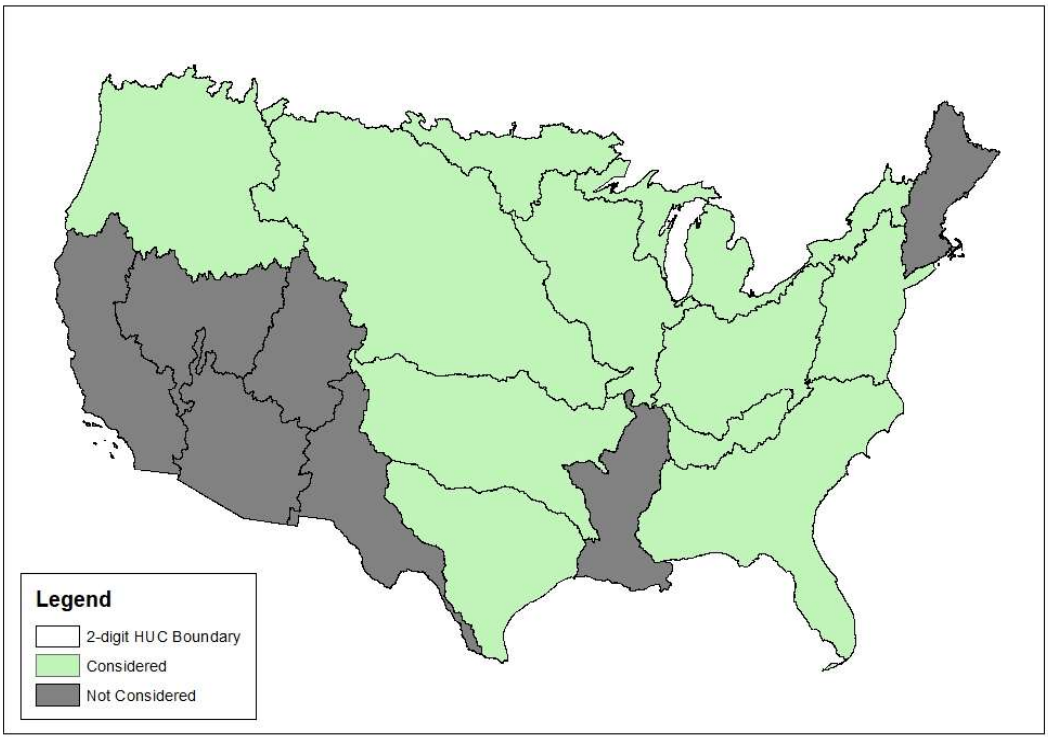


Figure 4. Summary of 2-Digit HUCs with Chlorpyrifos Uses Considered and Assessed in this Assessment

Consistent with the DWA Framework (USEPA, 2019), usage data, regional PCAs, and new methods for considering available surface water monitoring data are utilized. A detailed discussion of the methods and refinement strategies used in this assessment are described in the sections below. The general methods and refinements are well-established and have undergone FIFRA Scientific Advisory Panel (SAP) review or other external review process including formal public comment period and follow currently approved guidance.

b. Model Simulations

1. Pesticide in Water Calculator (PWC)

The Pesticide Root Zone Model (PRZM5) (Young and Fry, 2014) and the Variable Volume Water Model (VVWM) (Young, 2014) are used to estimate pesticide movement and transformation on an agricultural field and in the receiving surface water body (i.e., index reservoir), respectively. These models are linked with a user interface, the Pesticide in Water Calculator (PWC). The PRZM5 and VVWM documentation, installation files, and source code are available at the USEPA Water Models website.[11]

PRZM5 simulates pesticide sorption to soil, in-field decay, erosion, and runoff from an agricultural field or drainage area following pesticide application(s). The VVWM estimates water and sediment concentrations in an adjacent surface water body (i.e., index reservoir) receiving the pesticide loading by runoff, erosion, and spray drift from the field. The index reservoir has dimensions and characteristics

[11] Available: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

based on those of Shipman City Lake — a small, vulnerable midwestern reservoir located in an agricultural setting that was formerly used for source drinking water.[12]

All model simulations were run using the external batch function within the provisional version of PWC (v.1.89) for chlorpyrifos. This version of the model accommodates use of the new scenarios along with new weather files. A final updated version of PWC is scheduled for release in late 2020. Model outputs for chlorpyrifos were compared to the DWLOCs for chlorpyrifos. In addition, the model outputs for chlorpyrifos are converted to chlorpyrifos-oxon equivalents for comparison to the chlorpyrifos-oxon DWLOCs to complete the bounding approach.

2. Scenario Selection

PWC uses soil, hydrology, land cover/land use, weather, and waterbody properties to simulate environmental conditions. Prior to this assessment, a suite of PRZM5 scenarios were used to estimate pesticide concentrations. These scenarios were developed over time by different groups in EFED and for different purposes. As a result, the previous scenarios represented a range of conditions spanning a range of agricultural and non-agricultural pesticide use sites.; however, the percentile of vulnerability for these scenarios is unknown.

To develop scenarios consistently across the landscape, EFED developed a new method to generate PRZM5 scenarios. These scenarios include the use of more recent weather data (1961-2014) (Fry, et. al, 2016). In addition, a process was developed to compare and rank the millions of new scenarios (combinations of soil, land cover, and weather) in order to evaluate relative vulnerability.

New scenarios available at the time of this assessment include: cotton, hay (surrogate for alfalfa), evergreen orchards (for citrus), row and field crop (for sugar beet), soybean, fresh market (for strawberry), spring wheat, and winter wheat based on the regions where these crops are grown and uses considered in this assessment.

The existing scenario for asparagus was updated with new weather data. A new asparagus scenario is not planned as the existing asparagus scenario is suitable for modeling exposure to pesticides asparagus because asparagus largely occurs in a few isolated areas of the country. Furthermore, use of the fresh market scenario is not appropriate as the growth/management practices of asparagus is different from the other vegetables – harvest of the spears occurs before canopy growth starts; the fern canopy continues to grow until frost, when it is removed.

The existing scenarios for apple, cherry, and peach were updated with new weather data and used in this assessment to cover these respective crops, except for peach in HUC-12 (Texas-Gulf) where the evergreen orchard scenario was expected to be a better surrogate than use of the previous GA Peach scenario. a deciduous orchard scenario was not available at the time this assessment was completed.

The new scenarios were created to be the 90th percentile as ranked by the long-term average concentration in the receiving waterbody. Because rankings are sorption-dependent, scenarios were

[12] See "Development and Use of the Index Reservoir in Drinking Water Exposure Assessments" at http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-and-use-index-reservoir-drinking-water

created for 3 bins of chemicals: those carried primarily by runoff, those carried primarily by erosion, and those carried by both mechanisms. For more information see USEPA (2020b*)

3. Chemical Specific Input Parameters

Although limited environmental fate data are available for chlorpyrifos-oxon, the data suggest that in the environment, there is little or no formation of chlorpyrifos-oxon by routes other than photolysis. Therefore, it is only necessary to conduct aquatic modeling for chlorpyrifos. To address the exposure to chlorpyrifos-oxon in drinking water as a result of formation during drinking water treatment with chlorine (described in the *Water Treatment Effects* section of this document) aquatic modeling results for chlorpyrifos can be used to estimate concentrations of chlorpyrifos-oxon (see **Drinking Water Treatment** on **page 35**).

Summaries of the environmental fate input parameters used in the PWC modeling of chlorpyrifos are presented in **Table 10**. These values are the same as those used in the 2016 DWA and more details on the rational for selection is provided in that assessment. Input parameters were selected in accordance with the following EPA guidance documents:

- Guidance for *Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1[13] (USEPA, 2009),
- *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*[14] (NAFTA, 2012; USEPA, 2012c), and
- *Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessment*[15] (USEPA, 2013)

[13] http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm (accessed April 11, 2014)
[14] http://www.epa.gov/oppfead1/international/naftatwg/guidance/degradation-kin.pdf (accessed April 11, 2014)
[15] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676 (accessed April 11, 2014)

Table 10. Input Values Used for Tier II Surface Water Modeling Using the PWC and PFAM

Parameter (units)	Value	Source	Comments
Organic-carbon Normalized Soil-water Partitioning Coefficient (K_{OC} (L/kg-$_{OC}$))	6040	Acc. # 260794	The mean K_{oc} value (K_{oc} values = 7300, 5860 and 4960 mL/g_{OC}) is used for modeling.
Water Column Metabolism Half-life or Aerobic Aquatic Metabolism Half-life (days) 25 ˚C	91.2	MRID 44083401	Only one half-life value is available, so this value (30.4 days) is multiplied by 3 to get 91.2 days. This half-life value was not corrected for hydrolysis. Recall the hydrolysis half-life of chlorpyrifos at pH 7 ranged from 72-81 days. Since hydrolysis is likely to be the driver for transformation of chlorpyrifos in aquatic systems, use of aerobic aquatic metabolism half-life of 91.2 days will not result in substantially different model-estimated concentration than if hydrolysis were assumed to be the sole contributor to transformation in aquatic systems.
Benthic Metabolism Half-life or Anaerobic Aquatic Metabolism Half-life (days), 25ºC	203	MRID 00025619	The 90th percentile confidence bound on the mean chlorpyrifos half-life value determined following the NAFTA kinetics guidance is 87.6 + [(3.078 x 52.9)/√2)] = 202.7 days.
Aqueous Photolysis Half-life at pH 7 (days) and 40° Latitude, 25 °C	29.6	MRID 41747206	
Hydrolysis Half-life (days)	0	MRIDs 00155577 (Acc. # 260794) and 40840901	Since the aerobic aquatic metabolism half-life value was not corrected for hydrolysis, it is possible that hydrolysis would be double counted in the model simulation. Therefore, hydrolysis is set to 0 (stable) here as it is already accounted for in the aerobic aquatic metabolism study and input parameter.
Soil Half-life or Aerobic Soil Metabolism Half-life (days), 25 °C	170.6	Acc. # 241547 and MRID 42144911	Half-life values of 19, 36.7, 31.1, 33.4, 156, 297, 193, and 185 days are obtained from empirical data following the NAFTA kinetics guidance. The 90th percentile confidence bound on the mean chlorpyrifos half-life value is 118.9 + [(1.415 x 103.3)/√8)] = 170.6 days.
Molecular Weight (g/mol)	350.57	product chemistry	
Vapor Pressure (Torr) at 25 °C	1.87 x 10^{-5}	product chemistry BC 2062713	
Solubility in Water at 25 °C (mg/L)	1.4	MRID 41829006	The water solubility of chlorpyrifos is reported to be between 0.5-2.0 mg/L for temperatures between 20 – 25 °C. Based on data submitted to EPA, 1.4 mg/L was used in modeling.
Foliar Half-life (days)	0	Default value	
Application Efficiency	0.99 (ground; air-blast) 0.95 (aerial)	Default Values	
Application Drift	See **Table 12**	AgDRIFT modeling based on label restrictions	Labels contain aquatic buffer distances of 25, 50 and 150 ft for ground, airblast and aerial applications.

All PWC model input files, and output files are provided in **ATTACHMENT 3**.

Use Scenarios

Chlorpyrifos-specific modeling scenarios used in this assessment reflect usage data for chlorpyrifos for the critical and high benefit uses based on information provided by BEAD. This includes application rate, method, and timing. **ATTACHMENT 2** includes all the information provided by BEAD for this assessment while **Table 11** provides the application rates modeled by crop at the 2-digit HUC level. Formulation and application methods are considered in the context of the reported usage data when developing use scenarios and multiple scenarios may be modeled. For example, most applications for sugar beet occur by ground with 20% being the highest percentage of survey applications made by air. Furthermore, the maximum average application rate of 1.2 lb a.i./A and the upper bound rate of 1.5 lb a.i./A exceed the maximum permitted application (1 lb a.i./A) for aerial applications and only granular applications are permitted above 1 lb a.i./A. This is due to how usage rates are estimated. For example, usage rates are estimated across all application methods and formulations. In addition, usage rates are not calculated specifically for the critical or high benefit target pest but for all use on the specified critical or high benefit crop. Generally, the usage data would not be robust enough to estimate usage rates for specific target pests.

Table 11. Chlorpyrifos Use Rates Modeled

Use	2-digit HUC	Average Single Application Rate (lb a.i./ acre)	Upper-bound Single Application Rate (lb a.i./ acre)
Critical Uses			
Alfalfa	04	0.25	1.25
	07	0.53	1.00
	09	0.56	1.00
	10	0.50	1.00
	11	0.58	1.00
	13	0.50	1.00
	14	0.6	1.00
	17	0.52	1.00
Citrus	03	1.88	3.0
	12	2.7	3.5
Cotton	03	0.21	0.5
Soybean	03	0.53	1.00
	04	0.41	0.75
	05	0.33	0.75
	07	0.40	1.0
	09	0.33	0.75
	10	0.35	0.75
	11	0.37	0.75
Sugar beet	04	0.50	1.25
	07	1.16	1.50
	09	0.69	1.25
	17	0.66	1.25
Wheat, spring	09	0.36	0.75
	10	0.27	0.75
Wheat, winter	09	0.44	0.75
	10	0.32	0.50
	11	0.39	0.75
	12	0.21	0.75

High Benefit Uses			
Apple	02	1.5	2.0[1]
	04	1.5	2.0[1]
	05	1.5	2.0[1]
	06	1.5	2.0[1]
	17	1.5	2.0[1]
Asparagus	04	0.964	1.0
Tart Cherry	04	1.5	2.0[1]
Strawberry	17	1.24	2.0
Peach	03	1.3	3.0[1]
[1]The BEAD documents (**ATTACHMENT 3**) reported maximum rates; however, when the 90th percentile is lower it was reported. The 90th percentile use rates were used for modeling in this assessment. For peach, the maximum and the 90th percentile were reported to be the same.			

Spray Drift Exposure

Drift fractions used in this assessment for liquid formulation are consistent with those used in the 2016 DWA (USEPA, 2016) and are presented in **Table 12**. Spray drift estimates reflect the most recent offsite deposition guidance (USEPA, 2013a, 2013b) and consider the currently labeled buffer restrictions [25 ft. (ground), 50 ft. (air-blast), and 150 ft. (aerial)] for aquatic water bodies included on all agricultural chlorpyrifos labels. No spray drift is assumed for granular applications.

Table 12. Chlorpyrifos Spray Drift Estimates for Liquid Formulations for Use in PRZM5/VVWM (PWC) Model Simulations

Method	Buffer	Spray Drift Fraction (unitless) Application Method and Buffer	Calculation[1]
Ground	**25 ft**	0.008	Ground: 25 ft. distance to water body from edge of field based on labeled buffer; ASAE Fine to medium/course [$dv_{0.5}$ = 341 µm; labels specify 255-340 µm which is larger than ASAE very fine to fine ($dv_{0.5}$ = 175 µm); high boom; 90th percentile; Index Reservoir - downwind water body width 82 m (fraction applied 0.0061); Streams – 4 m (fraction applied 0.0164); Adjusted Spray drift fraction 0.0061 (spray drift fraction for the Index Reservoir) + [0.0164 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.0079
Air-blast	**50 ft**	0.009	Air-blast: 50 ft. distance to water body from edge of field based on labeled buffer; droplet size not specified; sparse (young, dormant); Index Reservoir - downwind water body width 82 m (fraction applied 0.0056); Streams – 4 m (fraction applied 0.0265); Adjusted Spray drift fraction 0.0056 (spray drift fraction for the Index Reservoir) + [0.0265 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.0086
Aerial	**150 ft**	0.039	Aerial: 150 ft. distance to water body from edge of field based on labeled buffer; ASAE fine to medium ($dv_{0.5}$ = 255 µm; labels specify 255-340 µm); Index Reservoir - downwind water body width 82 m (fraction applied 0.0331); Streams – 4 m (fraction applied 0.0552); Adjusted Spray drift fraction 0.0331 (spray drift fraction for the Index Reservoir) + [0.0552 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.039
[1] calculation taken from 2014 DWA.			

4. Post-processing or Output Adjustments

Drinking Water Treatment Adjustment Factor

EDWCs for chlorpyrifos-oxon were derived by multiplying the EDWCs for chlorpyrifos by 0.9541 (molecular weight adjustment factor) and 100% to account for the quantitative conversion of chlorpyrifos to chlorpyrifos-oxon during water treatment as well as the stability of oxon in the persistence in residual chlorine.

Percent Cropped Area Adjustment Factors

Community water system (CWS) watersheds large enough to support a drinking water facility rarely consist of a single crop (e.g., apples) or land cover type (e.g., orchards). To account for the variability in use patterns, PCA adjustment factors are used to reflect the percentage of a watershed that is covered by a particular use or land cover type. The application of PCAs has been extensively documented, reviewed, and utilized in drinking water assessments (USEPA, 2014). Prior to 2020, PCA values were only available for seven crops (e.g., soybean) or crop groups (e.g., vegetables) along with all-agricultural and turf, and combinations thereof. For additional information on the development of the CWS PCA values and use as a refinement in DWAs, see *Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update* (USEPA, 2014). PCAs are applied by multiplying the modeled estimated concentration by the PCA fraction that captures all the use sites for the pesticide under evaluation.

In this assessment, the PCAs used do not reflect all currently registered chlorpyrifos uses or those uses provided on the Master Use Summary document. Instead, the PCAs used only reflect the subset of critical or high benefit uses described in the Usage Data Section of this assessment by respective 2-digit HUC. In addition to the previously available PCAs, this assessment also uses the recently developed miscellaneous agricultural (misc-ag) PCA. The misc-ag PCA was developed as an alternative to using the all-ag PCAs when a use site does not fall within the existing crop, crop group, or combination of agricultural PCAs. For more information on the development of the misc-ag PCA see*: Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)*. If more use sites are added (i.e., beyond those considered in this assessment), the PCA used to calculate EDWCs may need to be increased to capture the larger use pattern specific footprint. For example, if non-agricultural uses need to be considered it would be necessary to use a PCA of 1 or add in the non-agricultural PCA depending on the region where the non-agricultural uses need to be considered.

This assessment begins by calculating the maximum use patten specific 2-digit HUC PCAs for each of the respective regions under consideration. Then, if the estimated concentration using the maximum use pattern specific PCA is above the 10x DWLOC, the full distribution of PCAs for the respective region is described. These two steps are described in more detail in the subsections below.

Modeling Refinement 1: Application of Use Pattern Specific PCA

The first refinement of the new drinking water improvement methods includes the use of a use pattern PCA (USEPA, 2020). The use pattern specific PCA is the PCA value for the combination of crops or crop groups specific to the registered uses of the individual pesticide under evaluation. A use pattern specific PCA can be calculated at the national or regional level. For example, in this assessment for HUC-03

where chlorpyrifos use on cotton, citrus, peach and soybean are being considered, the PCA used is the summation of the individual PCAs for cotton, orchards (to cover citrus and peach) and soybean within each individual watershed. While in HUC-04 where chlorpyrifos use on alfalfa, apple, asparagus, cherry, peach, soybean, and sugar beet is under consideration, the PCA used is the summation of misc-ag (to cover alfalfa and sugar beet), orchard (to cover apple, cherry and peach), soybean, and vegetable (to cover asparagus) within each individual watershed. This approach allows for the more accurate EDWC that captures the area of the watershed allocated to the uses under consideration, rather than using the default all-agricultural land PCA, which could encompass more area within the watershed.

For those 2-digit HUCs with concentrations above the 10x DWLOC after consideration of the maximum use pattern, the full distribution of PCA values are then characterized (see following section).

Modeling Refinement 2: Use of the Full Distribution of Watershed PCA Values

The second refinement of the new drinking water improvement methods includes assessing the full distribution of available PCA instead of only using the maximum regional PCA value (USEPA, 2020). EDWCs are calculated for each community water system. The full distribution of PCAs used in this assessment include the majority of the 6,550 CWS drinking water intake (DWI) locations from EPA's Safe Drinking Water Information System (SDWIS) database between the years 1997 and 2004. Of the 6,550 locations, 74% (4,840) had unique, delineated watersheds where PCAs have been calculated. Two of these intakes had watersheds that extend into Canada and, therefore, are not considered in the development of PCAs. In addition to the 4,840, the distribution includes surrogate PCAs (i.e., 12 digit HUC) for a set of community water system drinking water intakes locations that watershed delineation was determined appropriate but had not been validated at the time of the 2014 publication of the percent cropped area adjustment factors for community water systems.

The critical PCA, the ratio between the unrefined EDWC and the DWLOC, is the PCA value that would generate a refined estimated drinking water concentration equal to the DWLOC, was calculated. The critical PCA permits the quick identification of the number (or percentage) of watersheds with PCAs that would results in concentrations above the DWLOC. The critical PCA is used as a benchmark to determine the need to continue to consider additional refinements.

For watersheds with a PCA higher than the critical PCA, the crop-specific footprint (county level acres harvested) overlap is assessed for crops (e.g., cherries or apples) where a crop group (e.g., orchard) PCA is used since a crop-specific PCA is not available for individual crops like cherries and apples available. For more information on the overlap analysis, see the following section. For HUCs where the use-site specific PCA is less than the critical PCA, no further refinement is necessary as the concentrations would be below the DWLOC.

Use Site Overlap Analysis of Watersheds with PCAs Larger than the Critical PCA

Also included in the new drinking water improvement methods is the overlap analysis (USEPA, 2020). PCA values for groups of crops (i.e., orchards, vegetables) are derived from generalized crop data layers based on the National Land Cover Database (NLCD) and Census of Agriculture (Ag Census). Specifically, the calculated PCA is based on the reported acreage of crops/crop groups in a county, as reported in the Ag Census, proportioned to the footprint of agricultural land covers from the NLCD. This approach has the potential to overestimate the percent of a given watershed with the noted use site (e.g., planted with a single crop). For instance, an individual CWS watershed with an orchard PCA of 20% may very

well have little or no cherries or apples grown within the watershed. Spatial overlap helps further identify CWS watersheds with potential exposure concerns.

For these analyses, a visual inspection for overlap follows a spatial overlay of the 2007 USDA Census of Agriculture county-level acres harvest data with the watershed or surrogate watershed boundary for community water systems with PCAs above the critical PCA was completed using ArcMap (version 10.5). While there are more recent Census of Agriculture data (i.e., 2012 and 2017) the community water systems PCAs were developed using the 2007 census data. Therefore, for consistency in data sources the 2007 census data were used for the overlap analysis. If any part of the county with reported acres of crop under evaluation overlaps with the community water system under investigation it is considered an overlap for the purposes of this assessment.

For those watersheds with PCA higher than the critical PCA and county overlap, aggregated EDWCs are developed (see following section). Watersheds with no overlap are no longer considered for further refinement.

Development of Aggregated Estimated Drinking Water Concentrations

Another refinement included as part of the new drinking water improvement methods includes calculating EDWCs are based individual use site residue contribution. Prior to this step, EDWCs are based on the highest concentration of all uses modeled within the respective 2-digit HUCs, however, the relative contributions of each modeled use site can be determined by adding the contributing concentrations within each CWS watershed. This is the summation of the crop-specific PCA multiplied by the crop-specific model estimated concentration values for each registered crop or crop group within each watershed.

Aggregated EDWC =
(use pattern 1 individual EDWCs x crop specific PCA) + …
+ (use pattern (1+n) individual EDWCs x crop specific PCA)

Equation 1. Aggregation of Estimating Drinking Water Concentrations

There are two options for doing this aggregation (see the *Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)* for more details. The option used in this assessment, is to aggregate individual PCA adjusted 1-in-10 year estimated concentrations for each use site in a region without regard to timing (e.g., 1-in-10 year EDWCs may come from different calendar days).

Percent Crop Treated Adjustment Factors

In this case, one of new drinking water improvement methods includes the integrating percent cropped treated (PCT) data to adjust estimated concentrations to reflect only those sites which are treated based on available survey data (USEPA, 2020). Use of a PCT further refines the fraction of the area of the respective planted crop area treated with pesticide in a watershed. PCT values are typically aggregated at the state level Chlorpyrifos usage data are summarized in the Science Information and Analysis Branch (SIAB) Use and Usage Matrix (SUUM) which is provided by BEAD. The SUUM reports PCT data based on usage that occurred for a given 5-year range (depending on the crop this spans 2012-2017 or 2014-2018) for chlorpyrifos (Paisley-Jones, 2020). Three statistics for PCT are available for each state and crop combination (where states and crops are surveyed): 5-year average, 5-year minimum and 5-

year maximum annual value. This information is provided in **ATTACHMENT 3**. For chlorpyrifos, only the 5-year maximum annual PCT are considered in this assessment.

The PCT statistics are used to calculate the number of acres treated in each state (referred to as base acres treated). Then the acres treated need to be allocated within each individual community water system watershed. In this assessment, this is done using an upper distribution approach for allocating treated acres within each watershed, described below. A post-processing tool was used to estimate the maximum PCT/upper distribution. For more information on these approaches see: *Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)*. The files to support this work are provided in **ATTACHMENT 3**.

Upper Distribution: This approach assumes that all the treated acres for a given land cover class in a state can occur within a drinking water watershed boundary, up to the PCA adjusted acreage of the watershed including non-agricultural uses. A graphical depiction is provided in **Figure 5**. In this example, 400 acres (40 green squares) are assumed to be the potential use sites across Colorado. The PCT for Colorado is 10%. Therefore, 40 acres (4 filled green boxes) are treated within Colorado. If these acres are all placed within an individual community water system watershed 4 of the 7 green boxes (potential use sites) within the watershed (orange shape) become filled (as shown in the figure). The 4 green boxes or 40 acres are then divided by the total areas of the community water system watershed (orange shape) to generate the PCA-PCT value for the maximum PCT upper distribution.

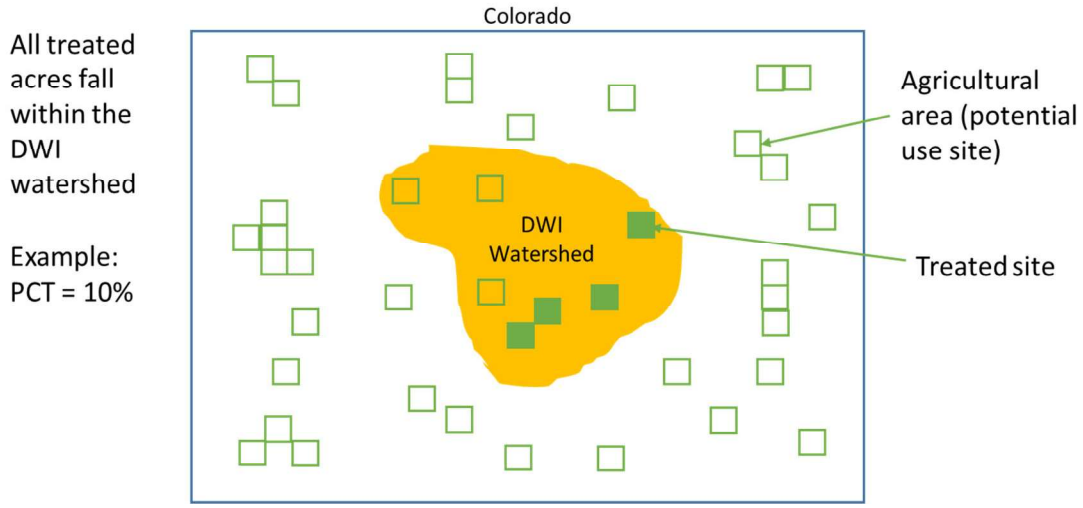


Figure 5. Conceptual Illustration of the "Upper" Distribution Method

PCT adjustments can be used to better understand exposure based on historical use, as well as provide a tool to facilitate the interpretation of model estimated exposure results compared to measured exposure concentrations. It should be noted that often watersheds are much smaller than a state. Use of the upper distribution is a conservative approach for allocating acres within a watershed providing an upper bound EDWC.

c. Monitoring Data

There are several challenges with interpreting available surface water monitoring data that may result in underestimating actual concentrations that people may be exposure as a result of consuming surface

sourced drinking water. However, tools are available to help account for and describe the uncertainty in the data.

A Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) meeting was held in November of 2019 on Approaches for the Quantitative use of Surface Water Monitoring Data in Drinking Water Assessments. EPA presented the use of the USGS model, the Seasonal Wave with Streamflow Adjustment with Extended Capability (SEAWAVE-QEX), and developed sampling bias factors. Both approaches allow assessors to quantify the uncertainty in available use surface water monitoring data such that the results can be used with reasonable confidence in pesticide drinking water assessments. Additionally, EPA explored presented methods to evaluate the spatial relevancy of monitoring sites and sampling bias factors with respect to vulnerable drinking water locations using quantitative methods such as regression equations, and qualitative methods such as a weight-of-evidence approach. These approaches are detailed in a White Paper. Supporting documents included a Standard Operating Procedure for using SEAWAVE-QEX, a drinking water assessment framework document, and two drinking water assessment case studies. All of these documents, including EPA's response to the SAP comments can be accessed on the docket at EPA-HQ-OPP-2019-0417.

A thorough analysis of available monitoring data for chlorpyrifos and chlorpyrifos-oxon was completed in the 2016 DWA. Based this prior work and preliminary analyses completed as part of this assessment, it was decided that a Tier 4 monitoring data analysis would be beneficial to the assessment and could be informative if additional crops were evaluated. The current assessment focuses on updating the monitoring data analysis based on feedback from the 2019 FIFRA SAP and therefore focuses on monitoring data for chlorpyrifos only, as use of SEAWAVE-QEX on a transformation product was not recommended without further investigation.

The monitoring data considered in this update were primarily data exported from the Water Quality Portal (WQP) downloaded on January 6, 2020, which includes data from NWIS and STORET. Data from Dow Agrosciences (now Corteva Agriscience) California Monitoring Program (DACMP), Washington State Department of Agriculture (WSDA), and the National Center for Water Quality Research (NCWQR) are also considered, as well as the modified chlorpyrifos data sets from the data release files supporting SEAWAVE-QEX (Vecchia and Williams-Sether, 2018). Data from WSDA and NCWQR were obtained recently as part of the preparation for the 2019 SAP and were subject to Quality Assurance/Quality Control (QA/QC) protocols by the organizations that collected the data; these have been provided to EPA and the data are considered reliable.

All monitoring data were analyzed by program and by site-year. To be considered a site-year, there only needs to be one sample taken per year at a given site. A site-year analysis approach was employed because pesticide occurrence depends on spatially specific site conditions including pesticide usage, agronomic practices, soil properties, meteorology, as well as temporally dependent conditions, including pesticide application timing and rainfall occurrence.

These data sources are briefly summarized below with more details provided in the 2016 DWA.

1. Monitoring Program Summary

The *NAWQA* program samples for many pesticides and pesticide transformation products and is larger than any other monitoring program in terms of scope and duration. Sampling sites are distributed across the United States and include a range of site vulnerabilities and waterbody types.

NAWQA is not designed to target a specific pesticide use (i.e., sample timing, frequency, site); however, many sampling sites are in pesticide use areas including agricultural and non-agricultural sites. In general, sample frequencies are sporadic and range from once per year to a couple times per month depending on the site and year.

The *DACMP* included sampling at three locations on the lower reach of Orestimba Creek (California) for one year (May 1, 1996 to April 30, 1997). Daily time-proportional composite samples were collected, along with weekly grab samples. The report included chlorpyrifos use information for fields that drained into the creek or had the potential to contribute spray drift (fields within 305 m buffer on either side of the mid-streamline).

The *WSDA* monitoring programs began sampling salmon-bearing streams in two different Washington State sub-basins in 2003. The program has gradually increased monitoring to 10 different sub-basins throughout the state. Sampling sites are monitored weekly for pesticides during the pesticide use season. While the study does not specifically target pesticide applications, the sampling sites are in agricultural areas with known pesticide use.

The *NCWQR* monitoring program is historically one of the most intensive pesticide sampling programs in the country with sample frequencies ranging from daily to monthly. The most frequent sampling occurs during the spring and summer months. Monitoring sites are in agricultural areas (i.e., corn production) and were established as part of a nutrient and sediment loading monitoring program well before pesticide monitoring began.

2. Evaluation

Monitoring data evaluation included in this update builds upon past work including the monitoring data analyses completed to support the 2016 drinking water assessment (USEPA, 2016), as well as work done as part of the 2019 SAP on the quantitative use of surface water monitoring data in drinking water assessments (USEPA, 2019). Prior work indicated that when the uncertainty in having non-daily sampling data for chlorpyrifos is quantified, it is possible concentrations in surface water may occur above the drinking water level of comparisons described in this document. Therefore, consistent with the drinking water assessment framework, Tier 4 tools (SEAWAVE-QEX and pesticide-specific SBFs) are utilized in this assessment.

Several sites from these combined data sources met the criteria for evaluating chlorpyrifos concentrations quantitatively in surface water using SEAWAVE-QEX and SBFs. Both methods were presented as part of the FIRFA SAP on the quantitative use of surface water monitoring data in drinking water assessments (USEPA, 2019). Analyses reported here consider comments received from the Panel. Specifically, this work focuses on addressing the uncertainty in available monitoring data due to non-daily sampling and limited spatial coverage across the landscape by:

1. using SEAWAVE-QEX to estimate chlorpyrifos concentrations between sampling events,
2. deriving and applying SBFs to measured chlorpyrifos concentrations, and
3. employing a weight-of-evidence approach to understand the relevance of sampling sites with respect to potential chlorpyrifos use sites within the watershed.

3. *Interpretation and Extrapolation*

SEAWAVE-QEX

Background

The U.S. Geological Survey SEAWAVE-QEX (Vecchia, 2018) model, a time series regression model run in R statistical computing software (R Core Team, 2017) that interpolates sparse pesticide monitoring data using a daily covariate (e.g., streamflow) to develop daily pesticide chemographs from non-daily sampling data at a specific site, is a tool that can be used to fill in concentration data between sampling events. The model creates multiple, equally probable estimates of daily concentrations (i.e., conditional simulations or chemographs), with each chemograph constrained by the measured input data. Since SEAWAVE-QEX pairs measured concentrations with daily streamflow measurements, the model is able to estimate concentrations that are larger than the measured concentrations, addressing a concern expressed by previous SAPs regarding the consistent underestimation of pesticide concentrations occurring between sampling events (i.e., missing the peak) from other infilling methods.

In addition to multiple estimated chemographs, the model produces a file of diagnostic plots that can be used to determine if the model assumptions were verified (e.g., if the model fit the data appropriately). Refer to the White Paper and the SEAWAVE-QEX SOP for more information on diagnostic plots (USEPA, 2019).

More information on SEAWAVE-QEX and its use in drinking water exposure assessment can be found in the supporting documents for the 2019 FIFRA SAP (USEPA, 2019).

Method

Chlorpyrifos surface water monitoring data for sites in the conterminous United States from the WQP and NCWQR were screened to determine which sites had adequate samples for SEAWAVE-QEX to be used to estimate concentrations between sampling events. This was done by screening available monitoring data to identify sites that met the following criteria:

1. 12 samples per year,
2. detection frequency greater than 25%,
3. minimum of 3 years of data meeting criteria 1 and 2, and
4. daily flow or stage data for the period meeting criteria 1, 2, and 3.

Sites were considered in all 2-digit HUCs for this assessment. While use of these data likely capture labeled and possible cancelled chlorpyrifos uses, all available data were included to capture the range of possible environmental and use conditions that are possible for the uses considered in this assessment. For example, while pecans are not considered in this assessment, chlorpyrifos application to pecans and subsequent occurrence concentrations could be a reasonable surrogate for peaches or other crops grown in the same areas with similar use rates. For this analysis, it is important to have a robust number of site-years to capture the variability in weather and use across years, thus, eliminating sites based on geographical location reduced the confidence in the ability to capture the true range of potential concentrations of chlorpyrifos in source drinking water. Furthermore, environmental variabilities can vary as much within a region as it does across the country.

SEAWAVE-QEX input and output files are provided in **ATTACHMENT 4**. All SEAWAVE-QEX diagnostic plots were evaluated according to the SEAWAVE-QEX Standard Operating Procedure (SOP) and in consultation with the 2019 SAP team. If the model assumptions are not verified by the diagnostic plots, then the data are not used quantitatively. Improvements to the model fits were attempted using options within the SEAWAVE-QEX model, as needed, and may have included: using a different subset of years of data or adding a small constant (e.g., fraction of the LOD) to concentration data for the purposes of model fitting (subsequently removed). This process is detailed further in the SEAWAVE-QEX SOP. When data were available a sensitivity analysis (i.e., using more data than the minimum requirements) was completed.

Confidence in the SEAWAVE-QEX results are noted as high, medium, or low based on evaluation of the diagnostic plots. **SEAWAVE-QEX Results** section summarizes the SEAWAVE-QEX analysis results, while a detailed narrative of each SEAWAVE-QEX analysis by site is provided in **Appendix B.** The narrative includes a discussion of the evaluation of the diagnostic plots including the waveform, sample collection timing, usage data as available, and a description of the watershed and waterbody characteristics. This information is also integrated into the **Spatial** Variability and Relevance Weight-of-evidence analysis.

To use the SEAWAVE-QEX data quantitatively from accepted sites, the maximum of the 99th percentile 1- and 21-day concentrations for each site are compared to the DWLOCs. These summary statistics were derived from calculating 99th percentile 1- or 21-day concentrations of the 100 SEAWAVE-QEX chemographs for each year, then taking the maximum of those 100, 99th percentile concentrations. The maximum of the 99th percentile 1- and 21-day concentrations are chosen to represent the maximum concentration occurring in the waterbody between measurements.

Sampling Bias Factor

Background

While SEAWAVE-QEX provides a way to estimate daily pesticide concentrations from non-daily surface water monitoring data, for many sites, there are not enough monitoring data to use SEAWAVE-QEX. This is because the data are too highly censored (i.e., values below the reporting limit) or there are not enough samples per year or across years. SBFs offer an alternative approach to overcome uncertainty around chlorpyrifos concentrations in source water from non-daily pesticide surface water monitoring data that do not meet the minimum requirements of SEAWAVE-QEX or the SEAWAVE-QEX model fits are not good enough to better understand the potential range of chlorpyrifos concentrations in surface water at that site.

In simple terms, SBFs are multiplicative factors used to calculate an upper level prediction interval (e.g., 95th percentile) on the measured concentration value. By multiplying the SBF and the maximum measured value from the available monitoring data, EPA can derive an upper-bound concentration to address the uncertainty in the measured pesticide concentrations due to infrequent sampling. The development of SBFs is a multi-step process requiring a daily concentration chemograph (i.e., 365 days) and is described in the *Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments* (USEPA, 2019).

Use of SEAWAVE-QEX chemographs to develop SBFs for those sites that meet the criteria (minimum data quantity criteria or flow data) resulting in reasonable model fits expands the ability to develop SBFs for most pesticides, including chlorpyrifos, as daily data often does not exist or is limited.

Method

SEAWAVE-QEX results from sites accepted for quantitative use (i.e., verifying the model assumptions) as described in the **SEAWAVE-QEX Analysis** Section were used to calculate pesticide-SBFs to be applied to other monitoring sites with insufficient data to run in SEAWAVE-QEX. SBFs were developed using a python code named "short term SBF calculator updated July 2020" (included in **ATTACHMENT 4**) and summarized on a site-year basis prior to application. The subsections below describe how SBFs are developed (Process Description) and subsequently applied (Application).

Process Description

The multi-step process for developing short-term SBFs, previously presented to the SAP, which uses a daily concentration chemograph, is detailed in the SAP White Paper (USEPA, 2020) and follows these general steps:

1. The maximum average 1- and 21-day concentration is calculated from the daily pesticide concentration chemograph for each year of available data.
2. Bootstrapped samples are drawn from the daily pesticide concentration data for each year of available data from Step 1. These bootstrapped samples are generated using several sampling frequencies (13, 17, 26, and 52 samples per year using a random sampling strategy.
3. The bootstrapped[16] samples are log-linearly interpolated to generate daily pesticide concentration chemographs.
4. The maximum 1- and 21-day average concentration from the interpolated daily pesticide concentration chemograph for each year of available data is calculated. Residuals of interpolated chemographs are calculated along with root mean square error (RMSE).
5. Steps 2 through 4 are repeated 10,000 times.
6. The 10,000 maximum average concentrations and RMSE for each year are ranked.
7. The ratio of the 5th percentile concentration from the 10,000 bootstrapped samples for each year is compared to the maximum concentration for each year from the input chemograph calculated in Step 1.

When SBFs are developed from daily measured concentration data, there is only one set of SBFs developed – one for each sampling interval and duration of exposure concern. The SBF program provides an output file that contains results for each SEAWAVE-QEX realization across all years of the simulation for each sampling interval and duration of exposure concern. To obtain a single SBF for a site-year, the data must be condensed across SEAWAVE-QEX realizations. For this assessment, the median across years is calculated.

[16] Bootstrapping is any test or metric that uses random sampling with replacement and falls under the broader class of resampling methods.

Application

Sampling Sites with Greater Than or Equal to 13 Samples per Year

The range of SBFs for all sites across the conterminous United States are applied to the available surface water monitoring sites and summarized on a 2-digit HUC basis based on respective sampling number per year (n=13-16, 17-25, 26-52, 52+ samples collected per year) to generate the upper confidence bound on measured concentration. All SBFs generated across the conterminous United States are considered to increase the robustness of the analysis. Having more sites and site years increases the number of SBFs increasing the likelihood of capturing the true range of watersheds and waterbody attributes that exist across the landscape and are represented by community water system watersheds. Even though sites where SBFs were developed fall outside the regions considered in this assessment does not mean that site does not represent areas that fall within the regions (and community water system watersheds) under evaluation. This is particularly important when few acceptable sites are available for SEAWAVE-QEX analysis.

The general equation used to apply sampling bias factor is as follows:

$\hat{Y}$=X*Bias Factor
Where:

$\hat{Y}$ = Estimated chlorpyrifos concentration
X = Chlorpyrifos concentration obtained from monitoring data
Bias Factor = Measured chlorpyrifos concentration / Estimated 5^{th} percentile pesticide concentration estimated from 10,000 simulated chemographs

The 1-day and 21-day sampling bias factor is multiplied by the maximum measured concentration based on the number of samples collected per year to provide the upper confidence bound on the measured value. The statistical implication of the bias factor is that 95% of the time, the bias factor adjusted chlorpyrifos concentrations from monitoring data will be equal to or greater than the true value in the monitoring data. The SBF-adjusted 1- and 21-day upper confidence bound on the measured concentration are compared to the DWLOCs. For site-years where the upper confidence bound for the 21-day average concentration using the maximum single day measured value in the calculation is above the DWLOC, the maximum 21-day average concentration was estimated from the available monitoring data using log-linear interpolation. In the analysis for 21-day average concentrations, the data were analyzed assuming non-detections were equal to ½ limit of quantification (or minimum reporting limit) or the limit of quantification in the log-linear interpolation when less-than values are reported for a sample. This was done as a sensitivity analysis to assess the impact of using different assumptions for the limit of quantification on the calculation of the 21-day average concentration. The 21-day sampling bias factor is then applied to the maximum 21-day average concentration for each site-year.

For any site-year with an SBF-adjusted concentration above the respective DWLOCs, additional analyses are conducted to confirm the appropriateness of the application of the SBFs. These include evaluating sample collection timing and frequency, usage data when available, and a description of the watershed and waterbody characteristics. This information is integrated into a weight-of-evidence analysis (see **Spatial Variability and Relevance Weight-of-evidence**).

Sampling Sites with Less Than 13 Samples Collected per Year

There is a lot of uncertainty in the ability to estimate pesticide concentrations at sites where there are less than 13 samples collected per year. For further characterization, maximum concentrations on a site-year basis are multiplied by the sampling bias factor for sample number 13-16. A count of the number of site-years where SBF-adjusted concentrations are above the DWLOC is reported on a HUC basis. No additional analysis of these sites is provided.

Spatial Variability and Relevance Weight-of-evidence

Background

Monitoring data used in a drinking water assessment should be relevant (i.e., hydrologically connected) to the drinking water intake in pesticide use areas. Evaluating an overlay of the monitoring sites using Geographic Information Systems (GIS) with potential use sites (e.g., cropland data) can provide confidence that the sites are relevant to pesticide use.

Conversely, monitoring sites that are located outside of potential use areas and are not hydrologically connected to these use sites probably will not provide useful information on pesticide concentrations, unless an alternative transport mechanism (i.e., spray drift) can be ascertained. If pesticide usage data are available indicating that the pesticide was applied when monitoring occurred, this adds confidence to the site's spatial relevance.

A lack of monitoring data in a CWS watershed, or the presence of monitoring data in a CWS watershed that is not co-located with potential pesticide use sites, suggest the need for monitoring data in this area or reliance on modeled estimated concentrations. However, additional spatial analysis can be performed to determine if surrogate monitoring sites could be used in lieu of additional monitoring data. If a site has similar or more vulnerable characteristics, such as soil and weather conditions, potential pesticide use patterns and pesticide usage, as areas in the same or another drinking water watershed, then the monitoring data for the site may be of potential use as a surrogate for those areas with missing monitoring data.

Method

GIS was used to determine how relevant monitoring sites are to a CWS intake, as well as determine how similar the SBF watersheds are to CWS watersheds. The weight-of-evidence approach integrates multiple lines of evidence including, chlorpyrifos usage, crop footprints, location of monitoring sites in relation to drinking water intake watersheds, and time of travel to the drinking water intakes, as described below.

Potential Use Sites

Potential use sites are defined in this assessment as alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, wheat, and strawberry in specific 2-digit HUC regions. 2007 USDA Census of Agriculture county-level acres of harvest data are overlaid with monitoring sites to determine if the sites, and the monitoring data, are representative of the uses.

Watershed and Waterbody Properties

Proximity of the site relative to the community water system drinking water intake is determined. Use of lines of evidence, such as hydrologic connectivity and the presence of nearby potential use sites, can add confidence, as the site is connected to the CWS intake and represents an area where the pesticide could be used.

Additionally, how far away the site is from the drinking water intake, how fast the flow of the stream is (i.e., time of travel), and the persistence of the pesticide is also considered. This information provides an approximation of how long the pesticide would take to reach the intake and, along with the pesticide persistence, gives an indication if the pesticide would be expected to persist long enough to reach the intake. If the monitoring site is at the top of the community water system watershed, the monitoring data might not reflect the potential dissipation that could occur before the pulse of flow (i.e., during time of travel) reaches the drinking water intake. This dissipation maybe the results of transformation or dilution, for example. If the monitoring site is near a community water system intake, then there is confidence that it is representative of the community water system.

Use of other lines of evidence, such as the presence of nearby potential use sites, can add confidence, as the monitoring site may represents an area where the pesticide could be used. If a site occurs downstream of a drinking water intake, it should be carefully evaluated, to determine if there are potential sources of pesticide load or dilution between the intake and the monitoring site, there may be uncertainty as to the source of the pesticide and its contribution to drinking water. The closer the monitoring site is to the intake the more confidence the concentrations represent concentrations in source water used for drinking water.

Contributing-area characteristics, such as soil properties, geology, slope, etc., and climatic factors, such as rainfall history and intensity, can provide information on the potential for the pesticide to be in runoff from a treated field. Soil and geology data, obtained from the Soil Survey Geographic Database (SSURGO), as well as the slope, obtained from topographic maps, of the potential pesticide use areas near the monitoring or SBF site can be used to see if the area is conducive to runoff. Likewise, the use of weather data, particularly average daily precipitation data, can be indicative of whether the site is in a wet or dry region and whether the short, intense rain events can generate flashy pesticide peaks. If the potential for runoff and the weather data for the site are like those observed at the potential use sites in the CWS, then there is confidence that the monitoring data may be representative of the CWS. More information on these types of factors can be found in ILSI, 1999.

d. Weight of Evidence

As available, all factors mentioned above are used to determine confidence in the model EDWCs and monitoring data and the representation of the concentrations and impact on drinking water. While analysis of monitoring data inherently considers all uses, this assessment focuses on the relevance of the available data to the uses considered in this assessment. This weighs heavily in the weight of evidence.

Results

a. Modeling

1. Pesticide Water Calculator

Application of Use Pattern Specific PCA

As mentioned in the **Post-processing or Output Adjustments** section, the first refinement considered in this assessment is the application of the use pattern specific PCA. Use pattern specific PCA were calculated for each of the 2-digit HUCs considered in this assessment and are specific to the uses considered in this assessment.

Results from PWC are presented in **Table 13** for both chlorpyrifos and chlorpyrifos-oxon resulting from upper bound average rate provided by BEAD after looking at the full distribution of survey results. A description is provided by crop in the supporting document provided by BEAD in **ATTACHMENT 1**. Application of use pattern specific PCAs indicate that the 1-in-10 year 21-day average chlorpyrifos-oxon concentration may be greater than the 21-day 10x DWLOC in four 2-digit HUCs (HUC-04, -07, -09, and -17) for upper bound applications rates. None of the 1-in-10 year 1-day or 21-day average chlorpyrifos-oxon concentrations are higher than the 1x DWLOC. In addition, none of the 1-in-10 year 1-day average chlorpyrifos concentration are greater than the 1-day 10x DWLOC.

Table 13. PCA Adjusted EDWCs for Upper Bound Application Rates of Chlorpyrifos

2-digit HUC	Use Site	2-digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EDWC (cpy)	21-day Model EDWC (cpy)	1-day Model EDWC (cpyo)	21-day Model EDWC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
02	Apple	0.07	127_4_PAappleSTD	10.8	7.6	10.3	7.3	0.8	0.5	0.7	0.5
	Peach			16.2*	11.4*	15.5	10.9	1.1	0.8	1.1	0.8
03	Citrus	0.27	136_4_FL-1421189-7026-72	6.5	3.8	6.2	3.6	1.8	1.0	1.7	1.0
	Peach[b]		216_4_GAPeachesSTD	11.6	6.9	11.0	6.6	3.2	1.8	3.0	1.8
	Cotton		196_4_GA-325617-11261-2	4.9	2.9	4.7	2.8	1.3	0.8	1.3	0.7
	Soybean		221_4_GA-325947-11736-5	11.9	6.8	11.4	6.5	3.2	1.8	3.1	1.8
04	Alfalfa	0.92[d]	2_4_MI-186800-22356-36	2.8	2.1	2.7	2.0	2.6	1.9	2.5	1.8
	Sugar beet		362_4_MI-186667-22116-41	7.2	4.8	6.9	4.6	6.6	4.4	6.3	**4.2**
	Apple[c]		128_4_MIcherrySTD	17.3	14.9	16.5	14.2	15.9	13.7	15.2	**13.1**
	Cherry		134_4_MIcherrySTD								
	Peach			26.0*	22.4*	24.8	21.4	23.9	20.6	22.8	**19.6**
	Soybean		245_4_MI-186667-22116-41	3.9	2.1	3.7	2.0	3.6	2.0	3.4	1.9
	Asparagus		133_4_MIasparagusSTD	3.7	2.1	3.5	2.0	3.4	2.0	3.3	1.9
05	Apples	0.58	129_4_PAappleSTD	9.6	7.2	9.2	6.9	5.6	4.2	5.3	4.0

2-digit HUC	Use Site	2-digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EDWC (cpy)	21-day Model EDWC (cpy)	1-day Model EDWC (cpyo)	21-day Model EDWC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
	Soybean		254_4_OH-198271-18810-5	5.4	3.3	5.2	3.1	3.1	1.9	3.0	1.8
06	Apples	0.02	130_4_NCappleSTD	20.8	13.0	19.8	12.4	0.4	0.3	0.4	0.2
07	Alfalfa	0.90	11_4_MO-2528577-19014-37	7.7	4.5	7.3	4.3	7.0	4.0	6.7	3.8
	Sugar beet		371_4_MN-2423043-23487-41	11.5	8.3	11.0	7.9	10.4	7.5	9.9	**7.2**
	Soybean		263_4_MN-2877271-22781-5	5.6	3.4	5.3	3.2	5.0	3.1	4.8	2.9
09	Alfalfa	0.95[e]	20_4_SD-416559-24423-36	2.0	1.5	1.9	1.4	1.8	1.4	1.7	1.3
	Sugar beet		437_4_ND-2642948-27020-41	9.7	6.5	9.3	6.2	8.7	5.8	8.3	**5.6**
	Soybean		281_4_ND-2571399-26297-5	3.6	2.3	3.4	2.2	3.3	2.1	3.1	2.0
	Spring wheat		473_4_ND-2585363-27001-23	2.9	1.8	2.8	1.7	2.6	1.6	2.5	1.6
	Winter wheat		527_4_ND-341303-27230-24	5.8	3.9	5.5	3.7	5.2	3.5	5.0	3.3
10	Alfalfa	1.0[e]	29_4_IA-404845-19717-37	5.5	3.4	5.2	3.2	5.5	3.4	5.2	3.3
	Soybean		299_4_NE-427060-20409-5	6.0	3.7	5.7	3.5	6.0	3.7	5.7	3.6
	Spring wheat		512_4_ND-339036-26757-22	5.1	3.3	4.9	3.1	5.1	3.3	4.9	3.2
	Winter wheat		536_4_CO-95043-18735-24	3.0	1.8	2.9	1.7	3.0	1.8	2.9	1.7
11	Alfalfa	0.79[e]	65_4_CO-2808264-16377-37	4.1	2.6	3.9	2.5	3.2	2.0	3.1	2.0
	Soybean		335_4_AR-565399-14294-5	3.8	2.3	3.6	2.2	3.0	1.8	2.9	1.7
	Winter wheat		572_4_TX-367160-13558-24	5.2	3.0	5.0	2.9	4.1	2.4	3.9	2.3
12	Citrus[h]	0.18	163_4_TX-367665-6012-72	6.3	3.9	6.1	3.6	1.2	0.7	1.1	0.7
	Peach		163_4_TX-367665-6012-72	5.4	3.3	5.2	3.1	1.0	0.6	0.9	0.6
	Winter wheat		590_4_TX-372533-12603-24	3.9	2.3	3.7	2.2	0.7	0.4	0.7	0.4
17	Alfalfa	0.53	110_4_WA-71453-24575-36	2.4	1.6	2.3	1.5	1.3	0.9	1.2	0.8
	Sugar beet		389_4_ID-79974-21766-41	7.0	4.9	6.7	4.7	3.7	2.6	3.5	2.5
	Apple[c]		131_4_ORappleSTD	9.6	6.2	9.2	5.9	5.1	3.3	4.9	3.1
	Strawberry		353_4_ID-80309-21523-12	16.8	12.1	16.0	11.5	8.9	6.4	8.5	**6.1**

a. Batch run name is truncated (DWA_2020 was removed for reporting purposes).
b. Model run was completed for 2.0 lb a.i./A; however, upper bound rate for peach on a national level is 3 lb a.i./a. Results were multiplied by 3/2.
c. Model run was completed for 2.0 lb a.i./A (maximum rate observed is noted as 3.0 lb a.i./A)
d. Use pattern specific PCA is slightly higher (0.93) than all-ag PCA (0.92). Use pattern specific PCA is capped at all-ag value.
e. Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at all-ag value.
f. Use pattern specific PCA is slightly higher (>1) than all-ag PCA (1.0) Use pattern specific PCA is capped at all-ag value.
g. Use pattern specific PCA is slightly higher (0.96) than all-ag PCA (0.79). Use pattern specific PCA is capped at all-ag value.
h. Model run was completed for 3.0 lb a.i./A and should have been 3.5 lb a.i./A for the upper bound rate. Results were multiple by 3.5/3 to adjust the concentrations.

*****Upper bound rate modeled for apples and cherries is 2 lb a.i./a. The upper bound rate for peach on a national level is 3 lb a.i./a. Results were multiplied by 3/2 to estimated concentrations for peach.
Green shading indicates concentrations below the 10xDWLOC.
Reg shading and bold font indications concentrations above the 10x DWLOC.
Chlorpyrifos (cpy)
Chlorpyrifos-oxon (cpyo)

Subsequent refinements focus on four (i.e., HUC-04, -07, -09, and -17) of the 11 HUC-02 regions considered in this assessment and focus on the 21-day average concentration assuming retention (i.e., 10x) of the FQPA safety factor.

Results for average application rates are provided in **APPENDIX B**.

Use of the Full Distribution of Watershed PCA Values, Critical PCAs, and Percent of Watersheds with PCA Values Larger than the Critical PCAs

Examination of the full distribution of PCAs for HUC-04, -07, -09 and -17 (i.e., those 2-digit HUCs with upper bound application rates resulting in EDWCs above the 21-day 10x DWLOC for chlorpyrifos-oxon) indicate that 232 community water system watersheds may have chlorpyrifos-oxon concentrations above the 21-day 10x DWLOC for upper bound application rates as shown in **Table 14**. This was determined by counting the number of community water systems with PCAs above the critical PCA for each respective region. In addition, **Table 14** provides a count of the total number of community water systems watersheds within each HUC so that the percentage of watershed with concentrations above the DWLOC can also be determined.

Table 14. Full Distribution of Watershed Specific PCA-Adjusted EDWCs for Upper Bound Applications of Chlorpyrifos-oxon

2-digit HUC	Total Community Water System Watersheds	Max[1] 1-in-10 year 21-day Concentration µg/L	Critical 21-day Percent Cropped Area	Number of Community Water Systems with Concentrations Above the 10x 21-day DWLOC	Percent of Community Water Systems with Concentrations Above the 21-day 10x DWLOC	Overlap Counties Crop Acres Community Water System Watersheds (number)
04	196	21.4	0.19	139	71	Yes (several)
07	158	7.9[2]	0.51	79	50	Yes (1)
09	16	5.2	0.67	12	75	Yes (several)
17	343	11.5	0.35	2	<1	-

[1] This column provides the maximum concentration associated with use of the maximum regional use pattern specific PCA. Concentrations would be lower for other community water systems within the 2-digit HUC.
[2] Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at the all-ag value in the prior refinement step; however, when aggregating the individual contributions, the concentration (max=6.1 µg/L) exceeds the prior estimate (max=5.6 µg/L). Therefore, since the model output value is higher for the misc-Ag use site the soybean contribution is low (3%) and a low estimated concentration and wheat falls in the middle, soybean contribution was made zero, and the wheat contribution (PCA) was adjusted down to be the difference in the all-ag and misc-ag. This approach is expected to be conservative yet accounts for the double cropping that is likely occurring in the watershed.
- refinement not considered

There are several community water systems with EDWCs above the 21-day 10x DWLOC in HUC-04, -07, and -09. Only two community water systems in HUC-17 had concentrations above the 10x 21-day DWLOC.[17] Therefore, HUC-17 was not considered for overlap refinements.

The same analysis is provided for average application rates and the results are provided in **APPENDIX B**. The excel file supporting this analysis is provided in **ATTACHMENT 3** (PCA_Analysis subfolder cpy pca_analysis.xlsx).

Overlap analysis of Watersheds with PCAs Larger than the Critical PCA with Use Site Footprint

As described in the **Post-processing or Output Adjustments** section of this document, one of the new refinement methods is to examine the overlap of community water system watersheds with estimated concentrations above the DWLOC with use pattern specific county level acres data. This is done because the PCA values are often calculated for crop groups (e.g., orchards) which contain multiple crops (e.g., citrus, apples, peaches, pecans (USEPA, 2020). Overlap analysis was completed for the community water systems with EDWCs above the critical PCA in HUC-04, HUC-07, and HUC-09. The results are discussed in the subsections below for each of the 2-digit HUCs suspected to have concentrations above the 21-day 10x DWLOC.

HUC-04 (Great Lakes)

Examination of county boundaries with reported acres associated with uses under consideration in HUC-04 suggests overlap with community water systems with PCAs higher than the critical PCA. In this region, chlorpyrifos use on orchard crops (apple, cherry, and peach) result in estimated concentrations above

[17] Concurrent examination of individual community water system watershed PCAs (i.e., aggregation) indicate the concentrations in these two community system watersheds should not be above the 21-day 10 DWLOC. See **ATTACHMENT 3** PCA analysis.

the 21-day 10xDWLOC for chlorpyrifos-oxon. The other uses considered (alfalfa, asparagus, and soybean) have estimated concentrations less than the DWLOC. Further spatial analysis of HUC-04 indicates there are several community water system watershed with use pattern specific PCAs greater than the critical PCA (0.19) for counties reporting acres of either apple, cherry, or peach in 2007 (**Figure 6**). Because there are several watersheds with overlap a count of the number of community water systems with overlap was not done. Instead, this region is considered for additional refinements.

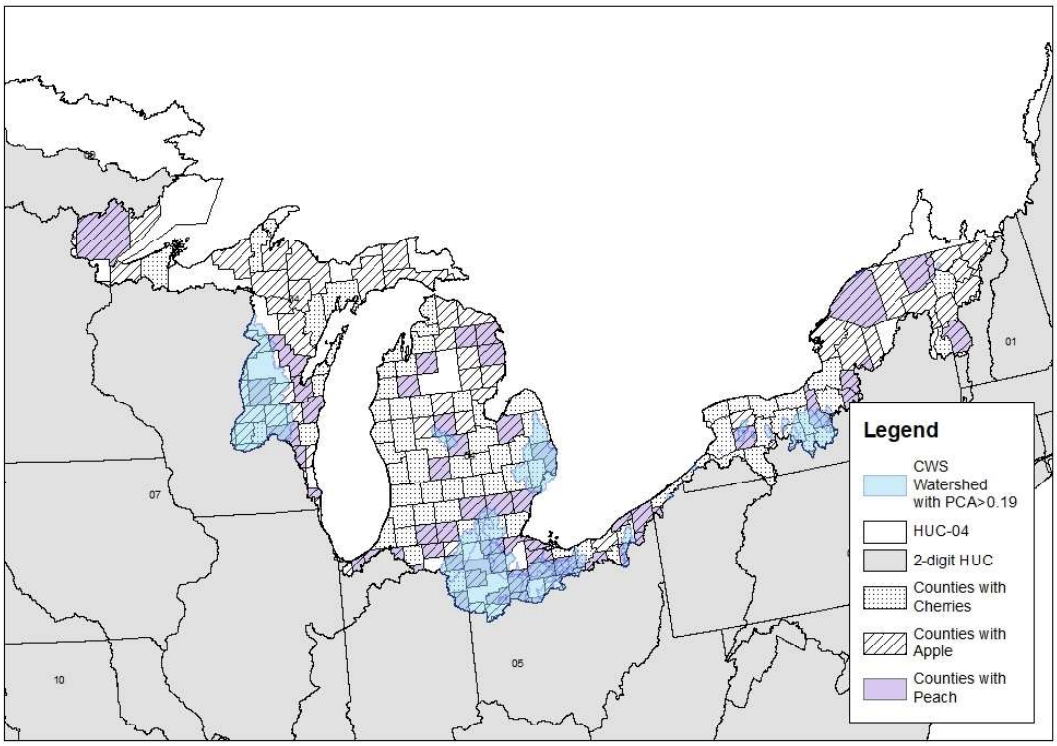


Figure 6. HUC-04 Crop Land Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.19)

HUC-07

Examination of county boundaries with reported acres associated with uses under consideration suggests overlap with community water systems with PCAs higher than the critical PCAs. In this region, chlorpyrifos use on sugar beet is the only use considered in this assessment with estimated concentrations above the 10x DWLOC. The other uses considered (alfalfa and soybean) have estimated concentrations less than for use on sugar beet and the 10x DWLOC. Further spatial analysis of HUC-07 indicates there is only one community water system with a use pattern specific PCA greater than the critical PCA for counties reporting acres of sugar beet in 2007 (**Figure 7**). This watershed (object ID 2703) has a use-site specific PCA of 0.69 (misc-ag PCA of 0.42 + soybean PCA of 0.27). Since there is spatial overlap with at least one community water system in HUC-07 this region is considered for additional refinement.

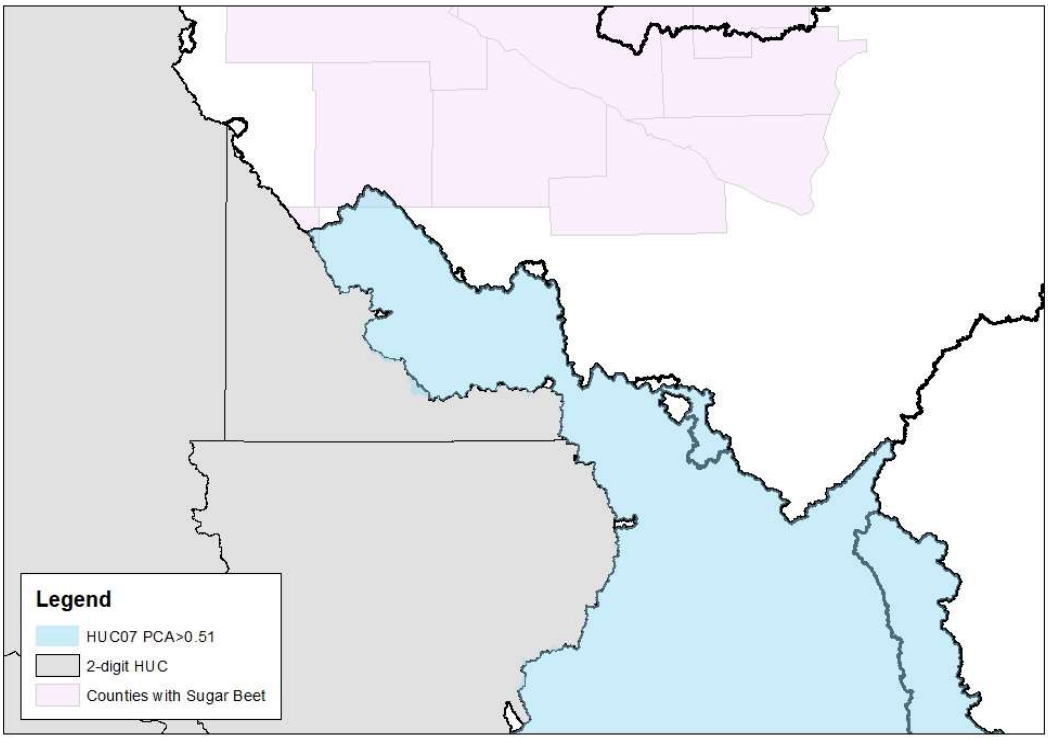


Figure 7. HUC-07 Sugar Beet Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.51)

HUC-09

The same spatial analysis was completed for HUC-09. It showed several community water system with use pattern specific PCAs greater than the critical PCA for counties reporting acres of sugar beet in 2007 (**Figure 8**). Again, chlorpyrifos use on sugar beets results in the highest model output for this region and is the only use with estimated concentrations above the 21-day 10x DWLOC. Since there is spatial overlap between county with acres of sugar beet HUC-09 is considered for additional refinement.

Because there are several watersheds with overlap a count of the community water systems with overlap was not done.

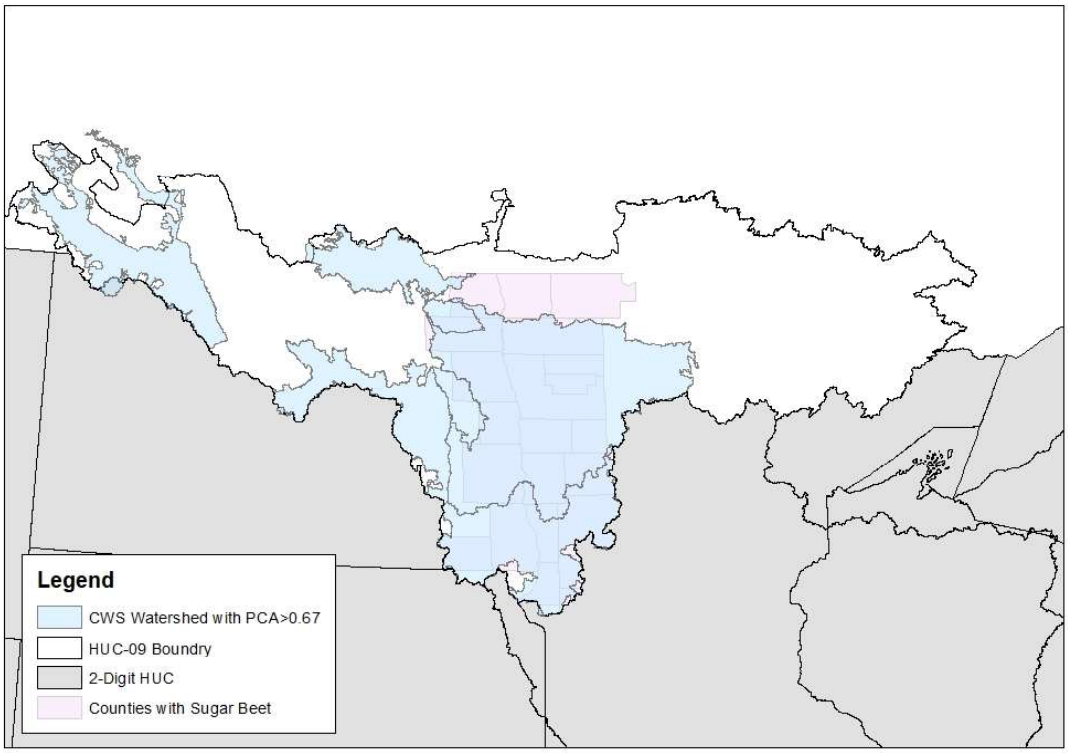


Figure 8. HUC-09 Sugar Beet Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.67)

HUC-17

Examination of county boundaries with reported acres associated with strawberry (2007) in HUC-17 suggests there is no overlap with community water systems with PCAs higher than the critical PCA (**Figure 9**). This region was no longer considered for refinement.

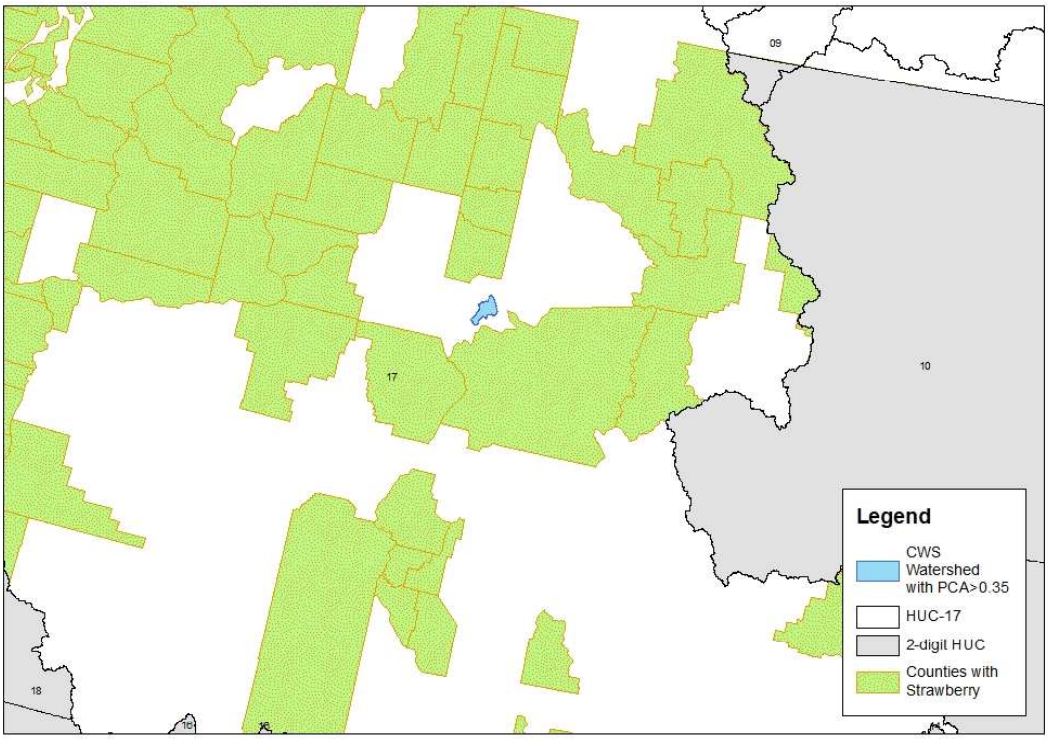


Figure 9. HUC-17 Crop Land Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.35)

Development of Aggregated Estimated Drinking Water Concentrations

As described in the **Post-processing or Output Adjustments** section of this document, one of the new refinement methods includes calculating EDWCs based individual use site residue contribution. Prior to this step, EDWCs are based on the highest concentration of all uses modeled within the respective 2-digit HUCs, however, the relative contributions of each modeled use site can be determined by adding (or aggregating) the contributing concentrations within each CWS watershed. This refinement step in this assessment focuses on aggregating 1-in-10 year aggregation.

The aggregated EDWCs reported in this section only represent the uses considered in this assessment and in the regions assessed. If additional uses patterns need to be considered the aggregated concentrations need to be updated to account for the additional exposure resulting from the contribution of additional uses to the overall EDWCs. The results are reported in the subsection below.

1-in-10 year Aggregation

Aggregation of the 1-in-10-year concentrations for community water systems with chlorpyrifos-oxon concentrations estimated to be above the 10x DWLOC indicate that community water systems in HUC-07 and HUC-09 continue to need to be refined as concentration are still estimated to be above the 10x DWLOC for upper bound application rates. Results are presented in **Table 15**. The aggregated concentrations only reflect the uses considered in this assessment and do not account for the temporal contribution of each use.

Table 15. Aggregation of 1-in-10 year PCA-Adjusted 21-day Average EDWCs for Upper Bound Application Rates of Chlorpyrifos

2-digit HUC	Total CWS	Aggregated 1-in-10 year 21-day Average Concentration (cpyo) µg/L	No. of CWS above 21-day DWLOC	Percent of CWS above 21-day DWLOC
04	196	3.4	-	-
07	158	**4.2**[1]	1	<1%
09	16	**6.1**	9	56%

Bold font indicates concentrations above the 10xDWLOC (21-day = 4.0 µg/L)
[1] The watershed (object ID 2703) identified as having overlap with the sugar beet has an aggregated 1-in-10 21-day average concentration of 4.2 ug/L. This value is above the 21-day 10x DWLOC.
- no calculation needed as the concentration is below the 21-day 10x DWLOC.

The watershed in HUC-07 previously identified to have overlap with HUC-09 is a region where the use-site specific PCA is greater than the all-ag, and in the prior step, the use site-specific PCA was capped at the all-ag value as the sum of the individual crop PCA should not exceed the PCA for all cropped land. However, when aggregating concentrations, the individual contributions are adjusted based on the individual crop contributions even if, when combined, the PCAs are greater than the all-ag value. Nevertheless, the maximum aggregated chlorpyrifos-oxon concentration is lower than that calculated concentration reported in the prior step; however, still not below the 21-day 10x DWLOC.

Based on this analysis, one community water system in HUC-07 and 9 in HUC-09 are expected to have concentrations above the 21-day 10x DWLOC. Aggregation of the 1-in-10 year 21-day average concentration does not account for the temporal contribution of residue concentrations in the EDWCs; however, due to the time and tools necessary to aggregate time series data the next refinement considered is percent crop treated.

The same analysis is provided for average application rates. Results are provided in **APPENDIX B**. The excel file supporting this analysis is provided in **ATTACHMENT 3** (PCA_Analysis subfolder cpy pca_analysis.xlsx).

Percent Crop Treated Adjustment Factors

The final new refinement method considered in this assessment includes the calculation of the aggregation EDWCs using percent crop treated data. The maximum PCT is calculated by state for HUC-07 and HUC-09. This information was provided by BEAD. These data were applied using the upper distribution approach for allocating treated acres within each watershed to calculate EDWCs for each individual community water system within the HUC with concentrations above the 10x DWLOC in the prior refinement step. The results for the four approaches are presented in **Table 16**. These results suggest that based on the upper bound application rates all concentrations are expected to be below the 21-day 10x DWLOC; therefore, no additional refinements were considered. The excel file supporting this analysis is provided in **ATTACHMENT 3** subfolder PCA_PCT_Aggregation_Analysis.

Table 16. Full Distribution of Watershed Specific PCA and PCT (all usage)-Adjusted EDWCs for Upper Bound Applications of Chlorpyrifos-oxon

2-digit HUC	Total CWS	Maximum 1-in-10 year 21-day chlorpyrifos-oxon µg/L
		PCA/PCT (max upper)
07	158	0[1]
09	16	3.3[2]

[1] The watershed (object ID 2703) identified as having overlap with the sugar beet was the only watershed in this region considered in this refinement step.
[2] Considers all watershed with use pattern specific PCAs above the critical PCA and not the subset of watersheds with use pattern overlap. This is because the PCT analysis and the overlap analysis were being conducted concurrently. Had a concentration been estimated above the DWLOC the overlap analysis could have been used to refine the estimated concentrations further.

2. Discussion and Conclusions

Using the upper bound application rates provided by BEAD for the high benefit uses identified by Corteva Agriscience and critical uses identified by BEAD, all use site-2-digit HUC region combinations resulted in concentrations below the 10x DWLOC with refinements. The refinements used in this assessment are briefly summarized along with the results below.

Recall, the first refinement considered was application of a use pattern specific PCA to reflect only specific crops within each 2-digit HUC. This refinement identified 4 of the 11 2-digit HUCs as potentially having concentrations above the 21-day 10x DWLOC based on the maximum use pattern specific PCA in each region. However, none of the regions were determined to have concentrations above the 1- or 21-day 1x DWLOC or the 1-day 10x DWLOC.

The second refinement included the use of the full distribution of watershed PCA values and calculation of critical PCAs and percent of watersheds with PCA values larger than the critical PCAs. Examination of the full distribution of community water system watersheds in the regions identified as potentially having concentrations above the 21-day 10x DWLOC indicate that in 3 of the 4 regions there are number of community water systems where chlorpyrifos-oxon concentrations may be above the 21-day 10x DWLOC. The number of community water systems with use-site specific PCAs greater than the critical PCA were reported (**Table 14)**.

Overlap analysis of watersheds with PCAs larger than the critical PCA with use site footprint for uses (e.g., sugar beet, cherries or apples) where a crop group (e.g., misc-ag or orchard) PCA was used to determine overlap with community water systems watersheds. This refinement was useful in HUC-07 and HUC-17. In HUC-07, overlap analysis was used to ruling out all most all the community water systems with PCAs above the critical PCAs. In HUC-17, overlap analysis was not used to rule out community watersheds with PCAs above the critical PCAs because were several counties with acres reported for use sites considered in this assessment that overlapped with community water systems with PCAs greater than the critical PCAs.

Up until this point, concentration estimates relied on use of the single highest modeled estimated across uses within in the 2-digit HUC. Therefore, the development of aggregated EDWCs for each community water system exceeding the 10x DWLOC was done. This was done to allocate individual crop contributions to the EDWCs and develop a refined EDWC.

Percent crop treated adjustment factors were integrated into the exposure estimates for the 1-in-10 year 21-day average concentrations. This analysis indicated that when assuming the maximum percent crop treated over 5-years and allocating the associated acres within each individual community water system the concentrations expected would be below the 21-day 10x DWLOC.

Consistent with previous work, this update suggests the concentrations vary across the landscape and depend on the uses under consideration. The model estimated concentrations are consistent with previous assessments for average and upper bound rates. The impact of using the new scenarios does not substantially change the exposure estimates for chlorpyrifos.

The primary reason why estimated concentrations are below the DWLOC in this assessment is the number of uses considered in the respective regions. Because so many uses are currently registered, past assessments relied on a PCA of 1 because chlorpyrifos is registered for uses that can occur anywhere within a community water system watershed. This assessment, however, focuses only on high benefit and critical uses in specific regions of the country. Importantly, the results of this work do not reflect potential exposure from all currently registered uses. If additional uses were to be considered, this analysis would need to be updated. It is expected that as the number of uses assessed increases, and if application rates are higher than those considered in this assessment, the estimated concentrations will likely be higher than those presented and further refinements would need to be considered.

b. Monitoring

1. General Data Observations

Generally, detections of chlorpyrifos are sporadic with low concentrations. This is expected based on the environmental fate and transport properties (i.e., high sorption), usage data (i.e., applied in response to pest pressure), and low sample frequency. Much of the higher frequency sampled chlorpyrifos data comes from monitoring programs that are older and thus may not represent current use conditions. While these data may not reflect current use scenarios, the data suggest that chlorpyrifos does move to surface water and can be present in concentrations within the range of PWC estimated concentrations, even before adjustment for infrequent sampling. A summary of data accessed through the Water Quality Portal on 01/06/2020 is provided **Table 17**.

Table 17. Summary of Chlorpyrifos Data Accessed via the Water Quality Portal

Source	Number of Samples	Number of Non-detections	Minimum Reported Concentration µg/L	Maximum Reported Concentration µg/L
NWIS	66,345	60,504	0.0009	5.62
STORET	33,975	20,477	2E-07	14.7
Data accessed 1/6/2020				

These data indicate a low over all detection frequency; however, detected concentrations occur at up to 14.7 µg/L.

Surface water monitoring programs typically collect samples on a weekly or biweekly basis, even in programs with a relatively high sampling frequency such as USGS National Water Quality

Assessment (NAWQA) or Washington State Department of Agriculture (WSDA). For example, **Figure 10** shows the range of the number of samples collected per site per year (gray circles) along with the number of sites sampled per year (red dash) for chlorpyrifos (Water Quality Portal accessed 01/06/2020). The gray circles were formatted with transparency so that the darker the circle appears, the larger the number of sites with the same number of samples collected per year.

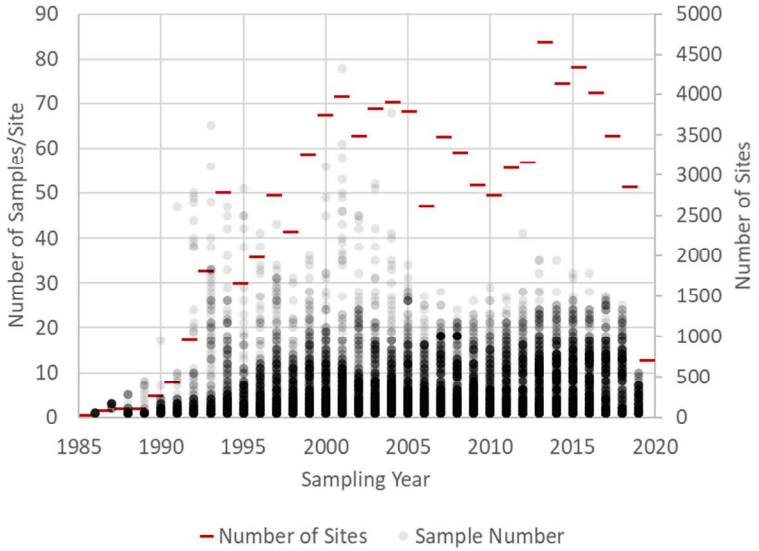


Figure 10. Sampling Quantity Characteristics for Chlorpyrifos Data from the Water Quality Portal

The sample number varies substantially across sites and the number of sites sampled varies by year. **Figure 10** also illustrates a downward trend in the number of sites as well as the number of samples collected at each site in recent years. Most sites have low sample numbers. The most samples collected at a site within a calendar year occurred in 2001 when 78 samples were collected at a monitoring location in San Joaquin River near Vernalis, California (USGS-11303500) with 53 of those samples occurring on different days. Closer analysis of this site shows that 45 samples were collected in the months of January and February. Many of the samples occurred on the same days in January and February.

Sample frequency at other sites and in other years is generally much lower, with the lowest being one sample per year for years that are sampled. **Figure 11** is a histogram showing the number of samples collected in 2016 for chlorpyrifos. Most sites do not have enough samples collected to meet the minimum data requirements for the applications of SBFs (≥ 13 samples/year) or for SEAWAVE-QEX analysis (≥ 12 samples/year with 25% detection frequency for 3 years).

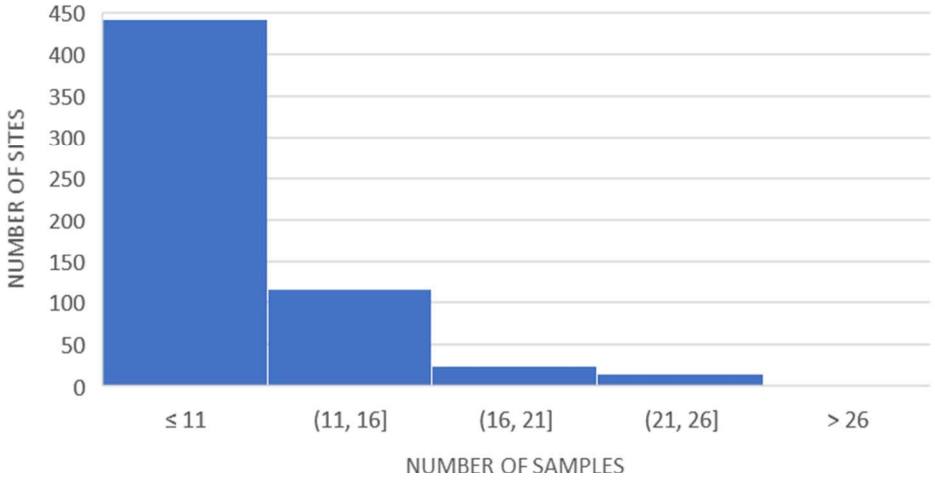


Figure 11. Histogram for Samples in 2016 for Chlorpyrifos (USGS) Across the United States

Further analysis of all years of data reveal that the number of days between sampling events ranged from 1 to 360 days across all years and sites with the average number of days between samples of 1 to 336 days across all site-years.

Analysis of data collected from programs with more frequent sampling suggest that as sample collection increases, the detection frequency also increases. For example, daily composite sampling on Orestimba Creek had detection frequencies between 42-52% for chlorpyrifos.

Sampling frequency should be considered in the context of use information, as an increase in the number of samples collected at an individual location where use is infrequent or absent, or during times of the year when applications or runoff events are not expected to occur, may reduce detection frequencies, as well as reduce the likelihood of measuring peak concentrations.

Most of the data in the Water Quality Portal come from grab samples. A grab sample is defined as an individual aliquot or volume of water collected over a short period of time (<15 minutes). For example, scooping up water in a cup, bottle or bucket. In contrast, a composite sample consist of a collection of several individual discrete samples taken at regular intervals over a period, usually 24-hours.

While differences in surface water concentrations can result from differences in the sampling design, frequency, and/or sample number with respect to the peak concentration on a daily time step, potential variation in concentrations may also occur over the course of a day for chlorpyrifos **Figure 12** shows measured chlorpyrifos concentrations from the Rock Creek sampling site from NCWQR. it is possible that daily grab samples can miss measuring peak concentrations on days which the sampling occurs. Grab samples are currently the most common sampling method within the available data sources.

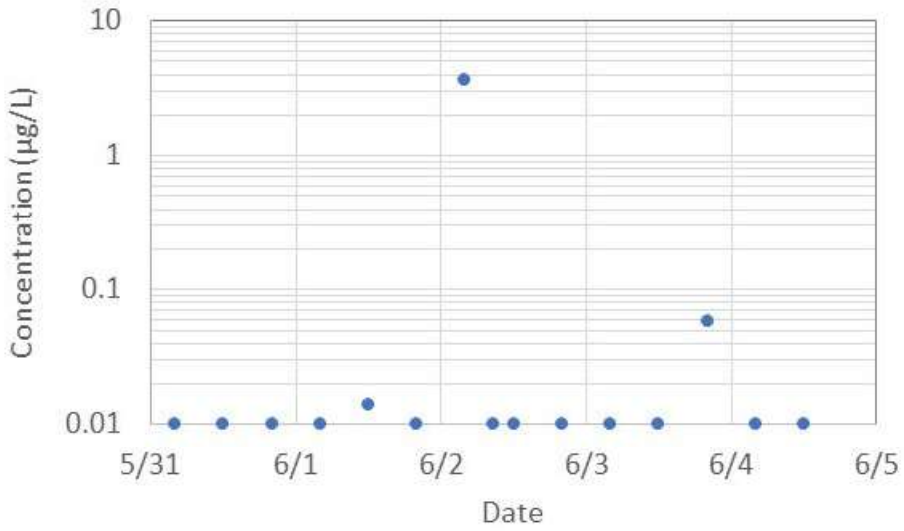


Figure 12. Pesticide Concentration Variation Over a Daily Time Step for Rock Creek (NCWQR)

Therefore, data need to be evaluated on a site-specific basis as the sampling frequency may impact the interpretation of the data. In many cases, there is not enough data either on an annual, multi-year, or multi-site basis to reliably estimate pesticide concentrations for short-term exposure estimates.

Several tables summarizing available surface water monitoring data, including more regionally-specific and site-specific summaries are provided in **APPENDIX C** and **Attachment 4**.

2. Data Interpretation and Extrapolation

SEAWAVE-QEX Results

Of the many sites with chlorpyrifos samples in the WQP datasets, 13 sites were determined to satisfy the model assumptions (see White Paper Chapter 3 and the SEAWAVE-QEX SOP for more information on satisfying model assumptions). However, upon further evaluation, two sites were excluded from quantitative analysis due to indications in the flow data that suggest the sites may not have year-round flow; however, the analysis of these sites is also included in **APPENDIX C**. A map of the sites considered for SEAWAVE-QEX analysis is presented in **Figure 13**. This map illustrates the need to consider all SEAWAVE-QEX sites across the contiguous states to capture as much of the range chlorpyrifos use conditions. For example, there are no SEAWAVE-QEX sites in HUC-10 or -11 and in most others HUCs there is only one SEAWAVE-QEX site.

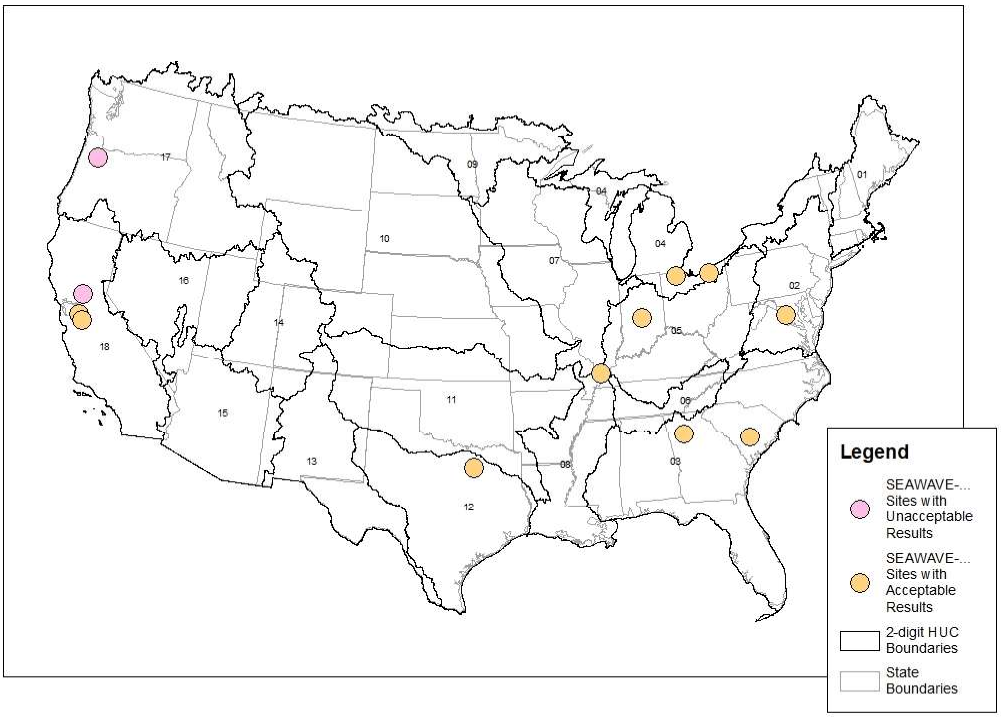


Figure 13. Monitoring Sites Meeting the SEAWAVE-QEX Data Quantity Criteria

Figure 14 describes the sampling quantity characteristics for the final 11 SEAWAVE-QEX sites, showing both the number of samples at each site (y-axis) and the number of sites sampled each year (z-axis). However, data used in SEAWAVE-QEX spans from 1987-2012 as other years may not have met the minimum SEAWAVE-QEX criteria. These years may represent use patterns that are no longer registered as well as uses not considered in this assessment. Of the sites flagged for use in SEAWAVE-QEX based on the minimum criteria, recent years (e.g., after 2012) generally have less monitoring and/or lower detection frequencies. The reduced detection frequency could be the result of reduced sampling frequency in more recent years, changes in use in the early 2000s, and/or timing of sampling.

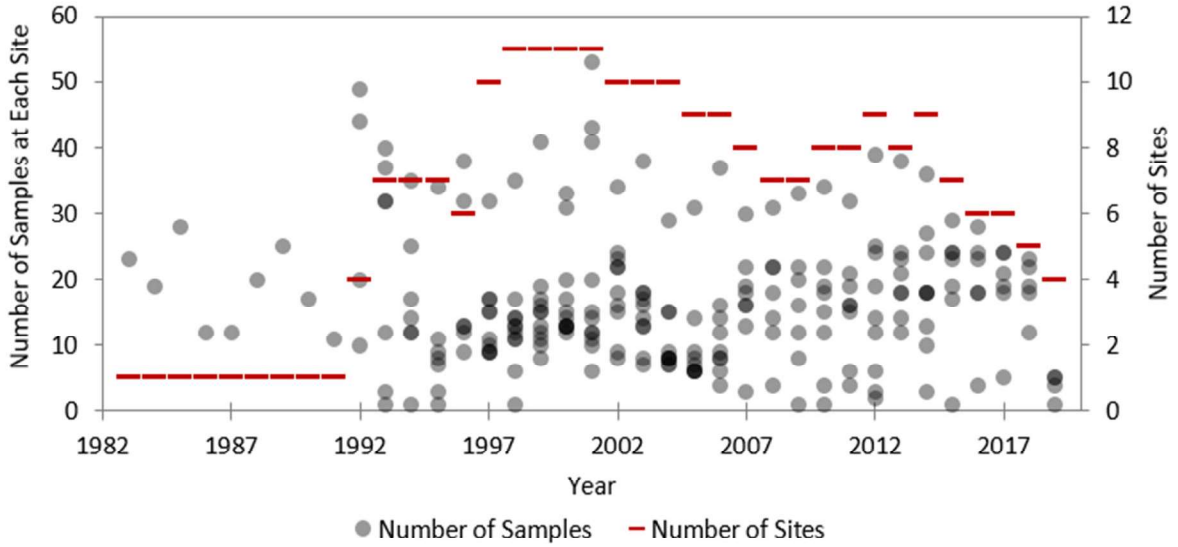


Figure 14. Sampling Quantity Characteristics for Chlorpyrifos Data for Sites Meeting the SEAWAVE-QEX Data Quantity Criteria

As observed in **Table 18** for several sites, the maximum measured concentration is lower than the reported censoring limit during other sampling events. For example, for USGS-01654000, the maximum measured concentration was 0.041 µg/L in 1994, but the reporting limit ranged from 0.0037 µg/L up to 0.0586 µg/L (i.e., greater than 0.041 µg/L) from 1994 to 2014. Reporting limits often vary between sampling events and descriptions included in the WQP are not always clear. For chlorpyrifos, which has relatively low measured concentrations that are of importance, these database issues create more uncertainty in the monitoring data. Additionally, a high censoring limit relative to measured concentrations may adversely affect the SEAWAVE-QEX output, which takes the censoring limit into account. This is because SEAWAVE-QEX randomly assigning values below the censoring limit. Therefore, a randomly high value may be selected that does not correspond with a flow event. However, not all high censoring limits occurred in years that were included in the SEAWAVE-QEX analysis.

Table 18. Summary of Monitoring Sites with Acceptable SEAWAVE-QEX Models

USGS Site No.	2-digit HUC (State)	Max Measured Conc. µg/L (Year)	Max Censoring Limit µg/L (Year)	Years Used in SEAWAVE-QEX	Final Simulation Filename (Confidence[1])	SEAWAVE-QEX Est. 1-day Conc. (µg/L)[2]	SEAWAVE-QEX Est. Est. 21-day Conc. (µg/L)[2]
01654000	02 (VA)	0.041 (1994)	0.0586 (2014)	1994-2000	cpy_1 (m)	0.026-0.060	0.011-0.036
02174250	03 (SC)	0.338 (2005)	0.02 (1999)	1996-2008	cpy_7 (m)	0.088-0.50	0.055-0.25
02335870	03 (GA)	0.034 (1993)	0.5 (2001)	1993-2000	cpy_2 (l)	0.022-0.085	0.013-0.041
03353637	05 (IN)	0.11 (1996)	0.3 (1993)	1992-1996	cpy_1 (m)	0.13-0.24	0.046-0.11
04193500	04 (OH)	0.0299 (1996)	0.21 (1998)	1996-2007	cpy_4 (l)	0.077-2.1	0.049-1.4
08057200	12 (TX)	0.0549 (2000)	0.025 (2016, 2017)	1998-2002	cpy_6 (h)	0.022-0.058	0.010-0.027
11274538	18 (CA)	0.3 (1992)	0.025 (2016)	1992-2010	cpy_4[3] (l)	0.48-2.1	0.20-1.1
11303500	18 (CA)	0.079 (1993)	0.025 (2016)	1994-2012	cpy_2 (h)	0.024-*0.073*	0.016-0.043
14211720	17 (OR)	0.0137 (2007)	0.013 (2006)	1997-2007	cpy_1 (m)	0.015-0.029	0.011-0.019
04208000	04 (OH)	0.5 (1988)	0.12 (2012-2014)	1987-1991	cpy_2 (m)	2.9-12.7	1.3-4.7
11447360	18 (CA)	0.0445 (1997)	0.02 (1998, 2002, 2005)	1997-2008	cpy_3 (n/a[4])	n/a	n/a
14201300	17 (OR)	0.401 (1995)	0.02 (2004)	1993-2018	cpy_1 (n/a[4])	n/a	n/a
03612500	05 (IL)	0.01 (2005, 2008-2010, 2013)	0.038 (1992)	1992-2000	cpy_6 (l)	0.031-0.35	0.021-0.23

[1] Confidence categories are: h=highest, m=medium, l=lowest
[2] Range of the yearly maximum of the 99th percentile concentration
[3] Additional data from Dow (now Corteva Agriscience) for 1996-1997 was included with the USGS site data for Orestimba Creek.
[4] Site excluded based on seasonal streamflow variation (i.e., intermittently flowing).
Italic font notes concentration measured is higher than summary statistic pulled from the SEAWAVE-QEX simulation.

Confidence in the SEAWAVE-QEX results are noted as high (h), medium (m), or low (l) (see **Table 18**). Reasoning based on goodness of fit of the diagnostic plots for these qualifiers are detailed in **APPENDIX C** on a site-by-site basis. For all sites except USGS-11303500, the highest 1-day estimated concentration was greater than the maximum measured concentration. For USGS-11303500, the SEAWAVE-QEX estimate was up to 0.073 µg/L while the maximum measured concentration was 0.079 µg/L. More than half of the sites have a single broad seasonal wave, likely because of either uses occurring year-round, applications occurring at different times across multiple years, and sporadic detections or a combination. Use of SEAWAVE-QEX may not be suitable for some pesticides with sporadic occurrence and low seasonality (e.g., not consistent use patterns at certain times of the year)

as observed at these sites. To date, EPA's evaluation of SEAWAVE-QEX has focused on pesticides with strong seasonality (i.e., atrazine, metolachlor) and was limited geographically as the data used in the evaluation was from the NCWQR for sites in Ohio (tile drained). Even chlorpyrifos sites that had more seasonality in the data have shallow seasonal waves, suggesting that the monitoring analysis is not likely underestimating concentrations due to low seasonality.

Figure 15. Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites summarizes several properties from the landcover data of the final 11 sites used quantitatively from SEAWAVE-QEX (National Land Cover Database reported in StreamCat). The graphed landcover data shown in **Figure 16** may not add up to 100% due to other contribution of other landcovers not presented. To determine the relevance of these monitoring sites to chlorpyrifos uses, landcover characteristics were examined. The 11 sites represent a mixture of urban environments with high percentages of impervious surfaces and agriculturally relevant sites, such as cropland and hay.

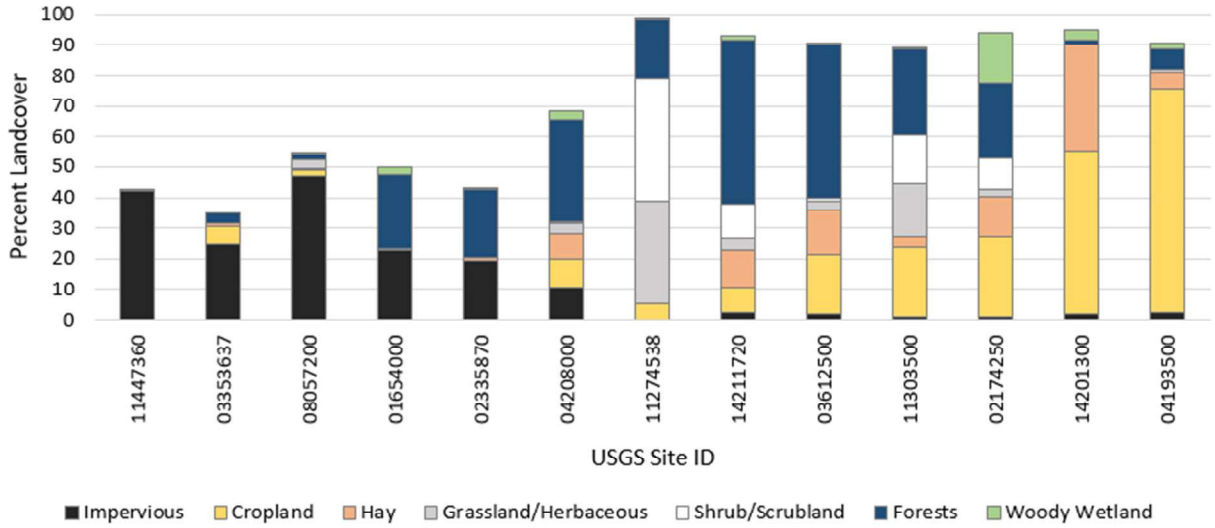


Figure 15. Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites

Figure 16 and **Figure 17** below provide a summary of the 1- and 21-day estimated concentrations derived for each site-year from SEAWAVE-QEX. Note that one site (USGS-04208000) has the highest estimates of any other, from 1987-1991. These are also the oldest sampling data included and may represent uses that are no longer registered. Based on the StreamCat landcover data (Hill et al., 2016) (**Figure 15.** Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites), the site is not substantially different from other sites with similar amounts of impervious surfaces and cropland; however, the gage station for the site is shared with the NCWQR Cuyahoga sampling site, and it is known that these are influenced by tile drainage. This is also true of USGS-04193500 (Maumee River), which includes higher concentrations than most other sites from 1996-2007. USGS-11274538 (Orestimba Creek) also stands out as having higher concentrations than most sites from 1992-2010.

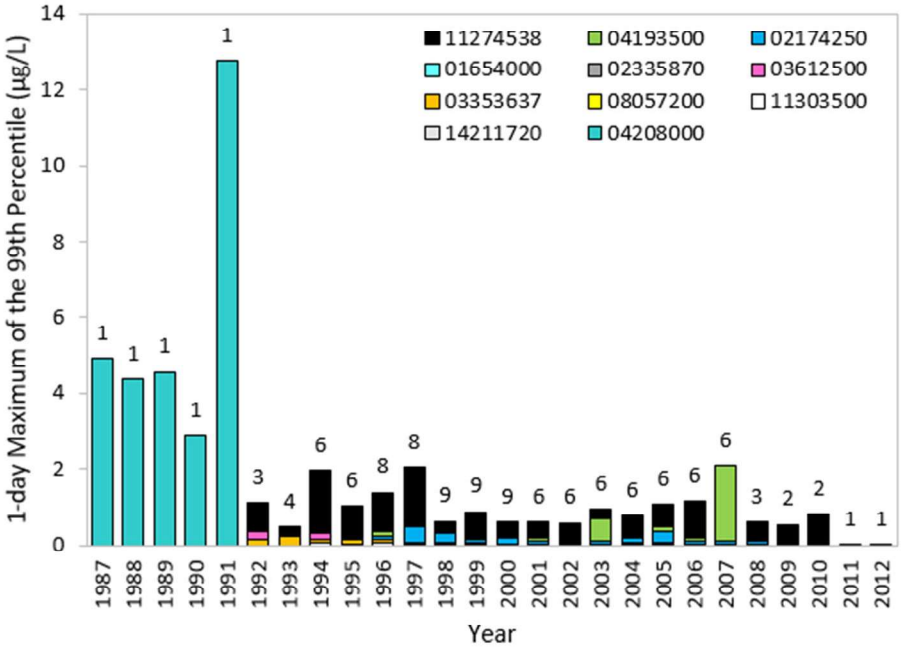


Figure 16. Summary of SEAWAVE-QEX 1-day Maximum of the 99th Percentile Chlorpyrifos Concentrations for Each Site (data labels are number of sites per year)

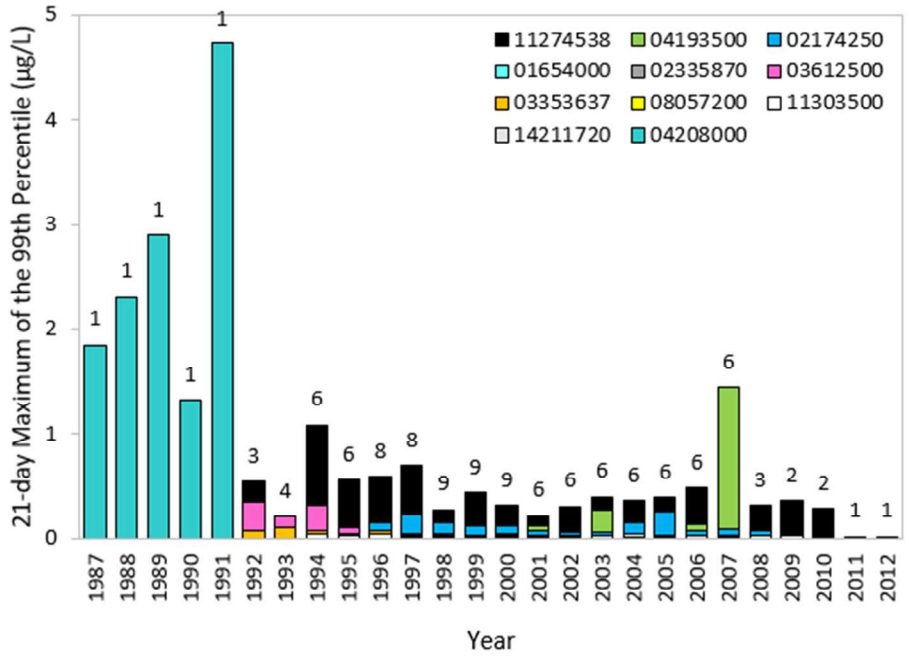


Figure 17. Summary of SEAWAVE-QEX 21-day Maximum of the 99th Percentile Chlorpyrifos Concentrations for Each Site (data labels are number of sites per year)

Sampling Bias Factors Development

SBFs were developed for 110-site years (11 sites) for estimating the upper bound confidence intervals on the 1- and 21-day average concentrations. The results are shown in **Figure 18** and **Figure 19**, respectively. The entire distribution of SBFs within each sampling frequency (e.g., 13-16 samples/year)

was used to assess the potential concentrations across time and across the landscape. The maximum SBFs for 52, 26, 17, and 13 samples per year are 11, 23, 29, and 55, respectively, for estimating the 1-day average concentration and 4, 6, 8, and 12, respectively, for estimating the 21-day average concentration. These SBFs are much lower than SBFs developed for chlorpyrifos presented to the FIFRA SAP in November 2019. This is because only a subset of the SEAWAVE-QEX simulations were determined to be adequate for the development of SBFs based on feedback from the SAP panel.

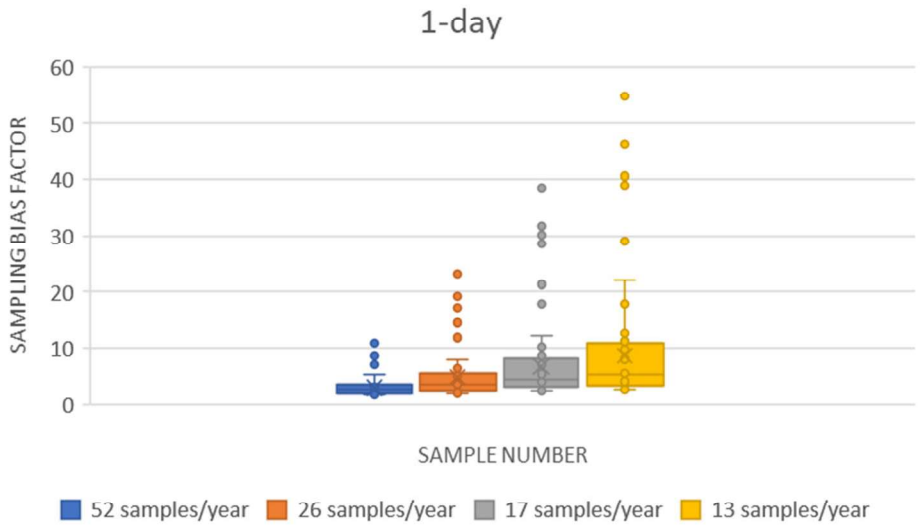


Figure 18. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across All Sites

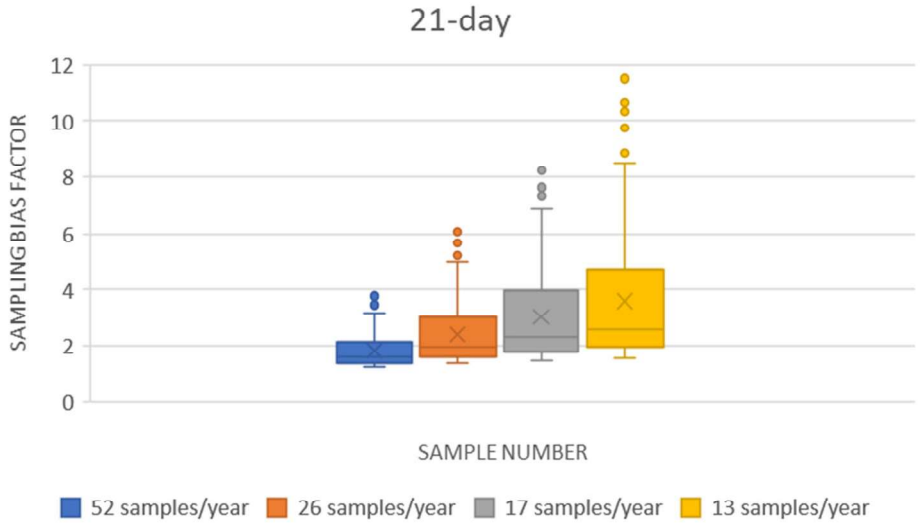


Figure 19. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across All Sites

Additional analysis of the developed SBFs revealed that SBFs varied more across sites than across years for most sites. **Figure 20** and **Figure 21** show the variability in the SBFs for 1- and 21-day across sites, respectively. However, there are a few sites where the SBFs notably varied across years. These sites

include USGS-02174250 (Cow Castle Creek near Bowman, SC), USGS-0420800 (Cuyahoga River at Independence, OH), and USGS-11274538 (Orestimba Creek near Crows Landing, CA).

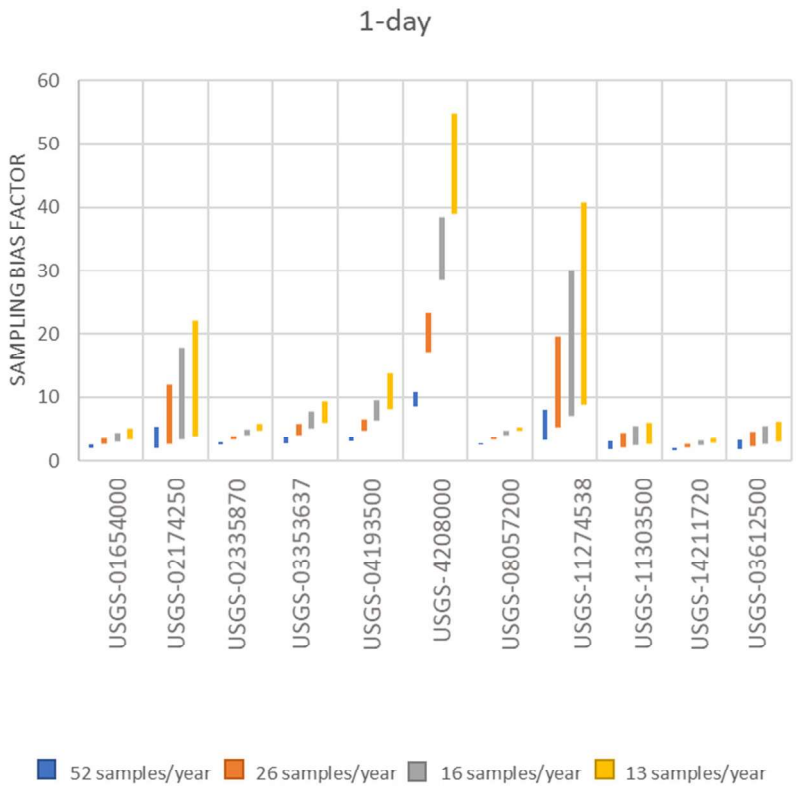


Figure 20. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration by Site

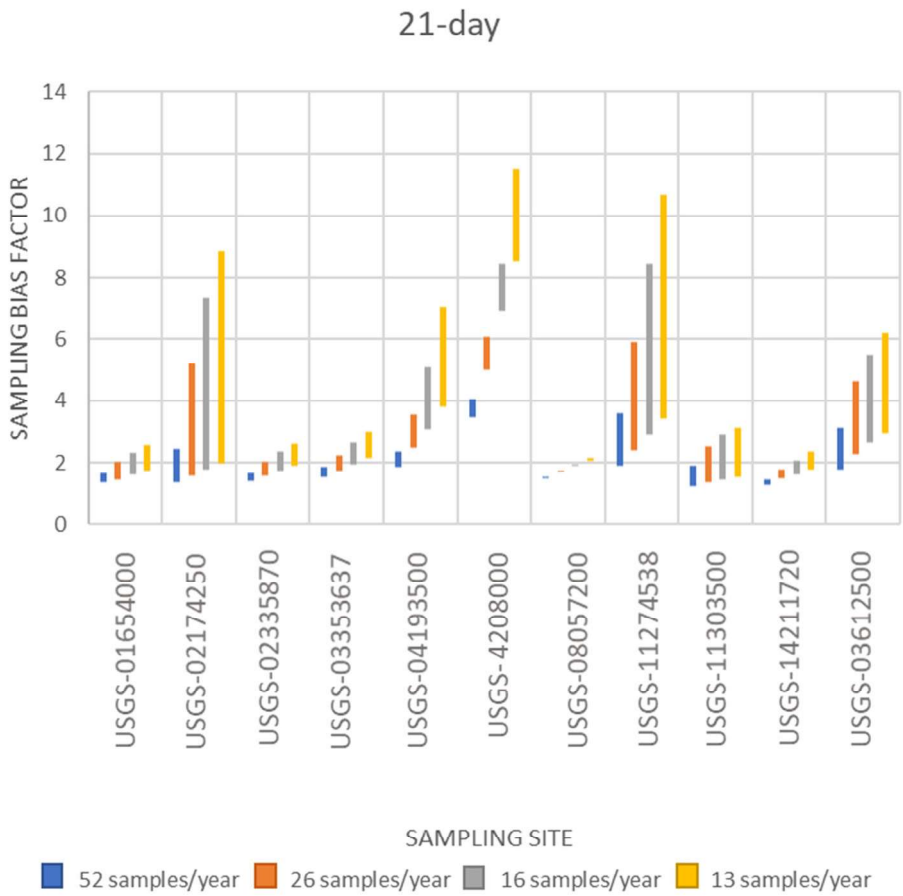


Figure 21. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration by Site

Further analysis of the sites indicates that:

For USGS-02174250, the large range and higher SBFs are due to a measured concentration in 2005 that resulted in much higher SBFs for 2005 than calculated for other years and sites. SBFs ranged from 2.0 to 2.9 for 52+ samples per year, 2.6 to 3.9 for 26-51 samples/year, 3.3 to 4.9 for 17-25 samples/year and 3.8 to 6.0 for 13-16 samples/year for estimating the upper bound concentration on the 1-day average for all years excluding 2005. In comparison, SBFs for 2005 are 5.3, 11.9, 17.8, and 22.2, for the corresponding sampling number.

For USGS-04208000, the large range and higher SBFs are observed for years 1987 through 1991. The SBFs are consistently high ranging from 9 to 11 for 52+ samples per year, 17 to 23 for 26-51 samples/year, 29 to 38 for 17-25 samples/year and 39 to 55 for 13-16 samples/year for estimating the upper bound concentration on the 1-day average concentration and 4 to almost 12 for 52+ samples per year and 13-16 samples/year, respectively, for 21-day average concentration.

For USGS-11274538, the larger range and higher SBFs are observed for 1996 and 1997. Again, the higher SBFs observed for this site are driven by a measured concentration. In addition, 1996 and 1997 had the most sampling data (i.e., daily) across years at this site and across sites.

This analysis, for USGS-11274538, suggests that for other years or other sites where peak occurrence concentration may have gone unmeasured, the SBFs may not capture the true range of potential chlorpyrifos concentrations. This is likely due to the sporadic application of chlorpyrifos and wide potential application window. In addition, chlorpyrifos is not observed to be persistent at a given point (e.g., sampling site) in a waterbody due to stream flow. Chlorpyrifos concentrations are driven by pulse inputs due to application or high runoff events. As discussed in the SEAWAVE-QEX section, the use patterns of chlorpyrifos and pulse inputs cause broad, shallow seasonal waves in SEAWAVE-QEX and fewer estimates of the pulse (peak) concentrations.

Figure 22 and **Figure 23** show the variability in the SBFs for 1- and 21-day across time, respectively. The number and specific sites where SBFs are calculated each year is different. The difference in sites is expected to be the primary contributor to the differences in magnitude of SBFs calculated across years.

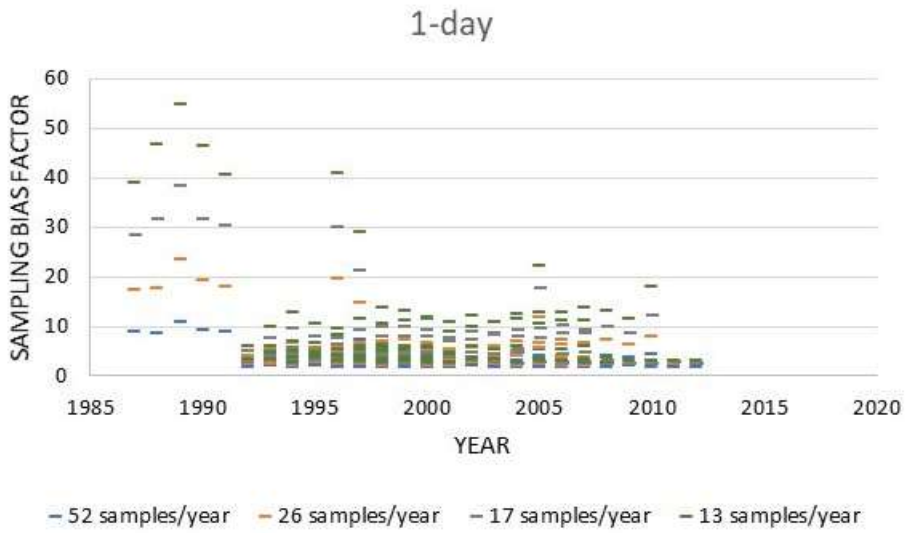


Figure 22. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across Years

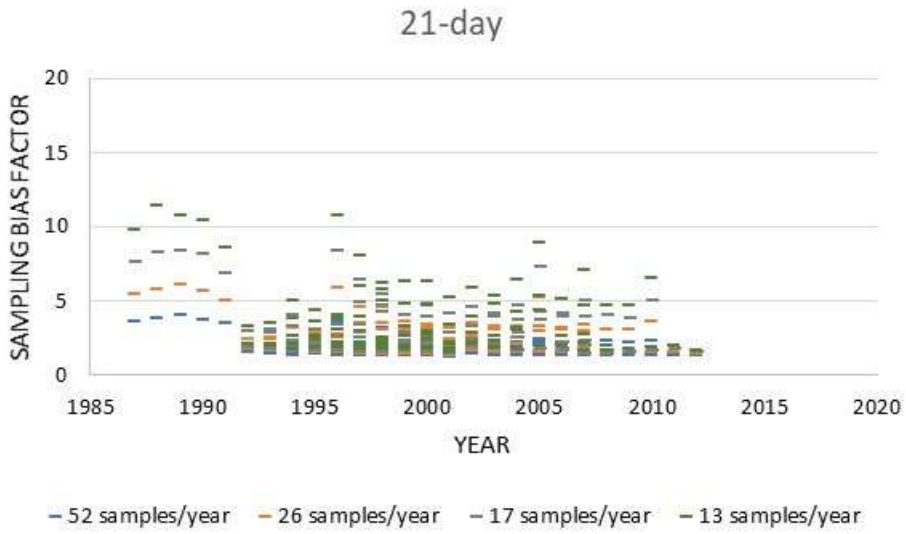


Figure 23. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across Years

Given that the use profile for chlorpyrifos changed in the early 2000s (see Use Characterization page 17 for more information), SBFs developed for 2005-2012 (post-registration review label changes) are presented in **Figure 24** and **Figure 25** for estimating the upper bound confidence interval on the 1- and 21-day average concentration.

The maximum SBFs for 52, 26, 17, and 13 samples per year are 5, 12, 18, and 22, respectively, for estimating the 1-day average concentration and 2, 5, 7, and 9 for estimating the 21-day average concentration, respectively. While these SBFs were developed based on data that likely better reflect current use, the data only represent 23-site years (5 sites) as compared to 110 site-years (11-sites) considering all available SBFs. Therefore, the abbreviated time span is not expected to represent a robust number of site-years to capture the range of potential chlorpyrifos concentrations in surface water. The 2012 FIFRA SAP suggested that 100 site years of data would be enough to capture a range of weather and site conditions.

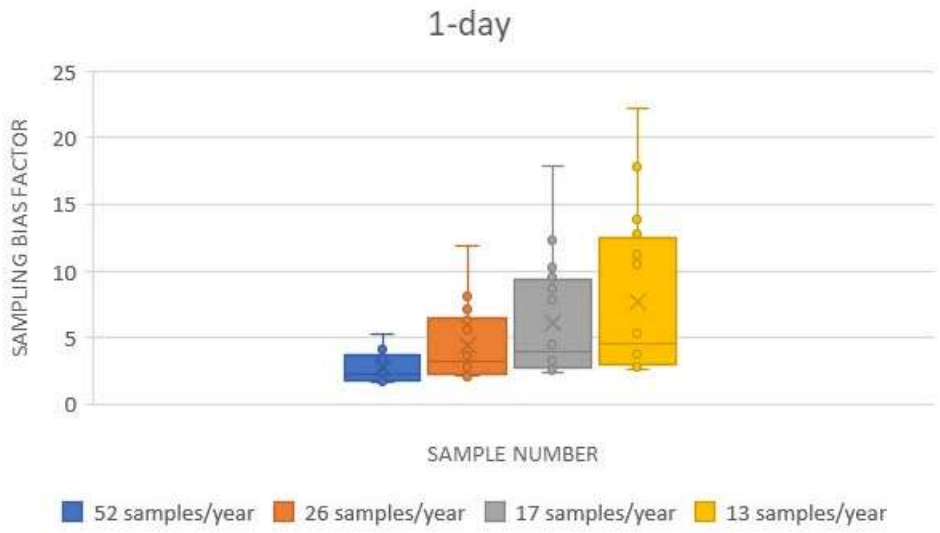


Figure 24. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across All Sites (2005-2012)

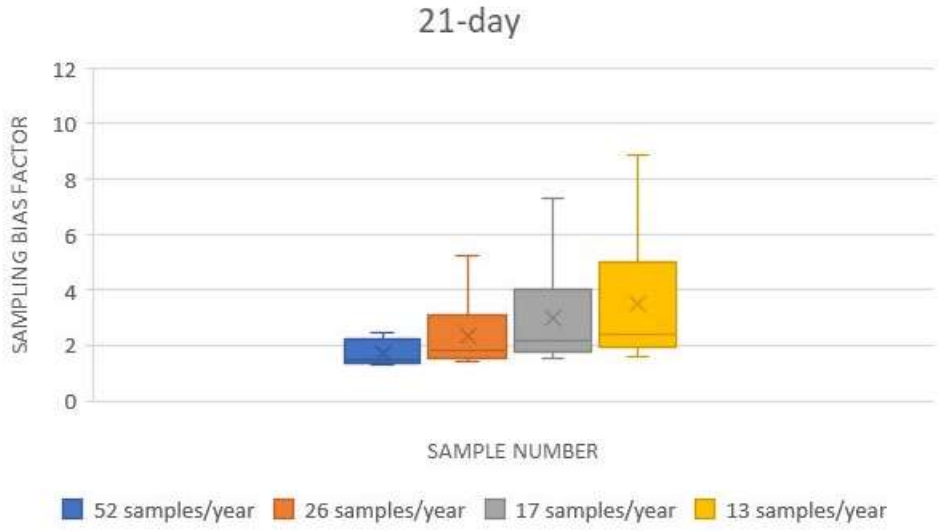


Figure 25. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across All Sites (2005-2012)

Sampling Bias Factors Application

Sampling Sites with Greater Than or Equal to 13 Samples per Year

SBFs for 1987-2012 (all years) and 2005-2012 (post-registration review label changes) are presented in **Table 19**. While there is a 2x difference in the 1-day SBFs for the two different periods of time the difference in 21-day SBFs is not that different especially when considering the 12-16 per year sampling category. Most chlorpyrifos data fall within the 12-16 per year sampling category or in the less than 13 sampling category. Therefore, to capture the most variability across time and space all SBFs years were considered and applied based on the number of samples per year for all site-years of data from the Water Quality Portal with greater than or equal to 13 samples per year (**Table 19**). A sensitivity analysis

using the SBFs for the abbreviated time period was also completed. The results for the sensitivity analysis were not notably different.

Table 19. Maximum Sampling Bias Factors

Sample Number	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor
	1-day		21-day	
52+	10.9	5.3	4.0	2.4
26-51	23.3	11.9	6.1	5.2
17-25	38.5	17.8	8.4	7.3
13-16	54.8	22.2	11.5	8.9

SBFs adjusted concentrations (i.e., the upper confidence bound) that are above the 10x DWLOC for 1-day or 21-day average concentration based on the maximum SBFs are shown in **Table 20** and **Table 21**, respectively. There are 7-site-years (4 sites in HUC-17) where concentrations may be above the 10x DWLOCs (1-day) using the maximum SBFs across all years. Considering only bias factors developed for years 2005-2012 (i.e., post label modifications) results in 4-site years (3-sites) where concentrations may be above the 10x DWLOC. There are 8-site-years (5 sites in HUC-17) with concentrations above the 10x DWLOCs (21-day) using the maximum SBFs across all years. Considering only SBFs developed for years 2005-2012 results in 5-site years (3-sites) where concentrations may be above the 10x DWLOC. The sites where concentrations may be above the DWLOC are consistent across the exposure duration of concern. The site-years of data resulting in potential concentration above the 10x DWLOC were collected in the mid-2000s to as recent as 2018, post label changes. Therefore, these sites would be expected to represent uses currently permitted on chlorpyrifos labels. For site OREGONDEQ-34235-ORDEQ, the highest concentration is for a censored value; however, this assumption has not been confirmed.

Table 20. Summary of Monitoring Sites with Sampling Bias Factor Adjusted Chlorpyrifos Concentrations Above the 1-day 10x DWLOC (24 µg/L)[1]

Monitoring Site	Year	Number of Samples	Detection Range (µg/L)	Range of Detection Limits (µg/L)	Maximum 1-day Sampling Bias Factor Adjusted Maximum 1-day Chlorpyrifos Concentration (µg/L)	Maximum 1-day Sampling Bias Factor Adjusted Maximum 1-day Chlorpyrifos-oxon Concentration (µg/L)
OREGONDEQ-32010-ORDEQ	2005	15	0.033-0.49	0.023-0.026	26.9	**25.7**
	2009	14	0.0618 - 0.6494	0.038-0.079	35.6	**34.0**
OREGONDEQ-32068-ORDEQ	2007	14	0.026 - 2.4	0.024-0.03	131.5	**125.5**
	2015	15	0.125 - 1.77	0.021 - 0.0865	97.0	**92.5**
	2016	13	0.039 - 0.722	0.0214 - 0.023	39.6	**37.8**
OREGONDEQ-32069-ORDEQ	2007	13	0.04 - 1.3	0.025 - 0.03	71.2	**67.9**
OREGONDEQ-34235-ORDEQ	2018	13	0.0591	0.0213-2.72[2]	74.5	**71.1**

Bold font Indicates concentration above the 10x DWLOC.

[1] The source water concentration of chlorpyrifos necessary to result in the chlorpyrifos-oxon concentration in drinking water following conversion during treatment was back calculated from the DWLOC for chlorpyrifos-oxon using a molecular weight adjustment factor (DWLOC/0.9541) (23 µg/L/0.9541) = 24 µg/L

[2] value is a censored concentration.

Table 21. Summary of Monitoring Sites with Sampling Bias Factor Adjusted Concentrations Above the 21-day 10x DWLOC (4.2 µg/L)[1]

Monitoring Site	Year	Number of Samples	Detection Range (µg/L)	Range of Detection Limits (µg/L)	Maximum 21-day Sampling Bias Factor Adjusted Maximum 1-day Concentration (µg/L)[2]	21-day Interpolated Concentration (µg/L)[2]	Maximum 21-day Sampling Bias Factor Adjusted Maximum Estimated 21-day Concentration (µg/L)
					1987-2012		1987-2012
OREGONDEQ-32010-ORDEQ	2005	15	0.033-0.49	0.023-0.026	**5.6**	0.14 (0.14)	1.6 (1.6)
	2009	14	0.0618 - 0.6494	0.038-0.079	**7.5**	0.14 (0.02)	1.6 (0.2)
OREGONDEQ-32068-ORDEQ	2007	14	0.026 - 2.4	0.024-0.03	**27.6**	1.7 (2.7)	**19.3 (19.3)**
	2015	15	0.125 - 1.77	0.021 - 0.0865	**20.4**	0.66 (0.63)	**7.6 (7.3)**
	2016	13	0.039 - 0.722	0.0214 - 0.023	**8.3**	0.57 (0.57)	**6.5 (6.5)**
OREGONDEQ-32069-ORDEQ	2007	13	0.04 - 1.3	0.025 - 0.03	**15.0**	0.42 (0.41)	**4.8 (4.7)**
OREGONDEQ-34235-ORDEQ	2018	13	0.0591	0.0213-2.72[3]	**15.6**	1.4 (0.7)	**16.4 (8.2)**
OREGONDEQ-37639-ORDEQ	2014	14	0.0274-0.395	0.0212 – 0.0862	**4.5**	0.22 (0.20)	2.5 (2.3)

[1] The source water concentration of chlorpyrifos necessary to result in the chlorpyrifos-oxon concentration in drinking water following conversion during treatment was back calculated from the DWLOC for chlorpyrifos-oxon using a molecular weight adjustment factor (DWLOC/0.9541) (4 µg/L/0.9541) = 4.2 µg/L

[2] The 1-day max concentration multiplied by the 21-day sampling bias as a surrogate from to estimate the upper bound 21-day average concentrations.

[3] 21-day average concentration was estimated using log-linear interpolation. Interpolated 21-day concentration using the detection limit was calculated using the detection limit, bracketed values include use of ½ the detection limit.

value is a censored concentration (i.e., below the minimum reporting limit)

Bold font Indicates concentration above the 10x DWLOC.

Watershed characteristics for these sampling sites are provided in **Figure 26**. All the sampling sites are in HUC-17 with sampling data collected by the Oregon Department of Environmental Quality. An overlap of the sampling site locations with counties associated with cropped acres for the use sites considered in this assessment is provided in **Figure 27**. Only three blue dots are visible on the map due to scaling as there are multiple sampling sites in proximity to one another (OREGONDEQ-32068-ORDEQ is near OREGONDEQ-32069-ORDEQ and OREGONDEQ-34235-ORDEQ is near OREGONDEQ-37639-ORDEQ).

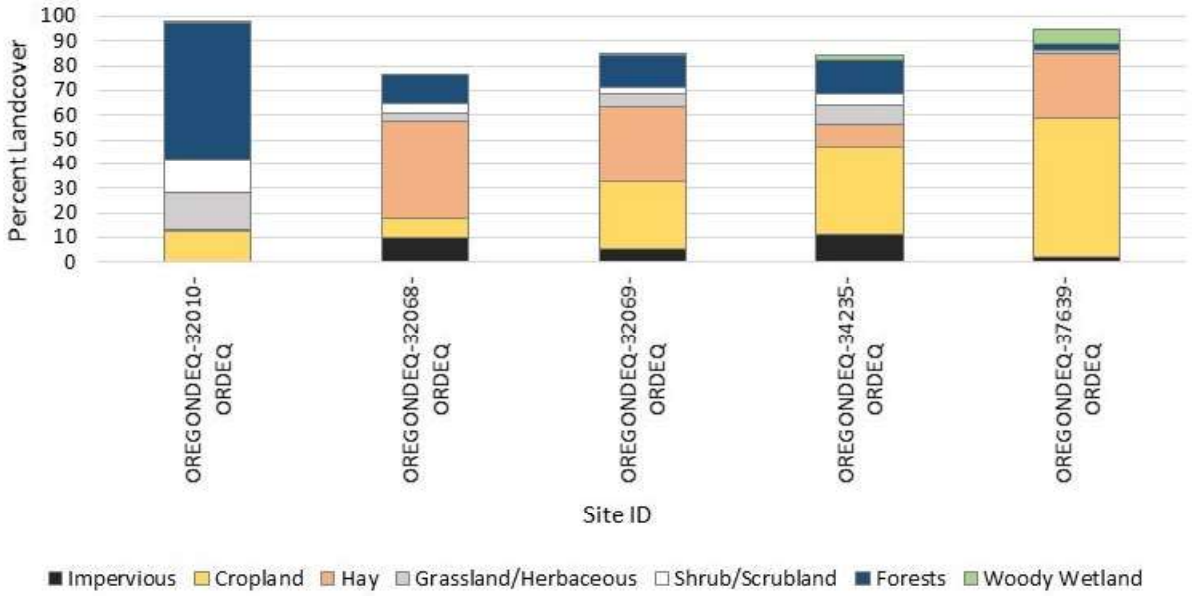


Figure 26. Summary of Site Landcover Characteristics for Sampling Sites with Sampling Bias Factor Adjusted Concentrations above 10x DWLOCs

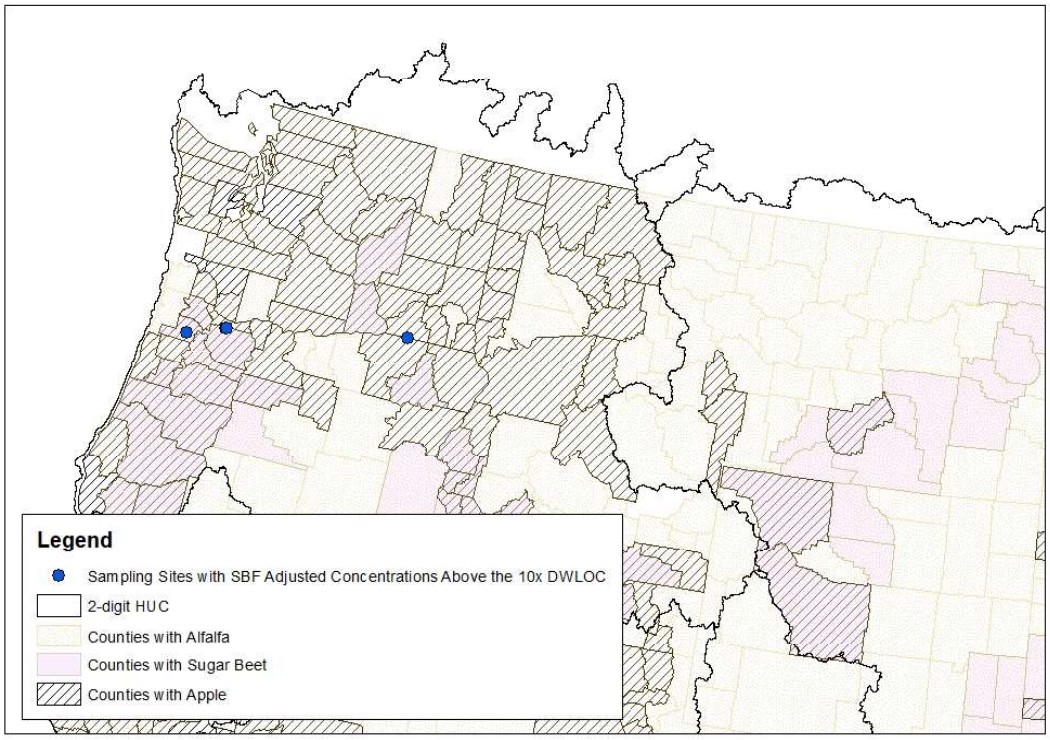


Figure 27. Summary of Site Landcover Characteristics for Sampling Sites with Sampling Bias Factor Adjusted Concentrations above 10x DWLOCs

Four of the sites have overlap with counties with all four uses (alfalfa, apple, strawberry and sugar beet) considered in this assessment in HUC-17 (**Figure 27**). These sites are in western Oregon. The occurrence timing is sporadic April through October. This suggest that there are likely multiple chlorpyrifos uses leading to occurrence in surface water within and across years. The other site OREGONDEQ-32010-ORDEQ is in eastern Oregon. This site overlaps with counties with three (alfalfa, apple, and strawberry) of the four uses considered in this assessment. For this site, chlorpyrifos is detected in surface water in March and April suggesting an early season dormant application such as to a tree fruits including apple, a use considered in this assessment. However, it cannot be determined if other uses are contributing.

Additional characterization of these sites is provided in **APPENDIX C.**

Sampling Sites with Less Than 13 Samples per Year

Sites with greater than 13 samples per year are appropriate for consideration quantitatively in DWAs, however, there is the potential that pesticide concentrations, from monitoring sites not meeting the criteria, could be higher and could lead to an underestimation of exposure in drinking water. Therefore, sampling data from sites where less than 13 samples per year are examined. Concentration data for these sites indicates there are several sites in several HUCs that may have concentrations above the 1-day and 21-day 10xDWLOC and a few sites that may have concentrations above the 1- and 21-day 1x DWLOC. There is overlap with the regions considered in this assessment (i.e., HUCs 03, 04, 06, 07, 08, 10, 12, 15, and 17.

Table 22 highlights the regions where concentrations may occur above the various DWLOCs. In addition, **Table 22** provides the total number of samples that suggest concentrations are above the respective DWLOCs. Additional characterization of these sites is provided in **APPENDIX C**.

Table 22. 2-digit HUC Summary of the Number of Sites with Potential Concentrations Above the DWLOCs

2-digit HUC	Max Measured Value	Site-Years			
		>1-day 10xDWLOC[1]	>21-day 10xDWLOC[2]	>1-day 1xDWLOC[3]	>21-day 1xDWLOC[4]
01	1.3	1	1		
02	0.2				
03	1.5	16 (1)	33 (4)		
04	0.8	3	3		
05	0.2				
06	1.5	6	10 (1)		
07	1.1	4 (1)	6 (1)		
08	1.7	1	1		
09	0.2				
10	14.7	1	2	1	1
11	0.2				
12	2.2	2	2		
13	0.2				
14	0.2				
15	0.6	1	1		
16	0.02				
17	3.3	4	6		
18	8.9	37 (13)	47 (18)	2	3
19	-				
20	0.9	1	1		
21	0.04				
Total Sites		76	113	3	4
Total Site-Years		119	165	3	4

1. 1-day chlorpyrifos-oxon 10x DWLOC = 23 µg/L; 1-day SBF = 54.8; reference concentrations >0.42 µg/L
2. 21-day chlorpyrifos-oxon 10x DWLOC = 4.0 µg/L; 21-day SBF = 11.5; reference concentrations >0.35 µg/L
3. 1-day chlorpyrifos-oxon 1x DWLOC = 230 µg/L; 1-day SBF = 54.8; reference concentrations >4.2 µg/L
4. 21-day chlorpyrifos-oxon 1x DWLOC = 43 µg/L; 21-day SBF= 11.5; reference concentration >3.7 µg/L

Bracketed values indicate the number of sites with multiple years where concentrations may be above the respective DWLOCs.
Gray shading indicates HUCs considered in the modeling analysis of this assessment.
SBF based on 13 samples per year was used although the same number may be much lower.

c. Weight of Evidence

Model estimated concentrations as well as measured concentrations of chlorpyrifos were evaluated to determine whether monitoring data suggested a potential DWLOC exceedance for either chlorpyrifos or chlorpyrifos-oxon (following drinking water treatment), with the lines of evidence described in **Table 23**.

Model estimated concentrations indicate that for the subset of assessed uses concentrations of chlorpyrifos and chlorpyrifos-oxon are not expected to be above the DWLOCs with or without the retention of the FQPA safety factor.

However, monitoring data suggest that in some areas of the country concentrations may exceed the DWLOC with and without the FQPA safety factor when all uses currently registered are considered since available monitoring data represent usage of chlorpyrifos. When considering the data with more than 13 samples per year, five sites all in HUC-17 indicated a potential for DWLOC exceedances. This is based on the application of sampling bias factors.

When considering the data with fewer than 13 samples per year, several sites indicated a potential for concentrations to be above the DWLOC. In one region, concentrations may exceed the 1x 1- and 21-day DWLOCs. Further analysis of sites with concentrations that could be higher than the DWLOCs could not definitively determine that the measured concentration was the results of a use or combination of uses considered in this assessment (i.e., the 11 critical or high benefit uses). It is possible that if more frequent monitoring data were available these conclusions could change.

Table 23. Lines of Evidence Used to Quantify and Characterize Potential Exposure to Chlorpyrifos and Chlorpyrifos-oxon

Lines of Evidence	
Modeling	
PWC Modeling	All uses and regions assessed are below DWLOCs. Some regions required a high-level of refinement. • **HUC-02 (apple and peach):** concentrations below DWLOCs based on upper bound application rates • **HUC-03 (cotton, citrus, peach, and soybean):** concentrations below DWLOCs based on upper bound application rates • **HUC-04 (alfalfa, sugar beet, apple, cherry, peach, soybean, and asparagus):** PCA aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-05 (apple and soybean):** concentrations below DWLOCs based on upper bound application rates • **HUC-06 (apple):** concentrations below DWLOCs based on upper bound application rates • **HUC-07 (alfalfa, sugar beet, and soybean):** PCA-PCT aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-09 (alfalfa, sugar beet, soybean, spring wheat, and winter wheat):** PCA-PCT aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-10 (alfalfa, soybean, spring wheat, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-11 (alfalfa, soybean, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-12 (citrus, peach, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-17 (alfalfa, sugar beet, apple, and strawberry):** PCA aggregated concentrations below DWLOCs based on upper bound application rates

Monitoring	
SEAWAVE-QEX	Concentrations are not expected to exceed the DWLOC for 11 sites dispersed across the country.
Sampling Bias Factors	Monitoring data in HUC-17 indicate that concentrations could be above 10x DWLOC. These monitoring sites are in areas where the crops considered in this assessment are grown. However, there is also expected to be other crops where chlorpyrifos is applied and the contribution of these uses to the measured concentrations cannot be precluded.
Sites <13 Samples/year	This dataset had the highest detected concentration (14.7 µg/L) across the sample number categories and is predicted to have the lowest probability of capturing upper-bound concentrations. Nevertheless, there are several sites across the country that indicate concentrations may exceed the 1x and 10x DWLOCs including in regions assessed in this assessment. This suggests that current usage of chlorpyrifos could lead to concentrations above the DWLOCs.
Monitoring in Major Usage Area	There is limited data (i.e., low sample frequency and a low number of sites) in many areas of the locations and across years.
Uncertainty	The major uncertainty in understanding the monitoring results is an understanding of the usage data in relation to where and when monitoring occurred and how those relate to the uses under consideration in this assessment.

1. HUC-02 (apple and peach)

Upper bound use rates used in this assessment were from national level data supplied by BEAD several years ago. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs for chlorpyrifos use on apple and peach in HUC-02.

Monitoring data where the uncertainty could be quantified were limited. There was only 1 SEAWAVE-QEX site in HUC-02, which indicated concentrations were below the DWLOCs. Application of SBFs also indicated concentrations are likely below the DWLOCs in this region; however, sample frequency is generally low thus higher occurrence concentration likely occurred.

2. HUC-03 (cotton, citrus, peach, and soybean)

Upper bound use rates used in this assessment were from national level data for peach supplied by BEAD several years ago while usage data for cotton, citrus, and soybean were provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs for chlorpyrifos use on cotton, citrus, peach, and soybean in HUC-02.

Monitoring data where the uncertainty could be quantified were limited. There were only 2 SEAWAVE-QEX sites in HUC-03, which indicated concentrations were below the DWLOCs. These sites are in the northern portion of the region and does not capture the citrus growing area within the region. Application of SBFs suggested that concentrations maybe above the 10x DWLOCs in this region. Cotton, peach, and soybean are grown through the region and likely overlap with some of the sites where potential exceedance are possible. Generally, sample frequency is low in this region limiting the ability to confidently estimate concentration in the region from available monitoring data.

3. *HUC-04 (alfalfa, sugar beet, apple, cherry, peach, soybean, and asparagus)*

Upper bound use rates used in this assessment were from national level data for apple, cherry and peach supplied by BEAD several years ago while usage data for alfalfa, sugar beet, soybean and asparagus were provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs following aggregation using available PCAs. This is primarily driven by the low overlap of orchard acres with community water system watersheds.

Monitoring data where the uncertainty could be quantified were limited. There were only 2 SEAWAVE-QEX sites in HUC-04, which indicated concentrations were below the DWLOCs. These sites are in northern Ohio. The monitoring sites fall in areas where alfalfa, apple, peach, and soybean. The SEAWAVE-QEX sites are not in areas where sugar beet, cherry, or asparagus are grown. Application of SBFs suggested that concentrations maybe above the 10x DWLOCs in this region. This region has high frequency monitoring data includes those supported by NCWQR. Again, these high frequency sampling sites do not coincide with sugar beet, cherry, or asparagus growing areas.

4. *HUC-05 apple and soybean*

Upper bound use rates used in this assessment were from national level data for apple supplied by BEAD several years ago while usage data for soybean was provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were limited. There was only 1 SEAWAVE-QEX site in HUC-05, which indicated concentrations were below the DWLOCs. This site falls withing a country with reported acres of soybean; however, there is no reported acreage of apples in the county where the sampling site falls. Application of sampling bias factor suggested that concentrations do not exceed the DWLOCs in this region. However, this region generally has low frequency monitoring data.

5. *HUC-06 apple*

Upper bound use rates used in this assessment were from national level data for apple supplied by BEAD several years ago. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs suggest there are sites that could exceed the 10x DWLOC. These sites overlap with counties reporting acres of apples. This region generally has low frequency monitoring data.

6. *HUC-07 alfalfa, sugar beet, and soybean*

Upper bound use rates used in this assessment were from usage data for alfalfa, sugar beet, and soybean provide at a state-level. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon

are below the DWLOCs based on PCA-PCT aggregation, the highest level of model refinement used in this assessment.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs suggest there are sites that could exceed the 10x DWLOC. These sites overlap with counties reporting acres of apples. This region generally has low frequency monitoring data.

7. HUC-09 Alfalfa, Sugar beet, Soybean, Spring Wheat, and Winter Wheat

Upper bound use rates used in this assessment were from usage data for alfalfa, sugar beet, soybean spring wheat, and winter wheat were provided at a state-level. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs based on PCA-PCT aggregation, the highest level of model refinement used in this assessment.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs did not lead to the identification of sites that could have concentrations above the DWLOCs. However, generally this region has a low frequency monitoring data.

8. HUC-10 Alfalfa, Soybean, Spring Wheat, and Winter Wheat

Upper bound use rates used in this assessment for alfalfa, soybean, spring wheat and winter wheat were provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. This region has the highest single measured concentration of chlorpyrifos (14.7 µg/L). Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC and 1x DWLOC. This is primarily driven by the one high detection. Generally, this region has a low frequency monitoring data.

9. HUC-11 Alfalfa, Soybean, and Winter Wheat

Upper bound use rates used in this assessment for alfalfa, soybean, and winter wheat were provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. This region has the highest single measured concentration of chlorpyrifos (14.7 µg/L). Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC and 1x DWLOC. This is primarily driven by the one high detection. Generally, this region has a low frequency monitoring data.

10. HUC-12 Citrus, Peach, and Winter Wheat

Upper bound use rates used in this assessment for citrus, peach, and winter wheat were provided at a state-level and are based on more recent data. Modeling suggests concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs. Recall, that at the time of this assessment a new model scenario was not available for deciduous orchards. Therefore, the evergreen orchard scenario was used. The impact on estimated concentrations is not known.

Monitoring data where the uncertainty could be quantified were not available for this region. There was only 1 SEAWAVE-QEX site in HUC-12, which indicated concentrations were below the DWLOCs. This site falls withing a county with reported acres of peach and wheat. However, this site does not cover areas where citrus is grown. Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC.

11. HUC-12 Alfalfa, Sugar beet, Apple, and Strawberry

Upper bound use rates used in this assessment for alfalfa, sugar beet was provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs following aggregation using available PCAs. Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC.

Monitoring data where the uncertainty could be quantified were not available for this region. There was only 1 SEAWAVE-QEX site in HUC-17, which indicated concentrations were below the DWLOCs. There are five sites in Oregon with enough sampling to have confidence in the prediction intervals to have confidence in the SBF-adjusted concentrations. In some cases, concentrations above the 10x DWLOC were estimated to occur over multiple years. Furthermore, these estimates were all estimated to occur after the labels for chlorpyrifos were updated in the mid-2000s. These sites were determined to be relevant to community water systems as all the sites were upstream with a short travel time to the often less than a day. These sites were in areas where may different chlorpyrifos uses could be occurring includes those considered in this assessment for HUC-17.

12. Other Considerations

One major uncertainty in understanding the monitoring results is the uncertainty in the usage data, which is only available at the state level for a limited number of use patterns. Additionally, how the monitoring relates to the usage in time and space is not readily available. This makes it extremely difficult to determine if any of the reported exceedance may have been the result of one of the uses considered in this assessment. Therefore, the results of this assessment indicate that it is important to consider all potential use sites when estimating potential exposure in drinking water.

Another major uncertainty is that in general sampling frequency for chlorpyrifos has tapered off over the last decade as well as detection frequency. It is unknow if the lack of sampling is contributing to the reduced detection frequency or if detection frequencies are decreased. Likely both are contributing factors. Often reduced testing lead to reduced detection frequency unless sampling is specifically started to use.

Higher SBFs were driven by measured concentrations value input into SEAWAVE-QEX. This generally resulted in tighter confidence bounds around the measured concentration; however, the ability of SEAWAVE-QEX to capture the peak occurrence concentration for a sporadically used pesticide is questionable. Furthermore, when more frequent data were input into SEAWAVE-QEX higher concentrations were estimated. Therefore, when infrequently sampling data are input into SEAWAVE-QEX it is possible that concentrations as well as SBFs developed from the resulting chemographs underestimate the potential range of concentrations occurring in the environment. It is possible that SBFs are underestimated for chlorpyrifos in this assessment and the exposure potential underestimated. More frequency data would help address this concern.

Chlorpyrifos-oxon concentrations in drinking water are primarily driven by chlorpyrifos concentrations in source water. In source water chlorpyrifos is stable compared to chlorpyrifos-oxon. Once formed during drinking water treatment chlorpyrifos-oxon has increased stability (t ½= 12 days) under drinking water conditions compared to environmental conditions. This suggests that chlorpyrifos -oxon is stable during the expected range of distribution times which can be a few hours to several days.

Conclusions

This assessment focuses on a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. This subset of uses was identified as being the most important of all the currently registered uses of chlorpyrifos. This assessment utilized new surface water model scenarios (i.e., soil, weather, and crop data), integrates the entire distribution of community water system percent cropped area adjustment factors and integrates state-level percent crop treated data, and considers the quantitative use of available surface water monitoring data.

Concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are not likely to exceed the drinking water level of comparison (DWLOC) with or without the retention of the FQPA safety factor for the subset of uses considered. This conclusion is based on upper bound application rates for the subset of assessed uses. Furthermore, a thorough analysis of monitoring data was completed and indicates that there are several monitoring sites across the United States that could have concentrations higher than the DWLOCs (with and without the retention of the FQPA safety factor). However, the contribution of other currently registered uses of chlorpyrifos (i.e., uses not considered in this assessment) could not be ruled out, nor could a definitive conclusion be made that the measured concentration data correlated to one of the specific uses evaluated in this assessment.

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APPENDIX A. Summary of Uses Considered

Critical Uses

Alfalfa

Use of chlorpyrifos to treat alfalfa weevil was identified as one of the most critical uses by Corteva Agriscience. Analysis completed by BEAD indicates that chlorpyrifos is only used on alfalfa in HUC-04, -07, -09, -10, -11, -13, -14, -15, -16, and -17. Application rates for alfalfa weevil larvae and adults are permitted between 0.47-0.94 lb a.i./A (Lorsban Advance Reg. No. 62719-591). This falls within the reported use range for chlorpyrifos use on alfalfa. Usage data across all regions with reported use, suggest that only one of the four permitted applications occurs per year in alfalfa. Most applications are applied by ground equipment; however, in some regions, such as HUC-14, almost half of the applications are made by aerial equipment. Generally, applications to treat alfalfa weevil occur mid-April through early June depending on the 2-digit HUC region.

Citrus – Oranges, Lemons, and Grapefruit

Since the introduction of the Asian citrus psyllid (ACP) to the continental U.S. in 1998, chlorpyrifos has become one of several insecticides used to control this pest, which transmits the incurable citrus greening disease, or Huanglongbing. Use of chlorpyrifos to treat scale insects[18] was identified as one of the most critical uses by Corteva Agriscience. While growers report the use of chlorpyrifos against scale insects over the largest area in HUC-12, usage of chlorpyrifos in HUC-03 against scale is over a much smaller area compared to ACP and citrus rust mites. Application timing and information focused on the most significant use. An analysis completed by BEAD indicates that (outside California) chlorpyrifos is only used on citrus in HUC-03 and HUC-12. Usage data suggest only one chlorpyrifos application occurs per year on average, and that most applications occur via ground equipment. The average application rate is 2.7 lb/A, while the upper bound application rate is 3.5 lb/A. Applications to treat ACP and citrus rust mite occur in early May in HUC-12, while applications targeting ACP, citrus rust mite and scales occur in early June in HUC-03.

Cotton

Chlorpyrifos is used against cotton aphid, silverleaf whitefly, and stinkbugs (various species) (**ATTACHMENT 2**). Analysis recently completed by BEAD indicates that chlorpyrifos is only used on cotton in HUC-03. Label rates for cotton are permitted at up to 1.0 lb/A three times per year. The average rate of chlorpyrifos made to cotton is 0.21 lb/A, with an upper bound application rate of 0.50 lb/A, with 99% of all application occurring via foliar ground spray. Usage data suggest that two applications of chlorpyrifos occur per year in cotton. Using the state of Georgia to represent use of chlorpyrifos on cotton in HUC-03, BEAD suggests the first application of chlorpyrifos occurs on May 20 with the second application occurring on June 30.

Soybean

Use of chlorpyrifos to treat two-spotted spider mites was identified as one of the most critical uses by Corteva Agriscience. An analysis completed by BEAD indicates that chlorpyrifos is only used on soybean

[18] Exclude California red scale (California and Arizona). California recently cancelled almost all chlorpyrifos use.

in HUC-03, -04, -05, -07, -09, -10, and -11. Application rates for two-spotted spider mites are permitted between 0.23-0.47 lb/A (Lorsban Advance Reg. No. 62719-591). This falls within the reported average use range for chlorpyrifos use on soybean. Usage data across all regions with reported use suggest only one application of chlorpyrifos occurs per year on soybean. Most applications are made by ground equipment, except in HUC-10, where about half of the applications are made by air. Generally, applications that are made to treat two-spotted spider mites occur in early to mid-July, depending on the region.

Sugar beet

Use of chlorpyrifos to treat sugar beet root maggot was identified as one of the most critical uses by Corteva Agriscience. Analysis completed by BEAD indicates that chlorpyrifos is only used on sugar beet in HUC-04, -07, -09, and -17. Applications rates for sugar beet root maggot larvae and adults are permitted between 0.23-0.94 lb/A (Lorsban Advance Reg. No. 62719-591) and 2.0 lb/A (Lorsban 15G). Average application rates range from 0.5 to 1.16 lb a.i./A with upper-bound rates ranging between 1.25-1.5 lb a.i./A. Usage data across all regions with reported use, suggest only one application occurs per year in sugar beet. Both at-plant and foliar applications are reported. Most applications are applied by ground equipment. The highest percent of application applied by air is 20% for HUC-17. Generally, applications to treat sugar beet root maggot occur in June for foliar applications. Soil applications are noted to occur earlier in the season – roughly 1.5 months.

Wheat

Use of chlorpyrifos to treat Russian wheat aphid was identified as one of the most critical uses by Corteva Agriscience. However, there are multiple species of aphids present in wheat (wheat aphid complex), and Russian wheat aphid is not necessarily the most targeted species in all states. Russian wheat aphid and other species in the wheat aphid complex can affect both spring and winter wheat. An analysis completed by BEAD indicates that chlorpyrifos is only used on spring wheat in HUC-09 and -10 and on winter wheat in HUC-09, -10, -11, and -12. Applications rates for all aphids are permitted between 0.23-0.47 lb a.i./A (Lorsban Advance Reg. No. 62719-591). Average application rates range from 0.21 to 0.44 lb a.i./A for winter wheat with upper-bound rates ranging between 0.5 to 0.75 lb a.i./A. Usage rates are similar for spring wheat. Usage data across all regions with reported use, suggest only one application occurs per year in wheat. Most applications are applied by ground equipment. The highest percent applied by air is 41% for HUC-10. Applications begin as early as April and extend through June depending on the region.

High Benefit Uses

Apple

The use of chlorpyrifos on apples is a high benefit in HUC-02, -04, -05, -06, and -17 for the control of scale insects. Chlorpyrifos applications up to 3 lb a.i./A are permitted on apples with no more than 2 lb a.i./A permitted as a dormant/delayed dormant application (no in season applications are allowed). The majority (95%) of applications are applied by ground equipment. The average application rate is 1.5 lb/A (USEPA, 2013). The maximum rate observed is 2.8 lb/A with the 90th percentile at 2.0 lb/A. Average number of applications is 1.2. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Asparagus

A high benefit use of chlorpyrifos identified by BEAD is managing cutworms in asparagus in HUC-04. All applications are expected to occur via ground equipment. Application rates are permitted up to 1.5 lb a.i./A for granular applications and up to 1.0 lb a.i./A for liquid applications. Based on usage data, only one application is expected to occur each year, either once in the spring or once in the fall. Spring applications are soil directed while fall applications are foliar. The average application rate is 0.96 lb a.i./A with the maximum observed application rate of 1.0 lb a.i./A. Only about 7% of applications are made at a lower rate of 0.5 lb a.i./A.

Cherry

The use of chlorpyrifos to control borers that damage tart cherry in HUC-04 is considered a high benefit use. Single application rates on cherries are permitted at up to 4.0 lb a.i./A, with maximum annual rates of 4.5 lb a.i./A for sweet cherries and 14.5 lb a.i./A for tart cherries. The majority (98%) of applications are applied by ground equipment. The average application rate is 1.5 lb/A (USEPA, 2013). The maximum rate observed is 3.0 lb/A with the 90th percentile at 2.0 lb/A. Average number of applications is 1.1. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Peach

The use of chlorpyrifos to control borers that damage peach trunks is a high benefit in the southeastern United States (HUC-02, 03, 04, and 12). Chlorpyrifos applications up to 3 lb a.i./A are permitted on peaches with no more than 2 lb a.i./A permitted as a dormant/delayed dormant application. The majority (95%) of applications are applied by ground equipment. The average application rate is 1.3 lb/A (USEPA, 2013). The maximum rate observed is 3.0 lb a.i./A with the 90th percentile at 2.0 lb/A. Average number of applications is approximately one per year. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Strawberry

A critical use of chlorpyrifos identified by BEAD is to treat garden symphylans and strawberry crown moth[19] in strawberry in HUC-17, specifically in Oregon. A single application at up to 2.0 lb a.i./A is permitted with a maximum annual rate of 4.0 lb a.i./A. All applications are expected to occur via ground equipment to the soil. Only one application is expected to occur each year. The average application rate is 1.24 lb a.i./A with the maximum observed application rate of 2.0 lb a.i./A. Usage data are based on data from 2011 to 2015. Insecticide usage has not been surveyed in Oregon since 2015.

[19] http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/Who_needs_chlorpyrifos_and_why_(by_crop).pdf accessed June 23, 2020.

APPENDIX B. Results for Average Application Rates

Results from PWC are presented in

Table 24 for both chlorpyrifos and chlorpyrifos oxon for average application rates. This table only presents results for the four 2-digit HUCs (HUC-04, -07, -09 and -17) where the upper bound EDWCs are above the 10x DWLOC. Application of PCAs indicates that only the 1-in-10 year 21-day average chlorpyrifos-oxon concentration may be greater than the 10x DWLOC in two 2-digit HUC regions (HUC-04 and -07) for average applications rates. It should be noted in using this approach, there are four regions where crop specific PCAs are greater than the all-agricultural PCA. This is due to how the misc-Ag value is calculated to account for the potential double cropping. In these situations, the use pattern specific PCAs are capped at the all-Ag PCA.

Table 24. PCA Adjusted EDWCs for Average Application Rates of Chlorpyrifos

2-digit HUC	Use Site	2-Digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EEC (cpy)	21-day Model EEC (cpy)	1-day Model EEC (cpyo)	21-day Model EEC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
04	Alfalfa	0.92[b]	608_4_MI-186800-22356-36	1.3	1.0	1.2	1.0	1.2	0.9	1.2	0.9
	Sugar beet		1016_4_MI-186667-22116-41	2.8	1.9	2.7	1.8	2.6	1.7	2.5	1.7
	Apple		734_4_MIcherrySTD	13.0	11.2	12.4	10.7	11.9	10.3	11.4	**9.8**
	Cherry		740_4_MIcherrySTD	13.0	11.2	12.4	10.7	11.9	10.3	11.4	**9.8**
	Peach		740_4_MIcherrySTD	9.5*	8.28*	9.1	7.9	8.8	7.5	8.3	**7.2**
	Soybean		851_4_MI-188235-22121-5	2.1	1.2	2.0	1.1	2.0	1.1	1.9	1.0
	Asparagus		739_4_MIasparagusSTD	3.6	2.1	3.4	2.0	3.3	1.9	3.1	1.8
07	Alfalfa	0.90	617_4_MO-2528577-19014-37	4.1	2.3	3.9	2.2	3.7	2.1	3.5	2.0
	Sugar beet		989_4_MN-2423043-23487-41	8.9	6.4	8.5	6.1	8.0	5.8	7.7	**5.5**
	Soybean		869_4_MN-2877271-22781-5	2.2	1.4	2.1	1.3	2.0	1.2	1.9	1.2
09	Alfalfa	0.95[c]	626_4_SD-416559-24423-36	1.1	0.9	1.0	0.9	1.1	0.8	1.0	0.8
	Sugar beet		1043_4_ND-2642948-27020-41	5.4	3.6	5.2	3.4	5.1	3.4	4.9	3.2
	Soybean		887_4_ND-2571399-26297-5	1.6	1.0	1.5	1.0	1.5	1.0	1.4	0.9
	Spring wheat		1079_4_ND-2585363-27001-23	1.4	0.9	1.3	0.9	1.3	0.8	1.3	0.8
	Winter wheat		1133_4_ND-341303-27230-24	3.4	2.3	3.2	2.2	3.2	2.1	3.1	2.0
17	Alfalfa	0.53	717_4_WA-71453-24575-36	1.3	0.9	1.2	0.9	0.7	0.5	0.6	0.4
	Sugar beet		1007_4_ID-79974-21766-41	3.7	2.5	3.5	2.4	1.9	1.3	1.8	1.3
	Apple		737_4_ORappleSTD	7.2	4.7	6.9	4.5	3.8	2.5	3.7	2.4
	Strawberry		966_4_ID-80309-21523-12	10.4	7.5	9.9	7.2	5.5	4.0	5.3	3.8

a. Batch run name is truncated (DWA_2020 was removed for reporting purposes).
b. Use pattern specific PCA is slightly higher (0.93) than all-ag PCA (0.92). Use pattern specific PCA is capped at all-ag value.
c. Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at all-ag value.

*****Average rate modeled for apples and cherries is 1.5 lb a.i./a. The upper bound rate for peach on a national level is 1.1 lb/a. Results were multiplied by 1.1/1.5 to estimated concentrations for peach.
Green shading indicates concentrations below the 10xDWLOC.
Reg shading and bold font indications concentrations above the 10x DWLOC.
Chlorpyrifos (cpy)
Chlorpyrifos-oxon (cpyo)

Examination of the full distribution of PCAs for HUC-04 and -07 (i.e., those 2-digit HUCs with average application rates resulting in EDWCs above the 10x DWLOC) indicate that there are 138 CWS watersheds where chlorpyrifos-oxon concentrations could be above the 10x DWLOC (**Table 14**).

Table 25. Full Distribution of Watershed Specific PCA-Adjusted EDWCs for Average Applications of Chlorpyrifos-oxon

2-digit HUC	Total CWS	Max 1-in-10 year 21-day (cpyo) µg/L	Critical 21-day PCA (cpyo)	No. of CWS above 21-day DWLOC (percent)
		Average Application Rates		
04	196	10.7	0.37	79 (40)
07	158	6.1	0.66	49 (31)

The prior analysis for the average application rates indicates there could be concentrations above the 10x DWLOC for HUC-04 and HUC-07. However, aggregation of the 1-in-10 year concentrations indicates that concentrations in HUC-04 are not expected to be above the 21-day 10x DWLOC. Therefore, aggregation of concentrations in only HUC-07 was completed for the average application rates.

Aggregation of the 1-in-10-year concentrations for watersheds in HUC-07 indicate that two CWS watersheds could have concentrations above the 10x DWLOC for average application rates. Results are presented in **Table 26**.

Table 26. Aggregation of 1-in-10 year PCA adjusted 21-day Average EDWCs for Average Application Rates of Chlorpyrifos-oxon

2-digit HUC	Aggregated 21-day (cpyo) µg/L	No. of CWS above 21-day DWLOC	Total CWS	Percent of CWS above 21-day DWLOC
07	4.1	2	158	1

Appendix C. Monitoring Data Analysis Technical Chapter

a. Introduction

This technical chapter is intended to supplement the drinking water assessment by providing the technical details of the analysis and interpretation of the available monitoring data considered quantitively and summarized in the drinking water assessment. Each subsequent subsection is dedicated to an individual sampling site. Depending on what analysis was done for the site each section may include: 1) site characterization based on size and landcover percentages of the National Land Cover Database for 2006 as reported in StreamCat 2) SEAWAVE-QEX analysis, 3) sampling bias factor development and 4) sampling bias factor application. For example, a summary of the available monitoring data for each site, procedures for fitting SEAWAVE-QEX, and description of the diagnostic plots from the final fit are provided for each site. In addition, developed SBFs are presented and described.

SEAWAVE-QEX Analysis

For SEAWAVE-QEX analysis, surface water monitoring sites were screened for potential use in SEAWAVE-QEX based on the minimum requirements of the model. A Microsoft Access query was used to determine which sites might be able to run in SEAWAVE-QEX (Access file is provided in **ATTACHMENT 3**). The tool searched for sites that met the minimum criteria (at least 3 years with 12 or more samples with a 25% detection frequency), which included comparing the results column with the detection limit column, as often data in the WQP are not properly identified as being detected or below the detection limit. The sites that remained were evaluated for use in SEAWAVE-QEX.

Sites that could not be successfully used in SEAWAVE-QEX are summarized in **Table 27** One site did not have accompanying flow data and two sites could not be confidently simulated by the model as model assumptions were not verified. Two additional sites were successfully run in SEAWAVE-QEX but a surface-level analysis of the streamflow data and how it is used in SEAWAVE-QEX for these sites indicated that the sites may not be appropriate to use quantitatively. Monitoring data from the 11 remaining sampling sites run in SEAWAVE-QEX were deemed acceptable for quantitative use based on goodness-of-fit criteria described in the model's Standard Operating Procedure (SOP; USEPA, 2019). The model fit was optimized for each site as needed by changing the years included in the analysis or adding a small constant to the concentration values within SEAWAVE-QEX. These sites are detailed in the following section along with the 11 sites selected for quantitative analysis.

Table 27. Summary Table of Sites Not Included in SEAWAVE-QEX Analysis

USGS Site ID	Site Name	No or limited flow data	Model assumptions not verified	Site not applicable	Comment
06800000	Maple Creek near Nickerson, NE		**X**		Estimated maximum concentration above blue boxes, large 2x SSD. Tight residuals. CTS maxed out and correlogram is too low (overestimating).
08364000	Rio Grande at El Paso, TX		**X**		Flow data not available at USGS but found data from the International Boundary and Water Commission.

USGS Site ID	Site Name	No or limited flow data	Model assumptions not verified	Site not applicable	Comment
					However, correlogram often missing from diagnostic plot at lower sampling times (e.g., 5-day).
11273500	Merced R A River Road Bridge near Newman, CA	X			No flow data found.
11447360	Arcade Creek near Del Paso Heights, California			X	Intermittently flowing site (see description below)
14201300	Zollner Creek near Mt. Angel, OR			X	Intermittently flowing site (see description below)
SSD standard deviation					

Sampling Bias Factor Development

Using the chemographs from the SEAWAVE-QEX analysis, short-term pesticide-specific SBFs were developed for chlorpyrifos for application to monitoring data that did not meet the SEAWAVE-QEX criteria. This was done using Python code (ncg_merg.py), a Python integrated development environment (IDE) (Spyder 3.7), and the methods described in Chapter 4 of the White Paper for the 2019 FIFRA SAP. Short-term SBFs are developed for all sites where model assumptions were satisfied for SEAWAVE-QEX (i.e., 11 sites) as data are only available to calculate SBFs for a limited number of sites.

Sampling Bias Factor Application

SBFs for 1987-2012 (all years) and 2005-2012 (post-registration review label changes) were applied based on the number of samples per year for all site-years of data from the Water Quality Portal with greater than or equal to 13 sampled per year (**Table 28**).

Table 28. Maximum Sampling Bias Factors

Sample Number	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Fact	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor
	1-day		21-day	
52+	10.9	5.3	4.0	2.4
26-51	23.3	11.9	6.1	5.2
17-25	38.5	17.8	8.4	7.3
13-16	54.8	22.2	11.5	8.9

b. Detailed Site Analysis

1. USGS-11303500

Site and Sampling Characterization

USGS site 11303500 (San Joaquin River near Vernalis, California) has a 13,844 mi^2 (35,855 km^2) watershed in HUC 18. The watershed for the collection site has 22% cropland along with a high percentage of natural areas (e.g., grasslands, forests, shrubs), as shown in **Figure 28.** Watershed Landcover Characteristics of Sampling Site USGS-11303500 . This sampling site is upstream of several community water systems drinking water intakes with a time of travel of less than a day to each intake, implying that the site is relevant to community water systems in the area. Additionally, the site may be representative of other agricultural areas that affect CWS, as it is downstream of many other intakes with travel times ranging from 2 to 8 days.

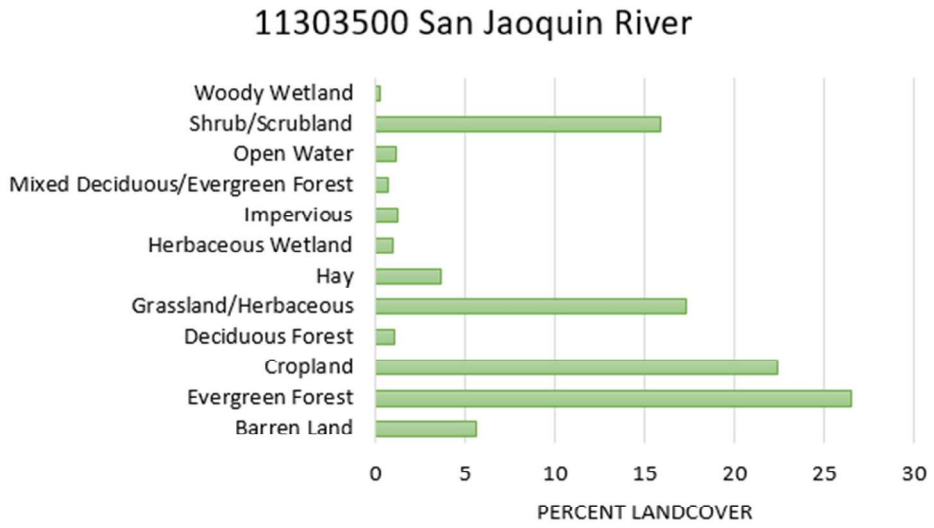

Figure 28. Watershed Landcover Characteristics of Sampling Site USGS-11303500

This site had a total of 190 chlorpyrifos detections out of 528 samples over 27 years between 1992 and 2019. Only 12 years of data have at least 12 or more samples and a detection frequency greater than 25%, as shown in **Table 29**. **Table 29** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 29. Data Summary for USGS-11303500

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	20	16	80%			
1993	37	23	62%			
1994	17	12	71%	✓	4	✓
1995	9	4	44%	✓	1	✓
1996	0	—	—	✓	—	✓
1997	11	6	55%	✓	0	✓
1998	12	3	25%	✓	0	✓
1999	12	1	8%	✓	0	✓
2000	31	23	74%	✓	10	✓
2001	53	31	58%	✓	14	✓
2002	22	9	41%	✓	2	✓
2003	17	7	41%	✓	0	✓
2004	8	5	63%	✓	0	✓
2005	6	1	17%	✓	0	✓
2006	8	3	38%	✓	0	✓
2007	22	9	41%	✓	0	✓
2008	22	14	64%	✓	0	✓
2009	22	0	0%	✓	0	✓
2010	22	4	18%	✓	0	✓
2011	21	7	33%	✓	0	✓
2012	25	9	36%	✓	1	✓
2013	21	0	0%			
2014	18	1	6%			
2015	23	0	0%			
2016	28	1	4%			
2017	21	0	0%			
2018	19	1	5%			
2019	1	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1994-2012 were used as SEAWAVE-QEX inputs. Expanding the years to include 1992 and 1993 was explored, however, the best fit was determined to be for the period from 1994 to 2012 with default SEAWAVE-QEX parameters.

The 80% confidence bounds on the estimated maximum for each year are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. Only two years (1995 and 2004) have 80% confidence bounds that overlap with the highest measured concentration from 1994-2012 (0.05 µg/L), occurring in 2004. One other higher concentration was measured in 1993, 0.079 µg/L, a year that was not included in the final run. When running 1992-2012, there is less confidence in the normality of the residuals than when running from 1994-2012. Additionally, the high concentration in 1993 is not

used by SEAWAVE-QEX due to the automatic sample spacing and higher frequency sampling occurring immediately before. The model gives a single shallow seasonal wave with a season spanning from early January to early October and few concentrations outside of the 2SSD bounds, which span less than an order of magnitude. Adjusted concentrations do not have much trend over time and have a significant (α=0.05) negative correlation with MTFA and significant positive correlation with STFA. The normalized residuals are centered on zero with one residual skewing very positive in 2004, likely corresponding with the large measured concentration in that year. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function with a CTS of 9 days.

Table 30 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 30. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-11303500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1994	0.073	0.043
1995	0.047	0.030
1996	0.054	0.035
1997	0.050	0.029
1998	0.031	0.016
1999	0.031	0.018
2000	0.042	0.023
2001	0.041	0.021
2002	0.043	0.028
2003	0.037	0.022
2004	0.065	0.042
2005	0.051	0.031
2006	0.026	0.017
2007	0.041	0.021
2008	0.034	0.021
2009	0.033	0.018
2010	0.031	0.017
2011	0.025	0.016
2012	0.024	0.017

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 29** and **Figure 30**, respectively. All the 1-day and 21-day SBFs figures have the same x- and y-axis scales to permit evaluation of the differences in magnitude of the values across sites and years. These figures show the variation in SBFs derived across the years where data are available to develop SBFs based on the number of samples collected (13-16 samples/year, 17-25 samples/year, 26-51 samples/year and 52+ samples per year). Recall, the median SBF is calculated across the 100 SEAWAVE-QEX chemographs. All SBFs associated data files are provide in **ATTACHMENT 4**.

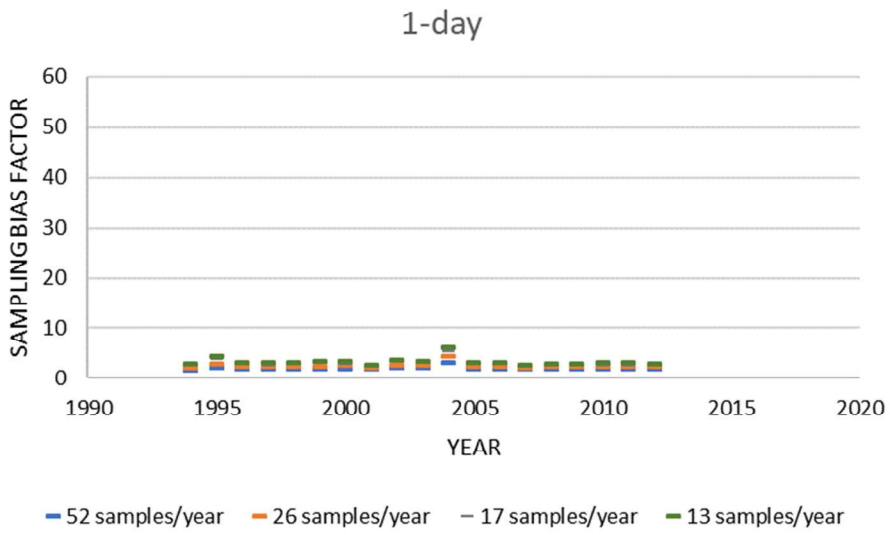

Figure 29. USGS Site 11303500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-11303500 for estimating the upper confidence interval on the 1-day average concentration except for two years, 1995 and 2004. SBFs for all sample number categories are below 4 for the upper confidence interval on the 1-day average concentration. The SBFs for 1995 and 2004 are noticeably higher than other years, SBFs are roughly 6 or below for all sample categories.

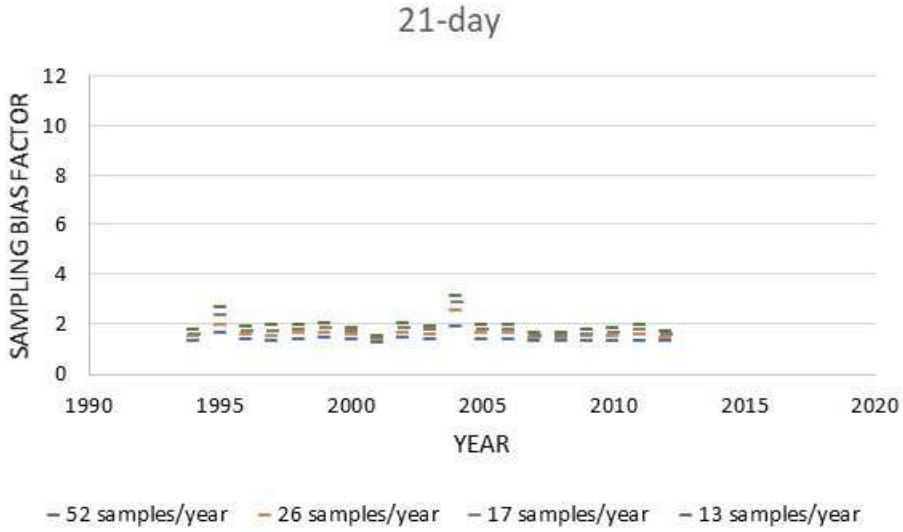

Figure 30. USGS Site 11303500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

A similar, consistent trend is observed for the SBFs for estimating the upper confidence interval on the 21-day average. SBFs for all sample number categories are below 2 for all years except 1995 and 2004. For these years, the maximum SBFs is below 4.

2. USGS-08057200

Site and Sampling Characterization

USGS site 08057200 (White Rk Ck at Greenville Ave, Dallas, TX) is in a 73.5 mi^2 (190 km^2) urban watershed in Hydrologic Unit Code (HUC) 12. The watershed landcover is 47% impervious surfaces and only 2% cropland (**Figure 31. Watershed Landcover Characteristics of Sampling Site USGS-08057200**). A spatial overview shows the sampling location is next to a golf course and recreational facility. The sampling location is upstream of two drinking water intakes with a 9 to 11 day time of travel from the sampling site to the intakes.

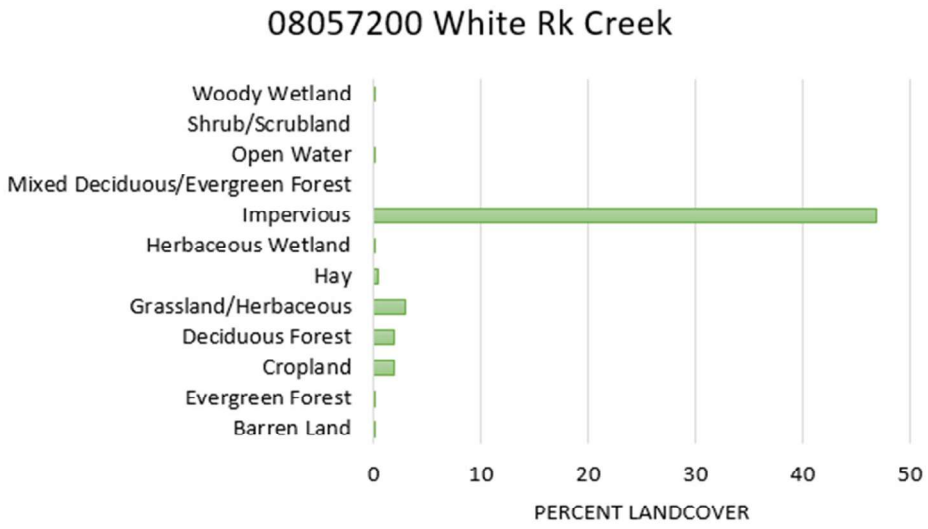

Figure 31. Watershed Landcover Characteristics of Sampling Site USGS-08057200

This site has a total of 63 chlorpyrifos detections out of 351 samples over 22 years between 1995 and 2019 (**Table 31**). Only 4 years of data (1998-2001) have at least 12 samples and a detection frequency greater than 25%, which were used as SEAWAVE-QEX inputs. **Table 31** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 31. USGS-08057200 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1995	7	7	100%			
1996	0	—	—			
1997	9	8	89%			
1998	17	12	71%	✓	0	✓
1999	17	9	53%	✓	1	
2000	15	12	80%	✓	6	
2001	12	4	33%	✓	0	✓
2002	24	3	13%	✓	3	
2003	18	1	6%			
2004	9	2	22%			
2005	6	1	17%			
2006	8	0	0%			
2007	16	2	13%			
2008	4	0	0%			
2009	16	0	0%			
2010	4	0	0%			
2011	16	1	6%			
2012	6	0	0%			
2013	23	0	0%			
2014	24	0	0%			
2015	24	1	4%			
2016	24	0	0%			
2017	24	0	0%			
2018	23	0	0%			
2019	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The site has an incomplete flow record through the years that meet the minimum requirements for use in SEAWAVE-QEX (1998-2001). The discharge data for these years is shown in black in **Figure 32**, which has short gaps in the flow, particularly in the year 2000. There was a drought in the summer of 2000 which may influence the amount of sampling done. The impact of missing days of flow results from the MTFA in SEAWAVE-QEX. For a given time step, the MTFA is calculated using covariate data from the preceding 30 days, so that a day of missing flow can result in many days of missing MTFA calculations and therefore no concentration output. The days for which there is no SEAWAVE-QEX output is shown in orange in **Figure 32**.

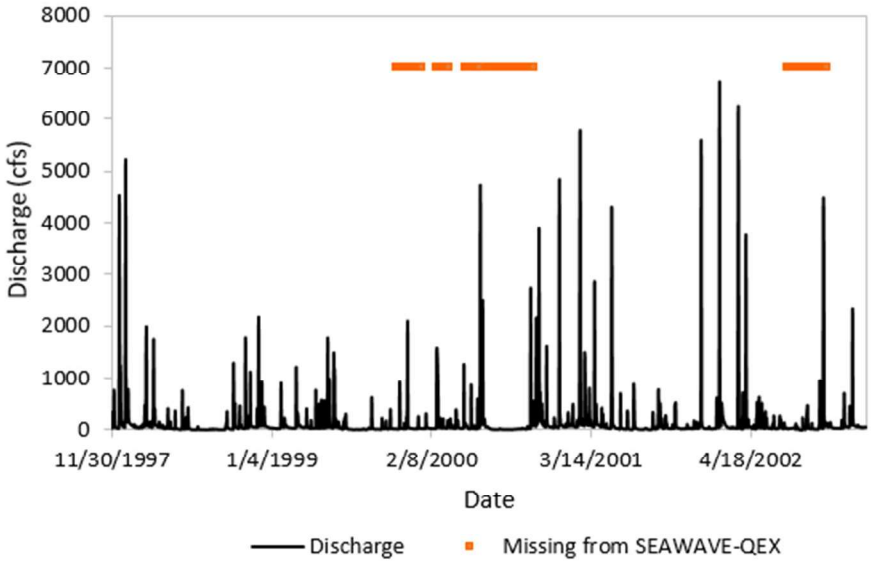

Figure 32. Discharge and Gage Height (unadjusted) Data for USGS-08057200 from 1998-2002

Using SEAWAVE-QEX on only the years 1998-2001 resulted in a poor empirical correlogram at short sampling intervals (i.e., the 5-day bar is absent from the diagnostic plot). An additional run was attempted by including the year 2002 with 13% detection. Although it does not meet the detection frequency criteria, the addition of the year 2002 resulted in a better model fit and allowed for the site to be included. The best fit was determined to be from 1998 to 2002 without modification of the default SEAWAVE-QEX parameters. The highest measured concentration at this site was 0.0549 µg/L in 2000.

The resulting diagnostic plots show 80% confidence bounds on the estimated maximum for each year well below 0.1 µg/L spanning less than an order of magnitude (**Figure 33**). There is a single a shallow wave with a season late September to late June with a short "off-season" of lower measured concentrations. All but one measured concentration fall within the 2x seasonal standard deviations (2SSD) bounds on the model (i.e., the data fall between the dashed lines on **Figure 34**), which span much less than an order of magnitude in size. There is a significant (α=0.05), slightly negative correlation of adjusted concentration with MTFA and a weakly positive correlation with STFA. The adjusted concentrations trend slightly downward over time and the normalized residuals center around zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function with a CTS of 4.2 days. All other model assumptions are satisfied (all diagnostic plots are provided in **ATTACHMENT 4**).

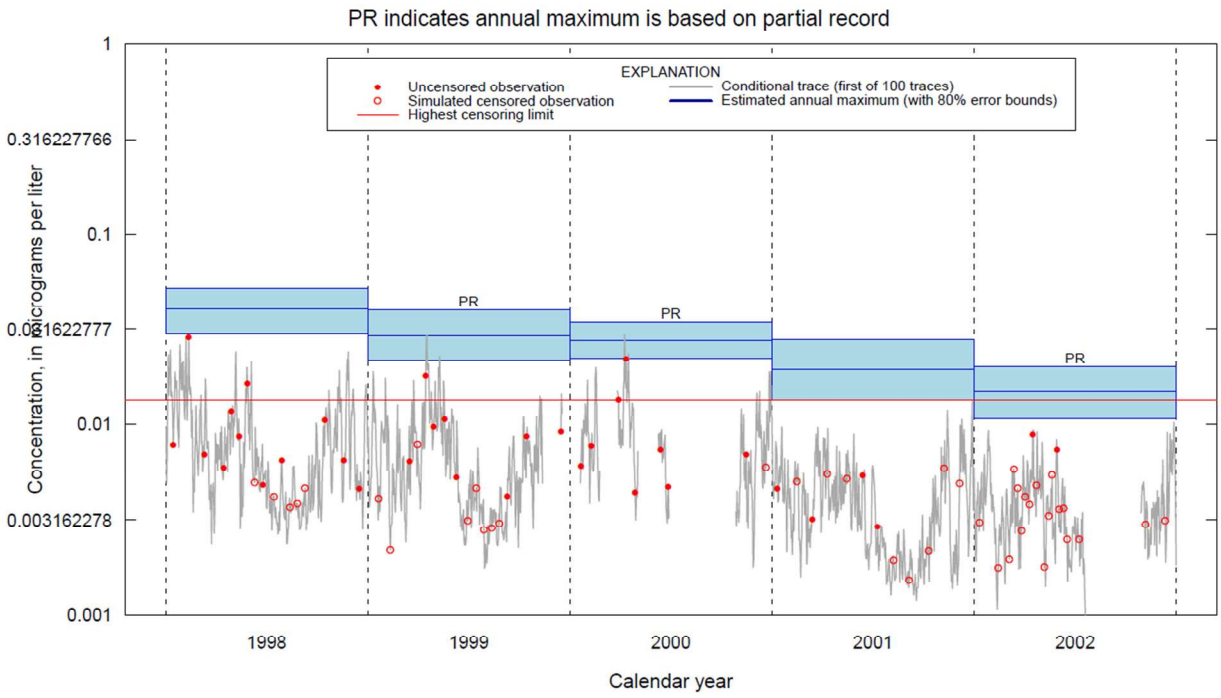

Figure 33. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-08057200

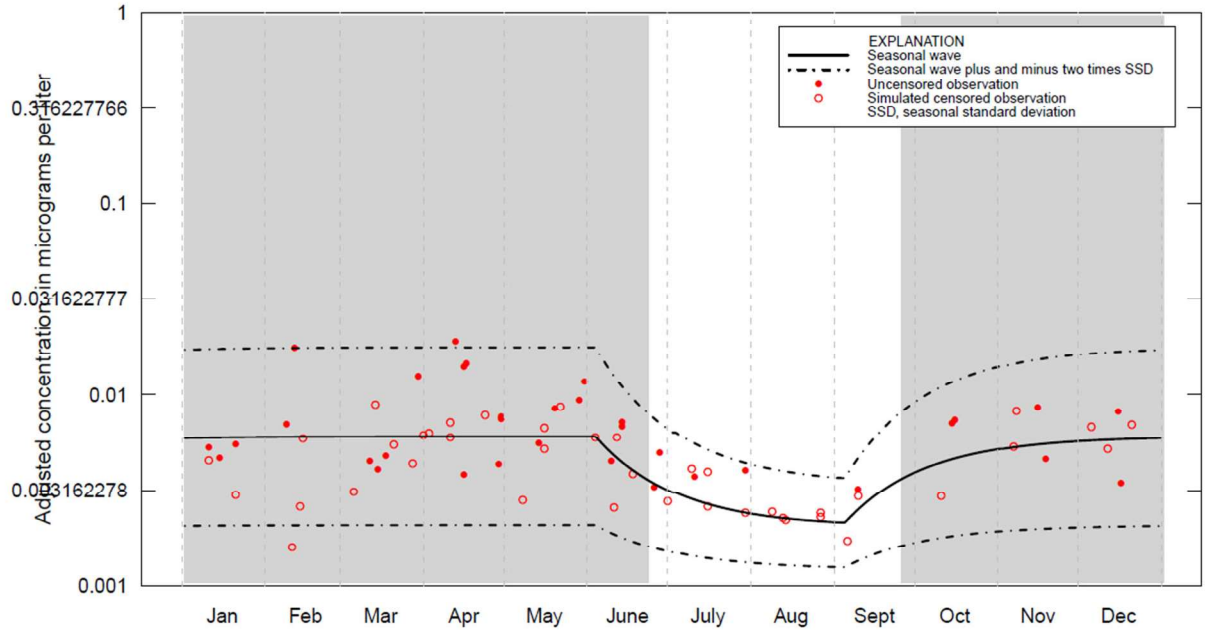

Figure 34. SEAWAVE-QEX Seasonal Wave Model for USGS-08057200 (Diagnostic Plot 2)

The resulting chemographs from this model were used to describe the estimated concentrations at site 08057200 by calculating the maximum of the 99th percentile 1- and 21-day concentrations. **Table 32** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 32. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-08057200

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1998	0.06	0.03
1999	0.03	0.02
2000	0.03	0.03
2001	0.03	0.02
2002	0.02	0.01

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 35** and **Figure 36**, respectively. Again, these figures show median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category. Only two years of the SEAWAVE-QEX output could be used for calculating SBFs due to periods of missing flow. Years with a partial flow record cannot produce daily concentration estimates for periods of the year when the flow is missing. More than two years were simulated in SEAWAVE-QEX; however, due to missing flow in the data (-9 reported in output files for those days with missing flow) the additional years were excluded from the SBF development.

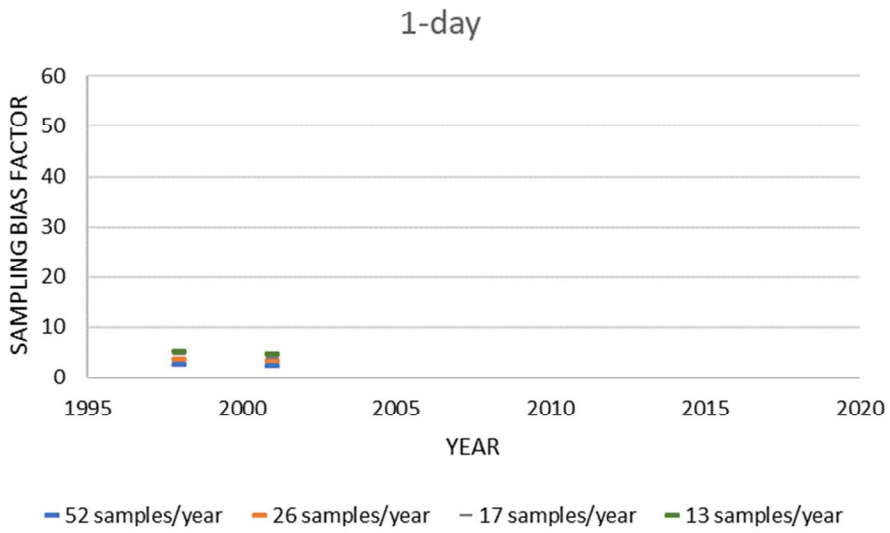

Figure 35. USGS Site 08057200: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

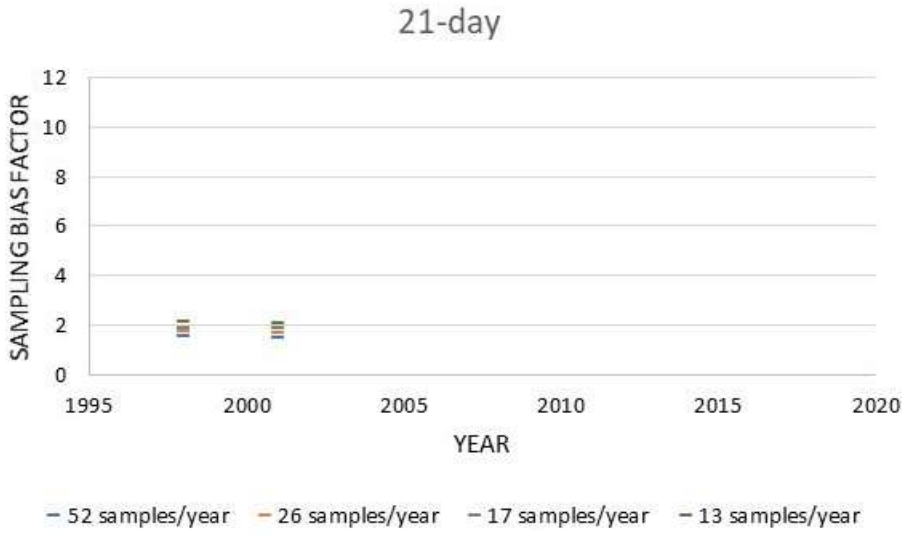

Figure 36. USGS Site 08057200: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

The SBFs are roughly equal for the two years where SBFs could be developed. SBFs for all sample number category are below 6 for estimating the upper confidence interval on the 1-day average and are roughly 2 or below for estimating the upper confidence interval on the 21-day average.

3. USGS-01654000

Site and Sampling Characterization

USGS site 01654000 (Accotink Creek near Annandale, VA) falls within a 24 mi^2 (62.3 km^2) urban watershed in HUC 02 with land use acreage comprising of <1% cropland, 23% impervious surfaces, and 23% deciduous forest (**Figure 37.** Watershed Landcover Characteristics of Sampling Site USGS-01654000). Although this watershed does not supply source drinking water, it is possible that this site is representative of other areas relevant to drinking water intakes that have similar watershed characteristics and chlorpyrifos use.

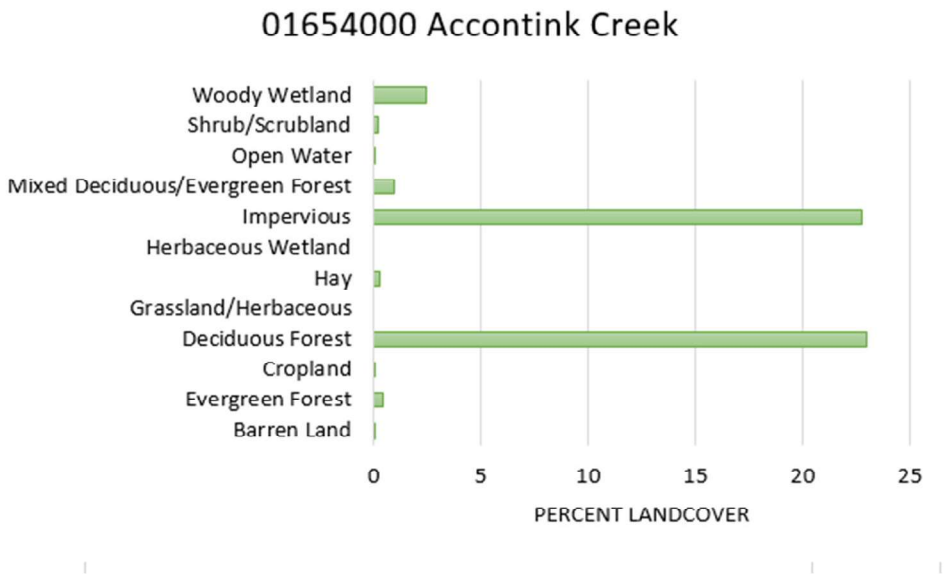

Figure 37. Watershed Landcover Characteristics of Sampling Site USGS-01654000

The site has a total of 37 chlorpyrifos detections out of 99 samples over 7 years between 1994 and 2014 (**Table 33**). Only 4 years of data have 12 or more samples and a detection frequency greater than 25%. **Table 33** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 33. USGS-01654000 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1994	25	12	48%	✓	2	✓
1995	0	—	—	✓		✓
1996	0	—	—	✓		✓
1997	15	9	60%	✓	0	✓
1998	11	5	45%	✓	0	✓
1999	19	6	32%	✓	0	✓
2000	13	5	38%	✓	0	✓
2001	6	0	0%			
2014[2]	10	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

[2] Years 2002-2013 without monitoring data excluded for brevity.

SEAWAVE-QEX Analysis

Several iterations of SEAWAVE-QEX were attempted to find the best fit to the data, such as including only the years 1997-2000 or 1994-1999. Ultimately, the best fit was determined to be for the period

from 1994 to 2000 without modification of the default SEAWAVE-QEX parameters (e.g., no constant added). The maximum measured concentration at this site is 0.041 µg/L in 1994.
The 80% confidence bounds on the estimated maximum for each year (blue boxes on first diagnostic plot) are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. SEAWAVE-QEX fit a shallow, two-season wave to the data, likely due to sporadic use of chlorpyrifos at various times and locations within the watershed over the period examined. The 2SSD bounds are not large (i.e., less than an order of magnitude) with most data falling within the 2SSD bounds. The first season has a slightly sharper peak than the second, with seasons running mid-April through late June and the end of August through early December. There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and weakly positive correlation with STFA. There is an overall downward trend of concentrations from 1994 to 2000 and residuals are centered on zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 4.7 days.

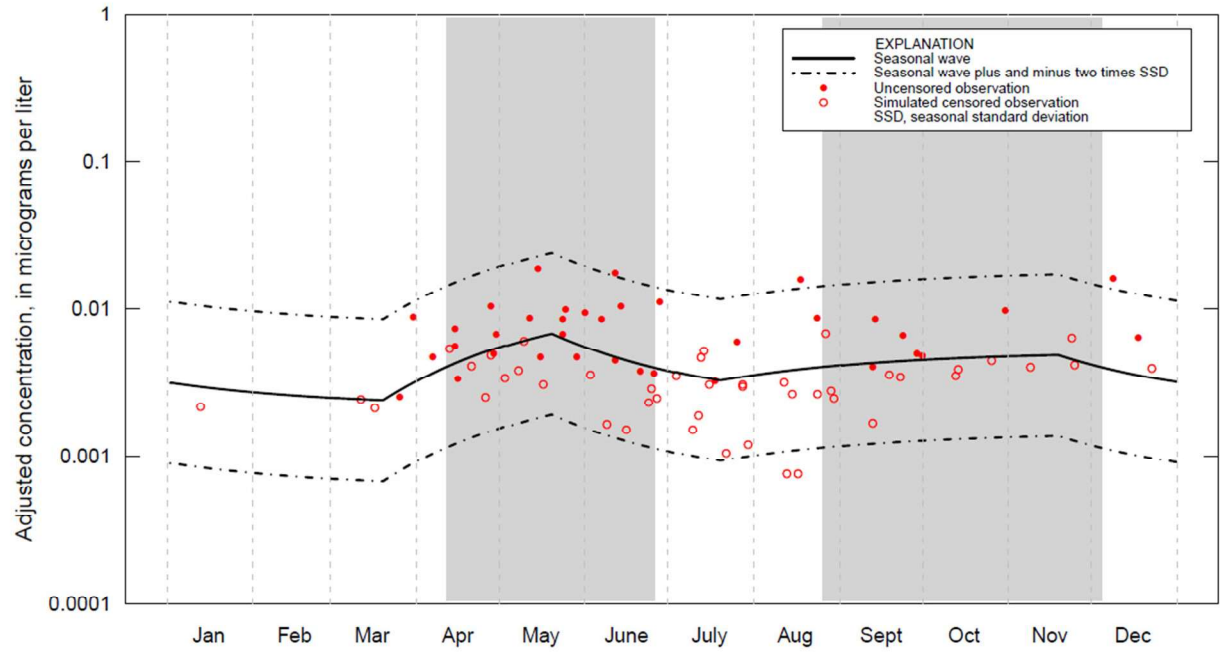

Figure 38. SEAWAVE-QEX Seasonal Wave Fit to Data for USGS-01654000

Based on the resulting estimated chemographs, concentrations of chlorpyrifos at this site are expected to be below well 1 µg/L. **Table 34** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. These do not range substantially higher than the highest measured concentration of 0.041 µg/L.

Table 34. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-01654000

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1994	0.060	0.033
1995	0.045	0.036
1996	0.048	0.033

1997	0.033	0.016
1998	0.042	0.027
1999	0.026	0.011
2000	0.027	0.014

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 39** and **Figure 40**, respectively. Again, these figures show median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

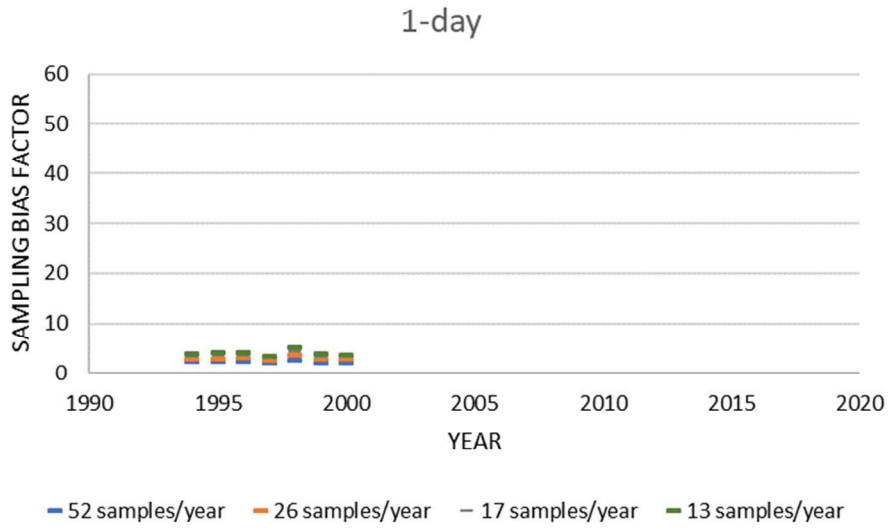

Figure 39. USGS Site 01654000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

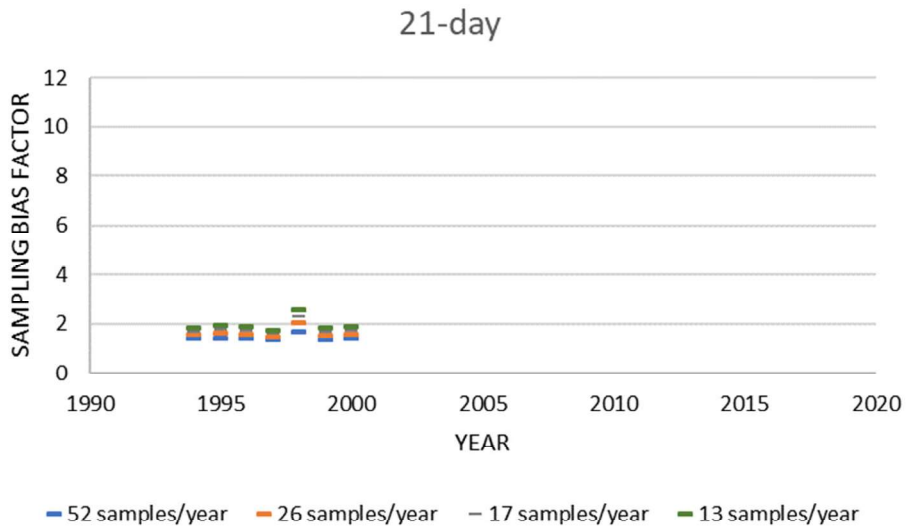

Figure 40. USGS Site 01654000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-0165400 for estimating the upper confidence interval on the 1- and 21-day average concentration. One year, 1998, results in notably higher SBFs; however, all SBFs are roughly 5 or below for all sample number categories for calculating the 1-day average or below 3 for the 21-day average.

4. USGS-02174250

Site and Sampling Characterization

USGS site 02174250 (Cow Castle Creek near Bowman, SC) falls within a 24.9 mi^2 (64.4 km^2) watershed in HUC 03. The sampling location is in a watershed with 26% cropland and a high percentage of other natural areas (e.g., woody wetland, shrub, hay, evergreen forest) as described in **Figure 41.** Watershed Landcover Characteristics of Sampling Site USGS-02174250 . The sampling location is upstream of a drinking water intake with a 2-day time of travel between the sampling site and the intake. This indicates that the site is relevant for source drinking water.

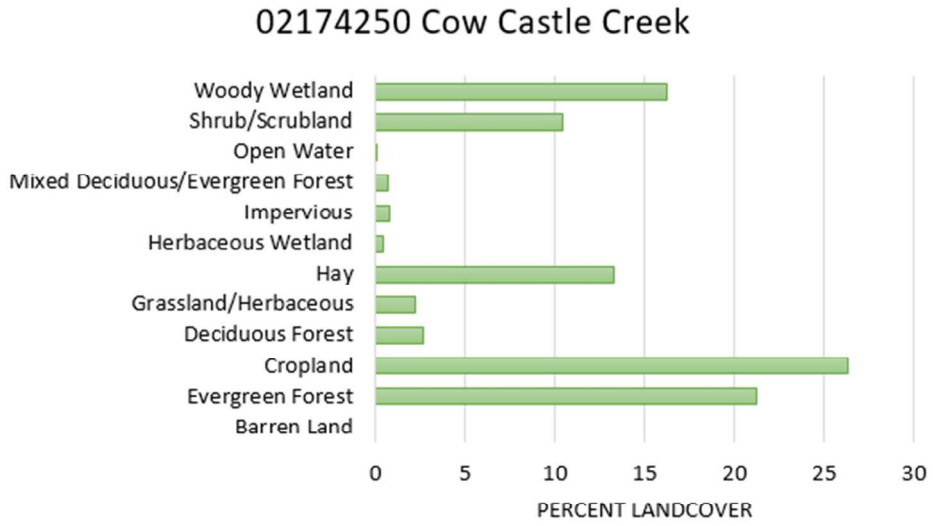

Figure 41. Watershed Landcover Characteristics of Sampling Site USGS-02174250

The site has a total of 83 chlorpyrifos detections out of 162 samples over 14 years of data between 1996 and 2012 (**Table 35**). Five of these years have 12 or more samples and a detection frequency greater than 25%. **Table 35** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 35. USGS-02174250 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	38	31	82%	✓	0	✓
1997	0	—	—	✓	0	✓
1998	1	1	100%	✓	0	✓
1999	15	10	67%	✓	0	✓
2000	17	10	59%	✓	0	✓
2001	10	6	60%	✓	0	✓
2002	9	2	22%	✓	0	✓
2003	7	2	29%	✓	0	✓
2004	8	2	25%	✓	0	✓
2005	8	5	63%	✓	0	✓
2006	14	5	36%	✓	0	✓
2007	3	1	33%	✓	0	✓
2008	14	8	57%	✓	0	✓
2009	0	—	—			
2010	0	—	—			
2011	4	0	0%			
2012	14	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Several cuts of the data were attempted in SEAWAVE-QEX as well as adding a small constant (e.g., a fraction of the LOD of 0.004). This included the following splices of the data based on the diagnostic plots of the full run: 1996-2008 (with and without addition of 0.0012 or 0.0016), 1999-2006, 1996-2000, 2000-2008, 1996-2006. The best fit was determined to be for the period from 1996 to 2008 with the addition of a small constant, 0.0012, which improved the fit of the empirical correlogram.

The 80% confidence bounds on the estimated maximum for each year (blue boxes on first diagnostic plot) span less than an order of magnitude. The highest measured concentration occurs in 2005 (0.338 µg/L); the 80% confidence bounds on the estimated maximum for all other years falls below this value (**Figure 42**). The model shows a single, very shallow seasonal wave from early December to early March, with most data falling within the 2SSD bounds and several outliers of higher concentrations from July to September (i.e., outside of the 2SSD bounds). There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. There is an overall downward trend of concentrations from and residuals are centered on zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 20.5 days.

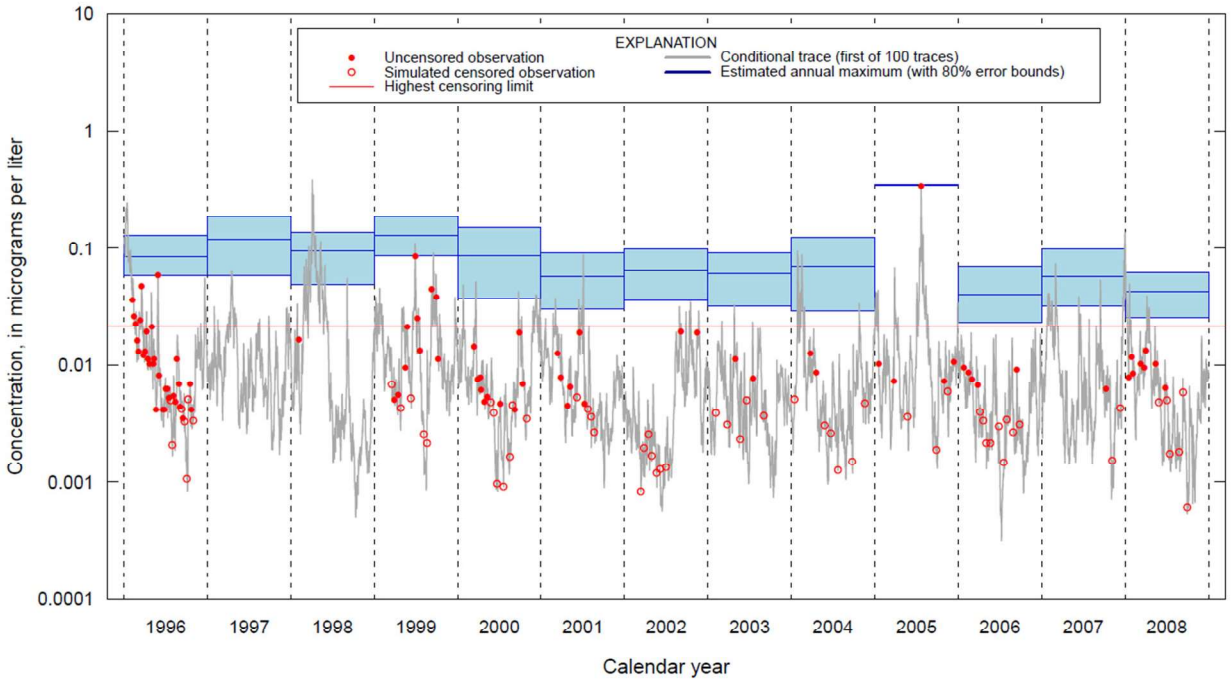

Figure 42. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-02174250

Table 36 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. From this table, choosing the maximum of the 99th percentile 1-day concentration ranges from 0.09-0.5 µg/L, encompassing the highest measured concentration from 2005 (0.338 µg/L) while accounting for uncertainty in infrequent sampling where the peak concentration might be higher than the highest measured.

Table 36. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-02174250

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1996	0.22	0.14
1997	0.50	0.23
1998	0.33	0.15
1999	0.17	0.12
2000	0.18	0.12
2001	0.13	0.06
2002	0.09	0.06
2003	0.12	0.06
2004	0.19	0.15
2005	0.37	0.25
2006	0.09	0.07
2007	0.11	0.08
2008	0.10	0.06

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 43** and **Figure 44**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

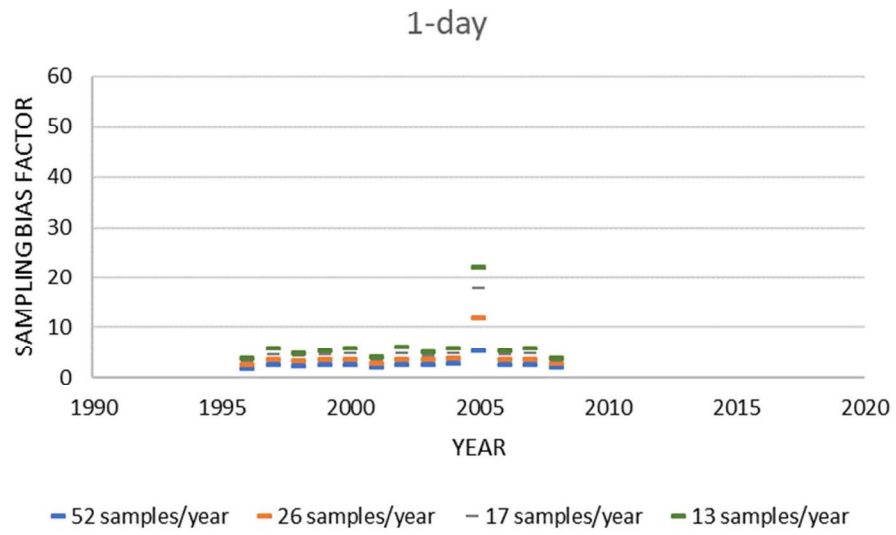

Figure 43. USGS Site 02174250: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

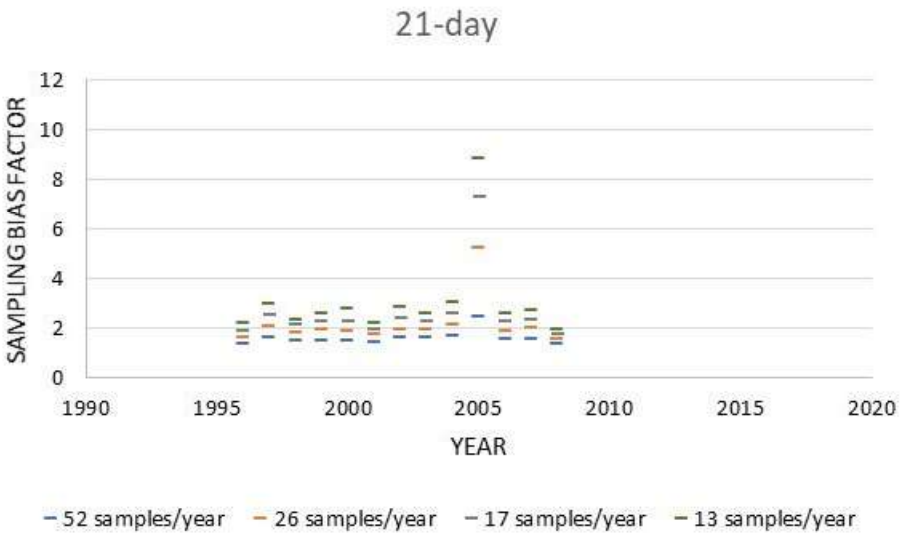

Figure 44. USGS Site 02174250: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-02174250 for estimating the upper confidence interval on the 1- and 21-day average concentration except for one year, 2005, which are much higher than for other years. Investigation of these higher SBFs reveal that the 2005 SBFs are driven by a measured concentration. This introduces uncertainty in the other years of data where peak

occurrence concentrations may have gone without being measured. Furthermore, since the other years have SBFs in the range of other sampling sites derived for other sites, it is possible that peak occurrence concentration may have gone undetected for other sites that would have resulted in generation of higher SBFs.

5. USGS-03353637

Site and Sampling Characterization

USGS site 03353637 (Little Buck Creek near Indianapolis, IN) falls within a 19.5 mi^2 (50.6 km^2) urban watershed in HUC 05, comprising of 6% cropland and 25% impervious surfaces (**Figure 45.** Watershed Landcover Characteristics of Sampling Site USGS-03353637). The sampling location is upstream of several community water systems with intakes on the Ohio River. The time of travel between the sampling site on Little Buck Creek and the intakes range from 12-14 days.

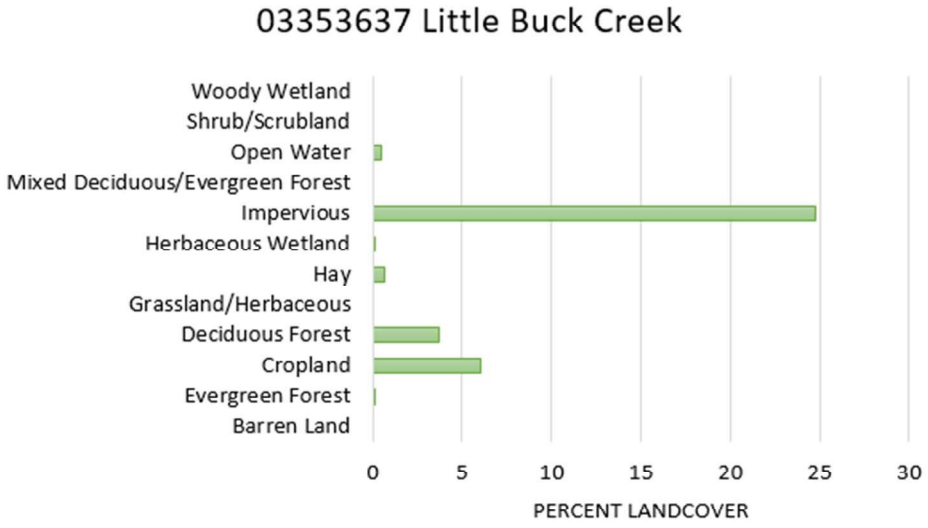

Figure 45. Watershed Landcover Characteristics of Sampling Site USGS-03353637

This site had a total of 96 detections out of 223 samples over 13 years between 1992 and 2004. Only 4 years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 37**. **Table 37** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 37. USGS-03353637 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	49	42	86%	✓	19	✓
1993	32	24	75%	✓	3	✓
1994	14	5	36%	✓	0	✓
1995	11	6	55%	✓	0	✓
1996	13	6	46%	✓	0	✓
1997	9	5	56%			
1998	11	2	18%			
1999	8	0	0%			
2000	13	2	15%			
2001	20	3	15%			
2002	22	1	5%			
2003	14	0	0%			
2004	7	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1992-1996 were input into SEAWAVE-QEX. Other subsets of years were explored (i.e., 1992-1994, 1993-1996) and data for 1992 to 1996 had the best model fit. As seen in **Table 37**, SEAWAVE-QEX excluded a number of samples in 1992 due to the temporal intensity of sampling (see **Figure 46**).

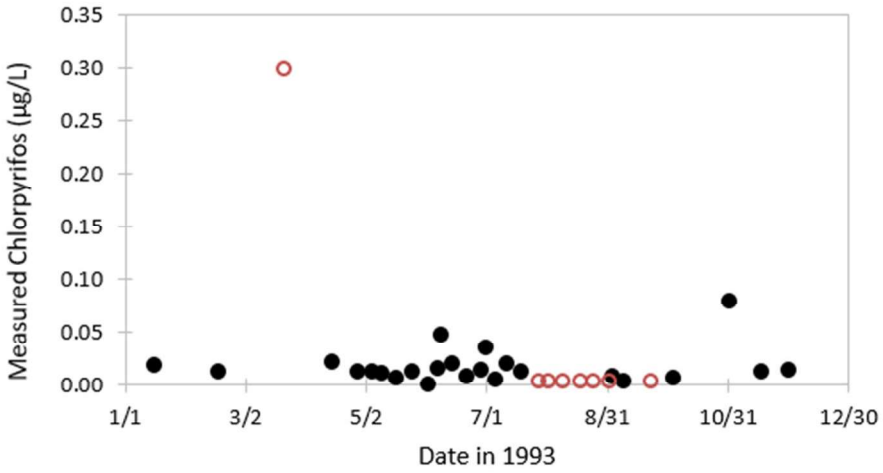

Figure 46. Sampling Intensity in 1993 of Measured Concentrations Above (black) and Below (red) the LOD

The final selected model had 80% confidence bounds on the estimated maximum for each year spanning less than an order of magnitude. The highest measured concentration occurs in 1996 (0.11 µg/L) which is encompassed by the 80% confidence bounds on the estimated maximum for several

years, indicating that the model estimated concentrations at and above this concentration. There was a shallow "inverse" seasonal wave with 2SSDs of less than one order of magnitude. This means that SEAWAVE-QEX fit a very long, flat seasonal wave (from mid-October to early July), with a period of lower concentrations in other months (**Figure 47**). While most of the measured observations fall within the 2SSD bounds, it is unclear that concentrations are substantially lower outside of the season. The low seasonality of concentrations combined with the high amount of impervious land cover at this site suggest that the measured concentrations may have resulted from residential applications.

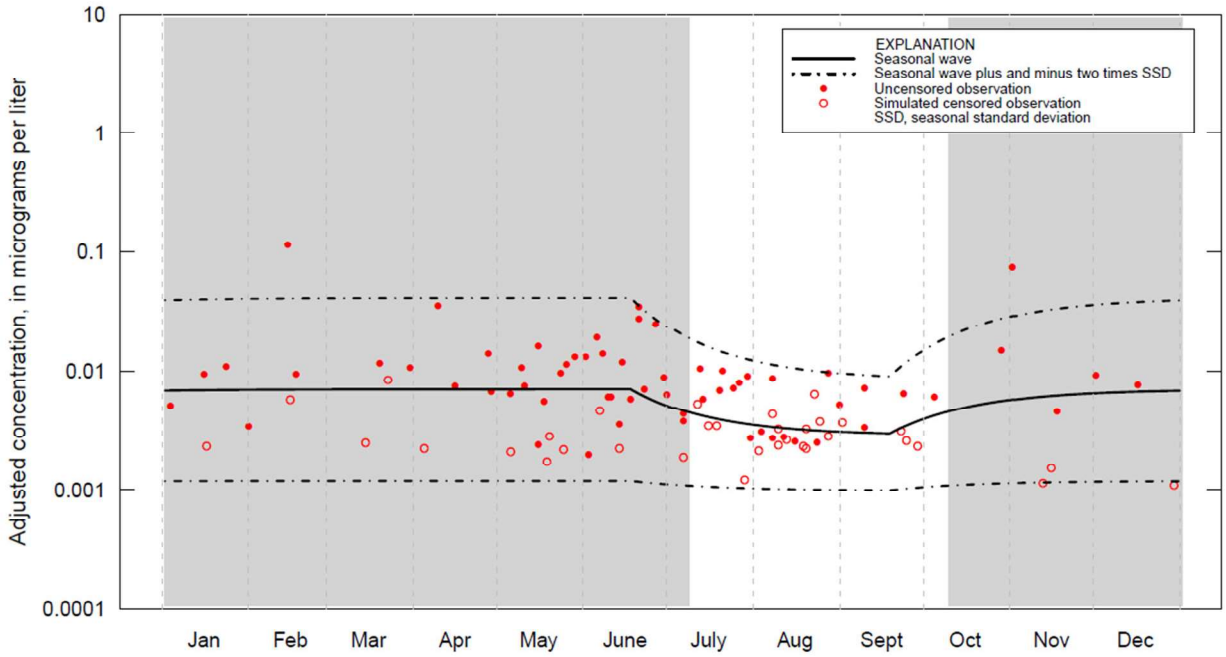

Figure 47. SEAWAVE-QEX Seasonal Wave for USGS-03353637

There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. There is an overall downward trend of concentrations from and residuals are mostly centered on zero with a slightly positive skew. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 3.6 days. **Table 38** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 38. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-03353637

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	0.152	0.077
1993	0.244	0.107
1994	0.152	0.073
1995	0.134	0.046
1996	0.147	0.075

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 48** and **Figure 49**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

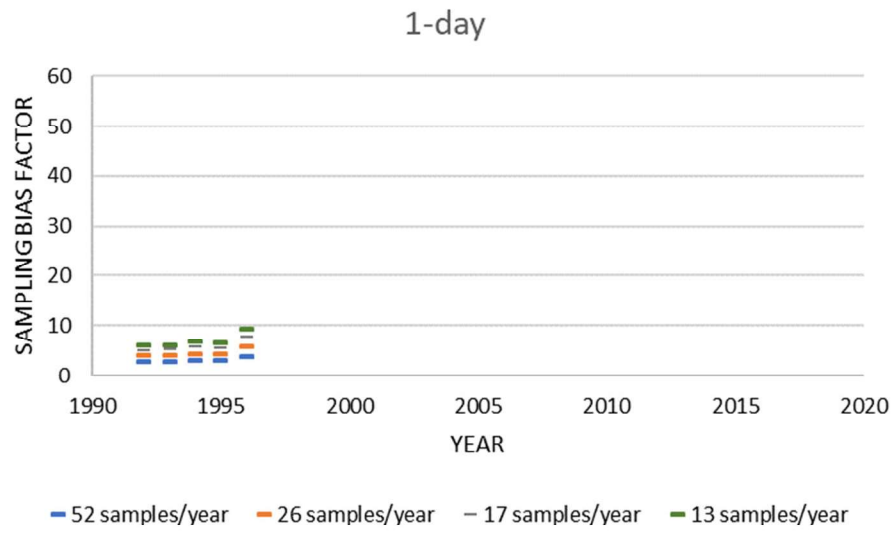

Figure 48. USGS Site 03353637: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

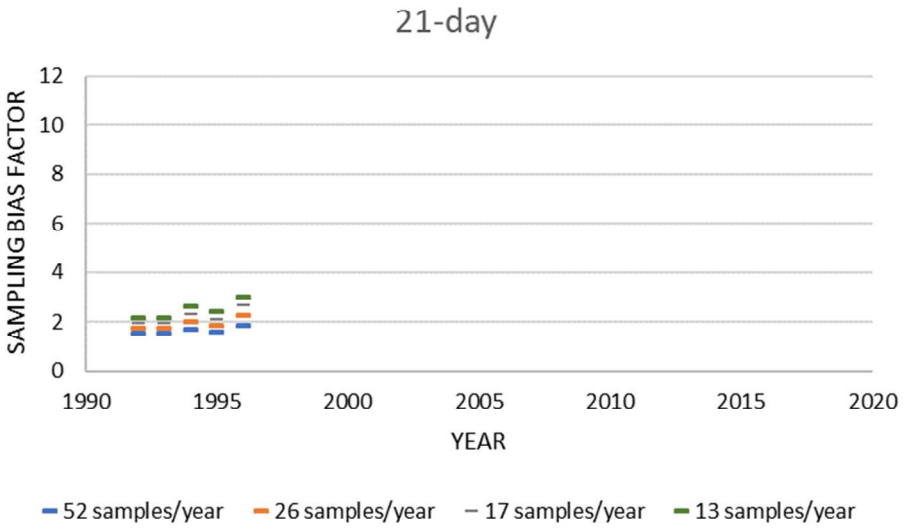

Figure 49. USGS Site 03353637: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

The SBFs are consistent across 4 of the 5 years. The 1996 SBFs are higher than for other years. In general, SBFs for this site are consistently higher for 1-day SBFs when compared to other sites; however, 21-day SBFs calculated for this site are consistent with other sites. SBFs for all sample number categories are below 10 for estimating the upper confidence interval on the 1-day average concentration and below 4 for estimating the upper confidence interval on the 21-day average concentration.

6. *USGS-14211720*

Site and Sampling Characterization

USGS site 14211720 (Willamette River at Portland, OR) is in a 11,167 mi^2 (28,922 km^2) watershed in HUC 17. The watershed is 8% cropland with a high percentage of evergreen forest (49%). The sampling location is upstream of a drinking water intake. The time of travel between the sampling site and the intake is less than a day, making the site relevant for drinking water.

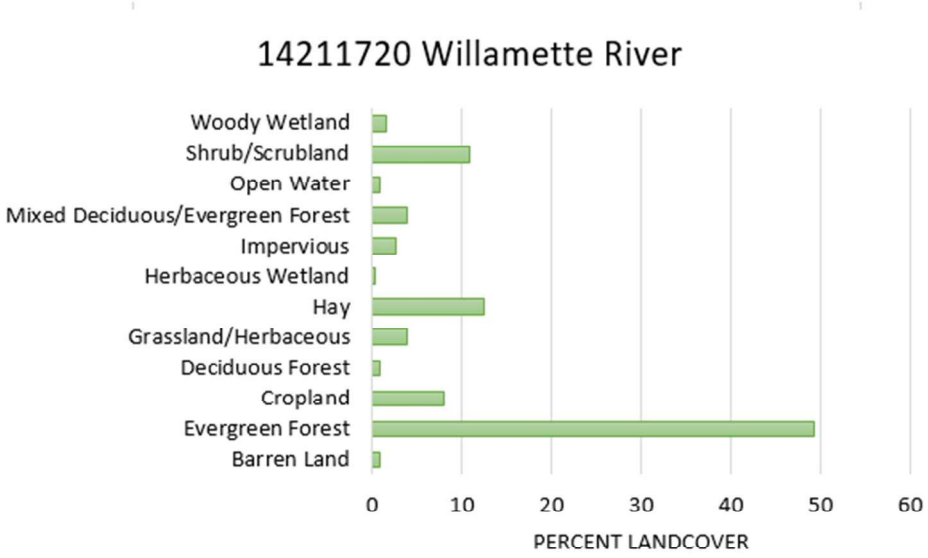

Figure 50. Watershed Landcover Characteristics of Sampling Site USGS-14211720

This site had a total of 69 detections out of 392 samples over 27 years between 1993 and 2019. Only 5 years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 39**. **Table 39** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 39. USGS-14211720 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	3	0	0%			
1994	12	1	8%			
1995	8	1	13%			
1996	9	5	56%			
1997	17	12	71%	✓	1	✓
1998	13	7	54%	✓	0	✓
1999	15	4	27%	✓	0	✓
2000	13	6	46%	✓	0	✓
2001	14	0	0%	✓	0	✓
2002	16	1	6%	✓	0	✓
2003	13	1	8%	✓	0	✓
2004	15	0	0%	✓	0	✓
2005	9	2	22%	✓	0	✓
2006	9	2	22%	✓	0	✓
2007	19	6	32%	✓	0	✓
2008	18	3	17%			
2009	20	0	0%			
2010	19	4	21%			
2011	19	3	16%			
2012	19	4	21%			
2013	18	0	0%			
2014	18	0	0%			
2015	17	1	6%			
2016	18	4	22%			
2017	19	2	11%			
2018	18	0	0%			
2019	4	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data encompassing the 5 years of data meeting the SEAWAVE-QEX criteria were used in modeling (i.e., 1997-2007). Another subset of years was explored (i.e., 1997-2000) but did not have an acceptable model fit. The years 1997-2007 gave an acceptable model fit and included the most years of measured data possible.

The annual estimated maximum concentrations (with 80% confidence bounds) generated are well below 0.1 µg/L and are all less than 0.03 µg/L. The model produces a single flat wave with most data within 2SSD bounds, which suggests that there is similar use throughout the year with a period of no use (off-season) from late June to late September (**Figure 51**). Adjusted concentration has a weakly positive correlation with MTFA and significantly positive correlation with STFA, and concentrations increase slightly between 1997-2007. Normalized residuals are centered on zero both within years and across

years. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function at time intervals less than the average with a CTS of 11.7 days.

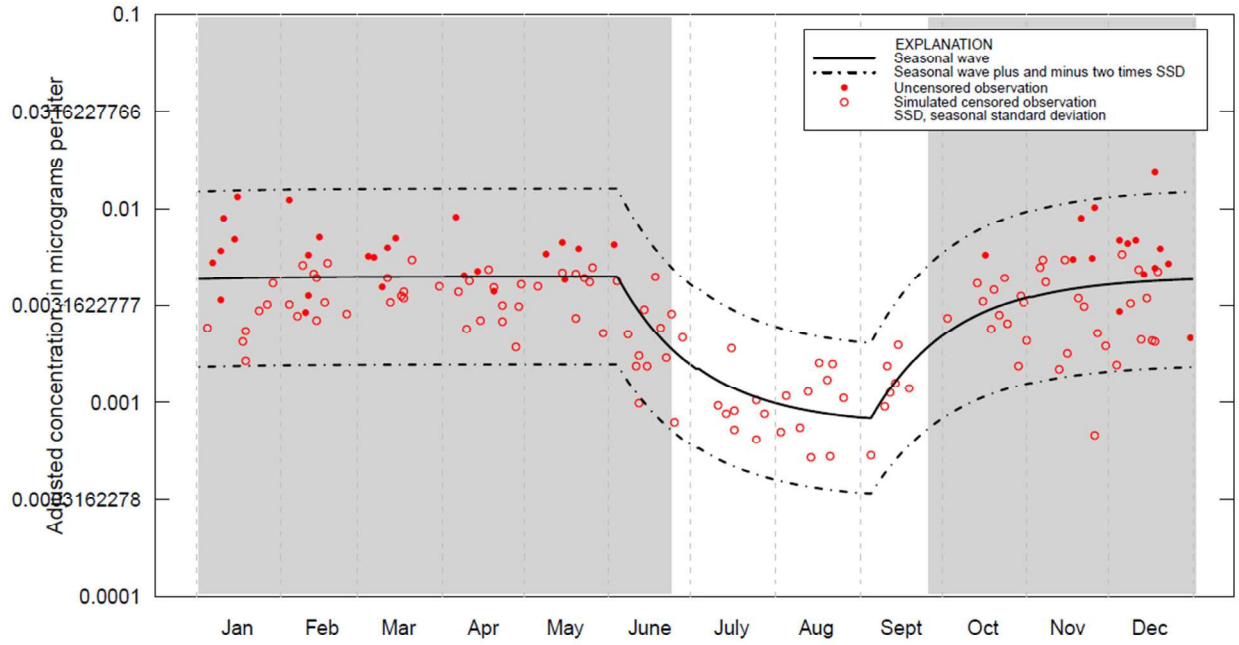

Figure 51. SEAWAVE-QEX Seasonal Wave for USGS-14211720

Table 40 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 40. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-14211720

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1997	0.018	0.012
1998	0.015	0.011
1999	0.020	0.012
2000	0.020	0.015
2001	0.024	0.015
2002	0.019	0.012
2003	0.027	0.019
2004	0.021	0.011
2005	0.029	0.017
2006	0.027	0.019
2007	0.027	0.015

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 52** and **Figure 53**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

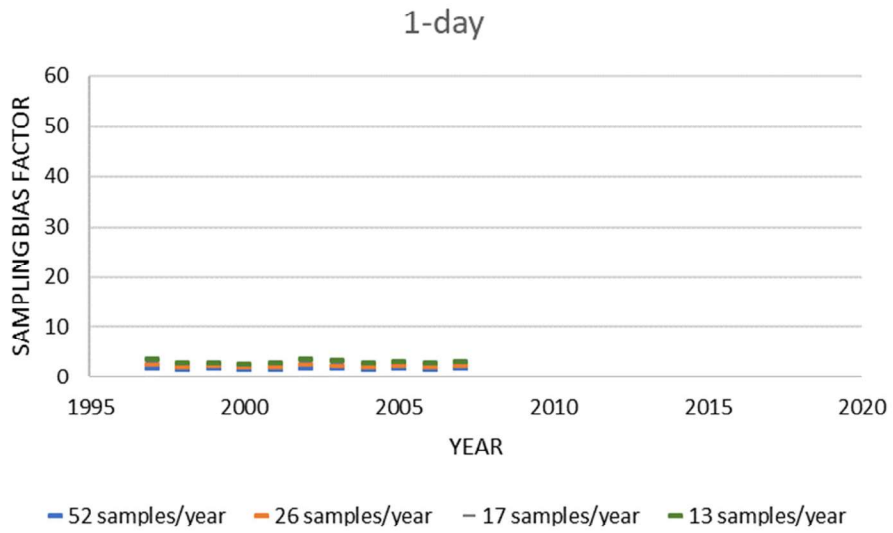

Figure 52. USGS Site 014211720: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

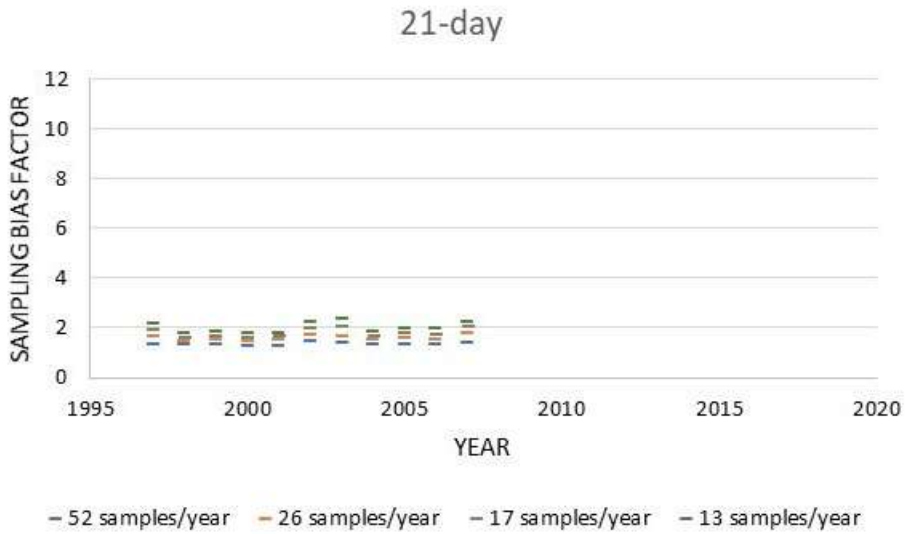

Figure 53. USGS Site 014211720: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

The SBFs are consistent across all years. SBFs for all sample number categories are roughly equal to or below 3.5 for estimating the upper confidence interval on the 1-day average concentration and below 2.5 for estimating the upper confidence interval on the 21-day average concentration.

7. USGS-04208000

Site and Sampling Characterization

USGS site 04208000 (Cuyahoga River at Independence, OH) is a 706 mi^2 (1829 km^2) watershed in HUC 04. The watershed is 9% cropland, 11% impervious surfaces, with a high percentage of forestry. This watershed does not supply source drinking water, though it may be representative of other similar sites where chlorpyrifos is used.

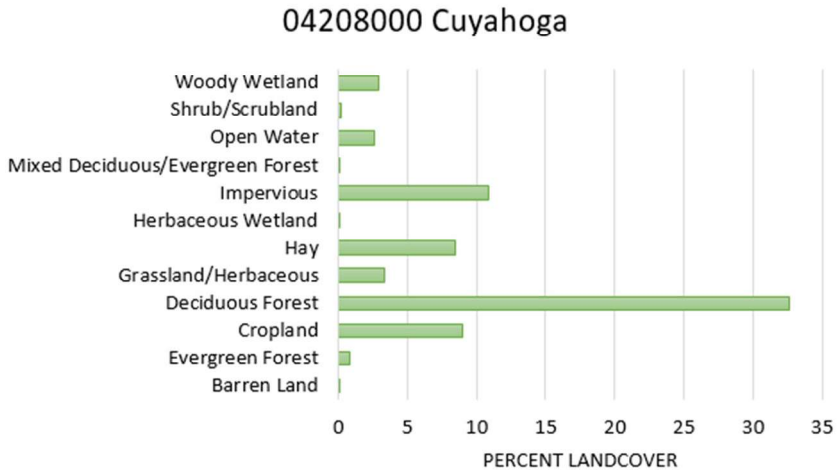

Figure 54. Watershed Landcover Characteristics of Sampling Site USGS-04208000

This site had a total of 40 detections out of 933 samples over 32 years between 1983 and 2015. Only 10 years have any detections, 3 years of which have 12 or more samples and a detection frequency greater than 25% (**Table 41**). **Table 41** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 41. USGS-04208000 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1983	23	0	0%			
1984	19	0	0%			
1985	28	0	0%			
1986	12	0	0%			
1987	12	6	50%	✓	1	✓
1988	20	6	30%	✓	1	✓
1989	25	4	16%	✓	2	✓
1990	17	7	41%	✓	0	✓
1991	11	10	90%	✓	0	✓
1992	12	1	8%			
1993	35	0	0%			
1994	34	1	3%			
1995	32	2	6%			
1996	32	2	6%			
1997	35	1	3%			
1998	41	0	0%			
1999	33	0	0%			
2000	41	0	0%			
2001	34	0	0%			
2002	38	0	0%			
2003	29	0	0%			
2004	31	0	0%			
2005	37	0	0%			
2006	30	0	0%			
2007	31	0	0%			
2008	33	0	0%			
2009	34	0	0%			
2010	32	0	0%			
2011	39	0	0%			
2012	38	0	0%			
2013	36	0	0%			
2014	29	0	0%			
2015	23	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

While only data from 1987 to 1990 met the SEAWAVE-QEX minimum criteria, the model fit was not acceptable using those years. Therefore, data for 1991 was included, which had a 90% detection frequency and 11 samples, and resulted in an acceptable fit.

The 80% confidence bounds on the estimated maximum concentrations for each year span roughly 1 to 10 µg/L for this site. The seasonal wave model selected has two shallow waves of similar amplitudes with most data within the 2SSD lines. The first season is from early March to early May and the second from early September to early January. There is not substantial correlation between adjusted concentrations and either MTFA or STFA and not much change in average concentration over time. Neither MTFA nor STFA are significantly correlated with the adjusted concentrations, and both correlations are generally flat (i.e., have little slope), suggesting that changes in streamflow do not have a strong impact on model outputs. The normalized residuals are centered around zero within years. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function with a CTS of 4.3 days.

Table 42 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. Concentrations were measured up to 0.5 µg/L, occurring in 1988.

Table 42. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-04208000

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1987	4.9	1.9
1988	4.4	2.3
1989	4.6	2.9
1990	2.9	1.3
1991	12.7	4.7

SEAWAVE-QEX estimated concentrations are more than 10x larger than the measured concentrations. While the model assumptions are satisfied based on the diagnostic plots, there are two indicators to evaluate when considering the potential for overestimation. The first can be seen in the first diagnostic plot (**Figure 55**), in which the annual maximum concentration estimates (blue line) are somewhat higher than the midway point in the 80% confidence bounds (blue boxes), particularly for 1988, 1989, and 1991. This gives an indicator that the average concentration for that year is somewhat higher than the mean, suggesting a slightly skewed distribution of concentrations. Generally, unacceptable plots have mean concentrations that are highly skewed to the top of the plot. Additionally, while the 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation, the overlap is toward the top of the confidence limits (gray boxes, **Figure 56**). When the empirical correlogram is entirely below the fitted exponential correlation, concentrations are estimated. In this case, it is not expected that the difference observed would cause substantial overestimation given that the confidence limits are overlapping. Variability in the degree of overlap is commonly observed in SEAWAVE-QEX diagnostic plots and not expected to indicate overestimation.

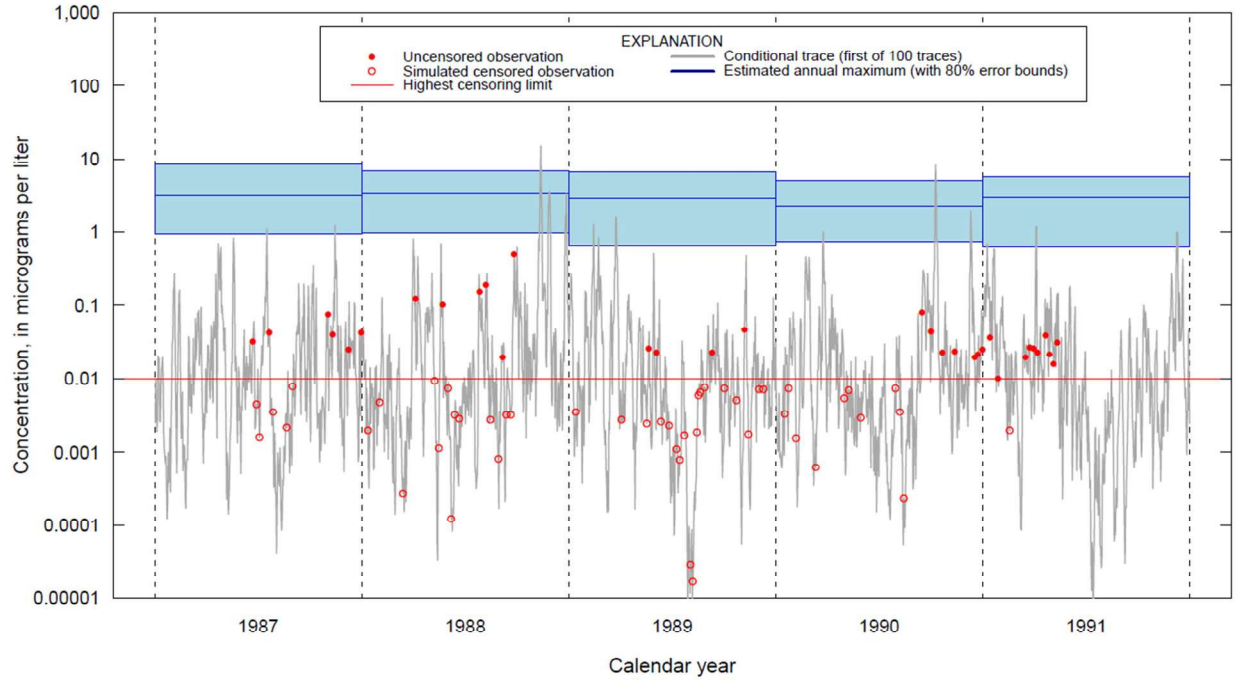

Figure 55. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-04208000

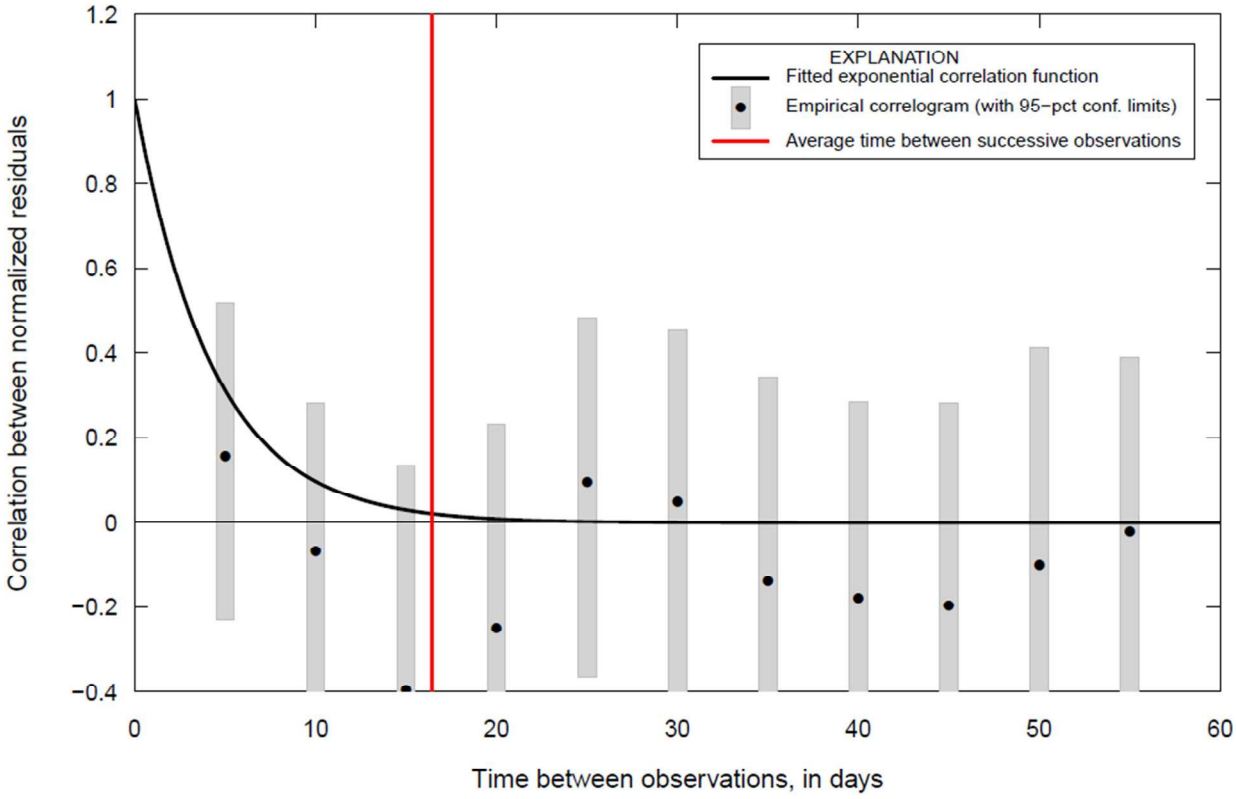

Figure 56. Plot of Correlation Between Normalized Residuals for USGS-04208000

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 57** and **Figure 58**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

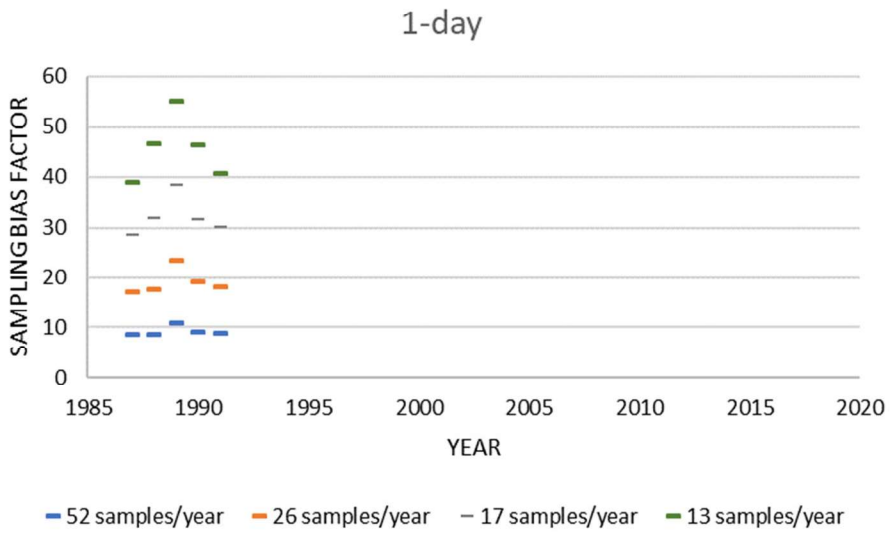

Figure 57. USGS Site 04208000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

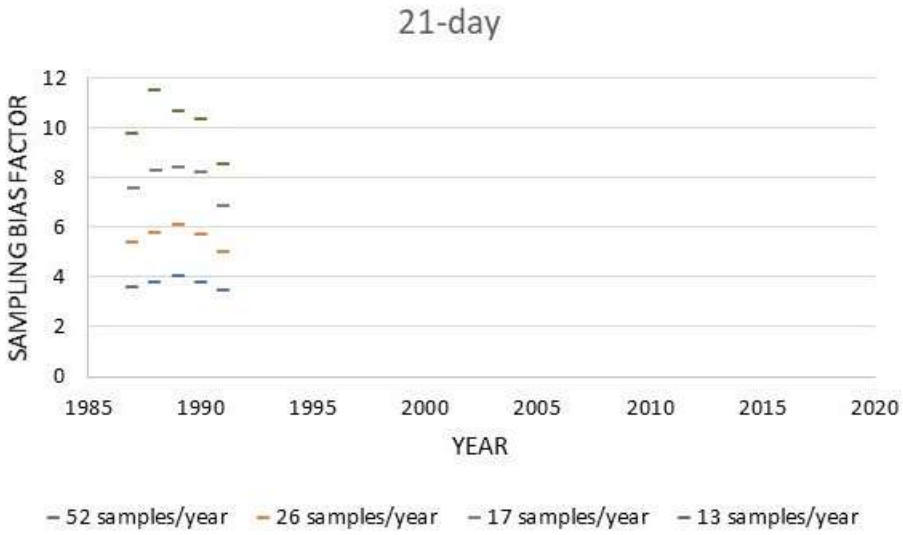

Figure 58. USGS Site 04208000: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

The SBFs are consistently high across all years. SBFs for all sample number categories are much higher for all years than all the other sites. SBFs for estimating the upper confidence interval on the 1-day average concentration ranged from 9 to 11 for 52+ samples per year, 17 to 23 for 26-51 samples/year, 29 to 38 for 17-25 samples/year and 39 to 55 for 13-16 samples/year. SBFs for estimating the upper

confidence interval on the 21-day average concentration ranged roughly 4 to almost 12 for 52+ samples per year and 13-16 samples/year, respectively.

8. USGS-02335870

Site and Sampling Characterization

USGS site 02335870 (Sope Creek near Marietta, GA) is in a 33.3 mi^2 (86.3 km^2) urban watershed in HUC 03. The watershed has no cropland but 20% impervious surfaces and 22% forested areas (**Figure 59**). The sampling location is upstream of seven drinking water intakes serving community water systems, with several pulling from the Chattahoochee River. Travel times of the water range from <1 day up to 3 days from the sampling site to each intake.

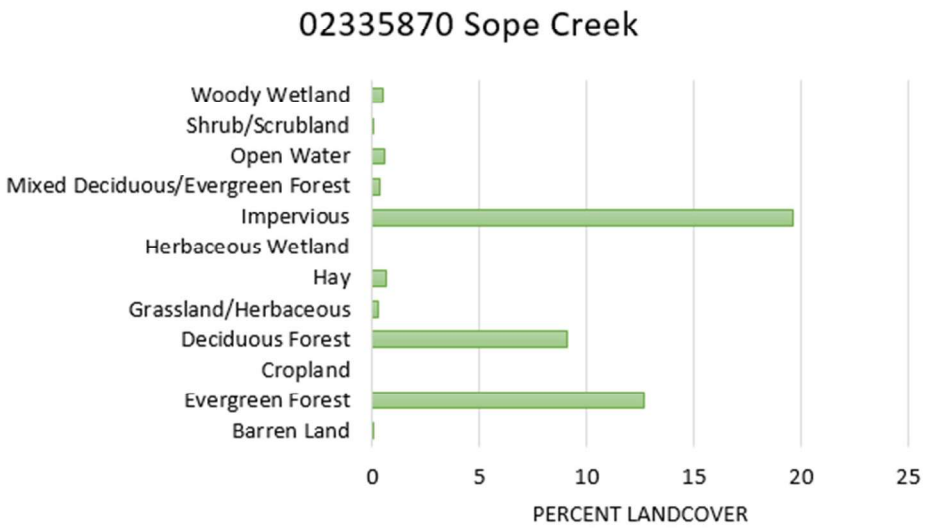

Figure 59. Watershed Landcover Characteristics of Sampling Site USGS-02335870 (2006 data)

This site had a total of 41 detections out of 401 samples over 26 years between 1993 and 2019. Only 3 years have 12 or more samples and a detection frequency greater than 25% (**Table 43**). **Table 43** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 43. USGS-02335870 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	32	17	53%	✓	0	✓
1994	12	7	58%	✓	0	✓
1995	3	1	33%	✓	0	✓
1996	0	—	—	✓	0	✓
1997	9	5	56%	✓	0	✓
1998	6	2	33%	✓	0	✓
1999	10	1	10%	✓	0	✓
2000	12	4	33%	✓	0	✓
2001	12	1	8%			
2002	23	0	0%			
2003	18	0	0%			
2004	7	0	0%			
2005	6	2	33%			
2006	6	0	0%			
2007	18	0	0%			
2008	22	0	0%			
2009	8	0	0%			
2010	18	0	0%			
2011	6	0	0%			
2012	24	0	0%			
2013	24	0	0%			
2014	27	0	0%			
2015	24	0	0%			
2016	23	0	0%			
2017	24	1	4%			
2018	22	0	0%			
2019	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

SEAWAVE-QEX was run only with the years encompassing the 3 years meeting the minimum requirements. The model did not produce an acceptable fit using SEAWAVE-QEX default parameters and the fitting was attempted by adding a small constant (0.0006 or 0.0009). Fitting with the addition of 0.0006 resulted in acceptable results with low confidence.

The 80% confidence bounds on the estimated maximum for each year are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. There are two shallow seasonal waves of similar amplitude; one season spanning early April to early August and the second from mid-December to early February. Most data are within the 2SSD bounds. There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. The adjusted concentrations trend slightly downward over time. The normalized residuals are centered on zero although have more spread

(positive and negative) in 1993 compared to other years (**Figure 60**). The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 3.5 days.

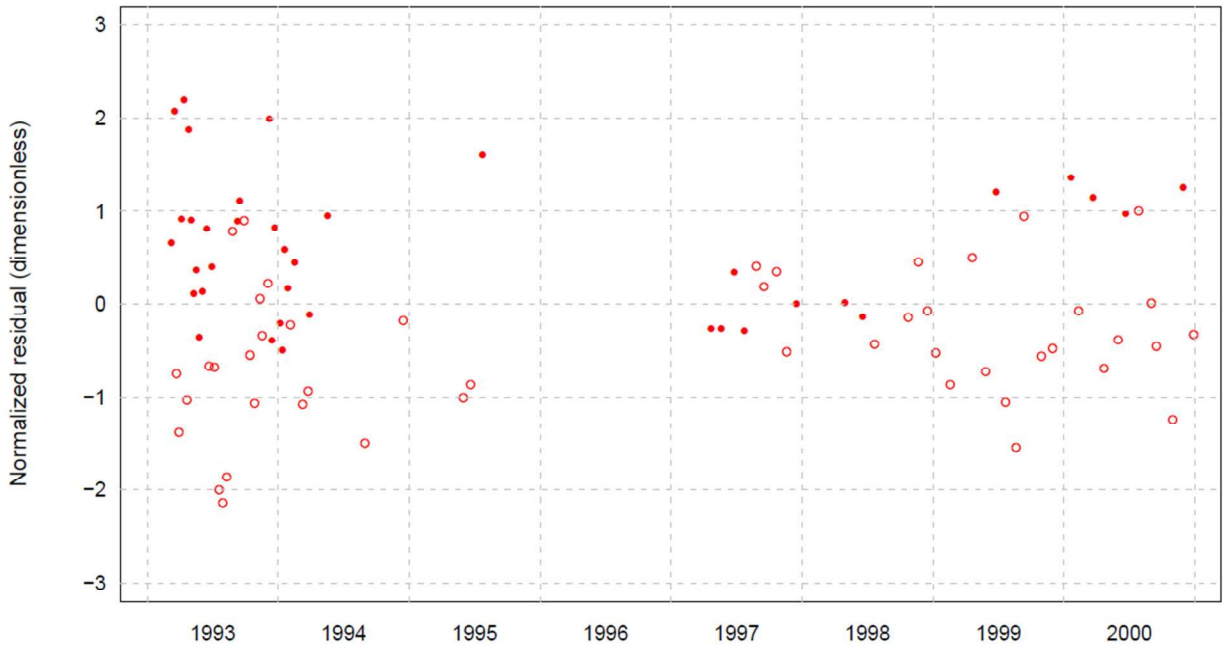

Figure 60. Normalized Residuals Across Years for USGS-02335870

Table 44 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 44. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-02335870

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1993	0.085	0.041
1994	0.065	0.032
1995	0.040	0.020
1996	0.051	0.027
1997	0.052	0.021
1998	0.061	0.031
1999	0.056	0.022
2000	0.022	0.013

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 61** and **Figure 62** respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

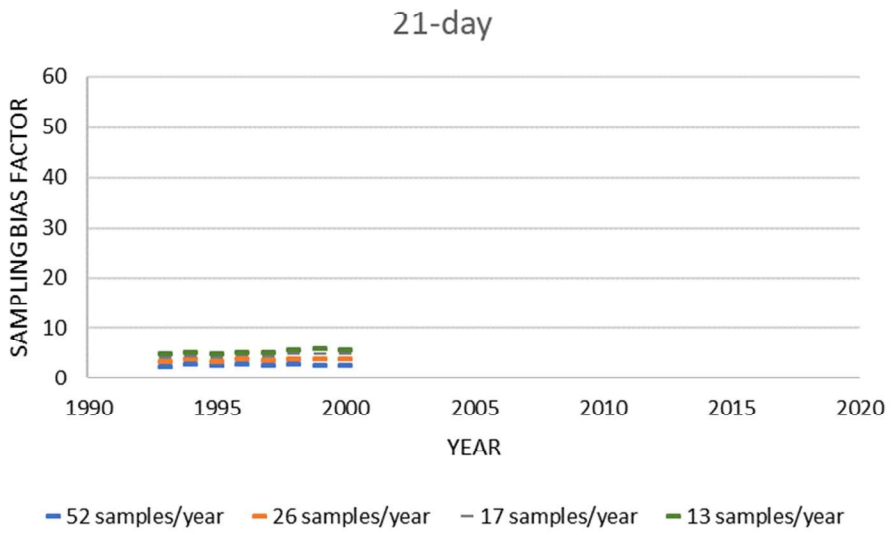

Figure 61. USGS Site 02335870: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

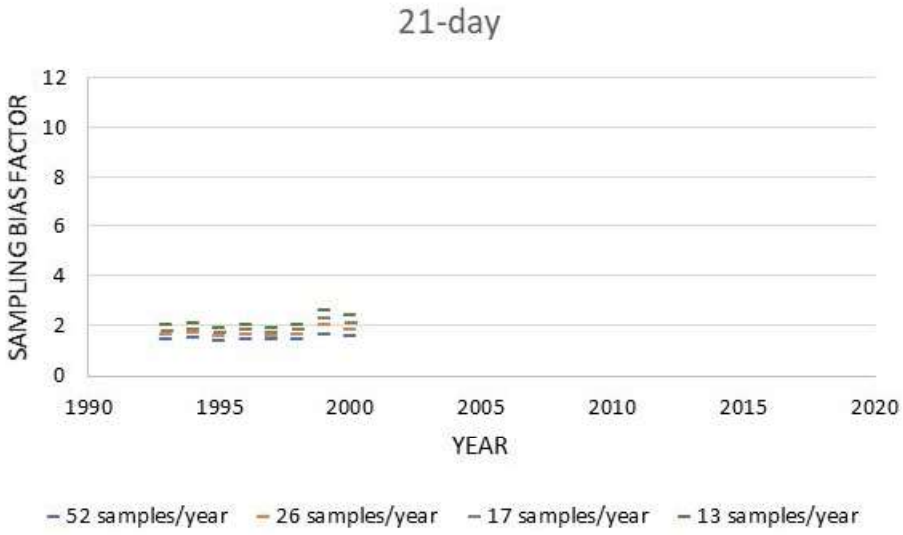

Figure 62. USGS Site 02335870: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

SBFs for estimating the upper confidence interval on the 1-day and 21-day average concentration for all sampling intervals were below 6 and 3, respectively. The values were generally consistent across the years with the last two years (1999 and 2000) having the highest SBFs.

9. USGS-04193500

Site and Sampling Characterization

USGS site 04193500 (Maumee River at Waterville, OH) is in a 6,283 mi^2 (16,274 km^2) agricultural watershed in HUC 04 dominated by cropland (73% of landcover) (**Figure 63.** Watershed Landcover

Characteristics of Sampling Site USGS-04193500). This watershed does not supply source drinking water, though it may be representative of other similar sites where chlorpyrifos is used, particularly given the high percentage of cropland landcover. Additionally, the site is downstream of numerous intakes, several with travel times less than a day and it is unclear whether measured concentrations result from chlorpyrifos use within this watershed or upstream.

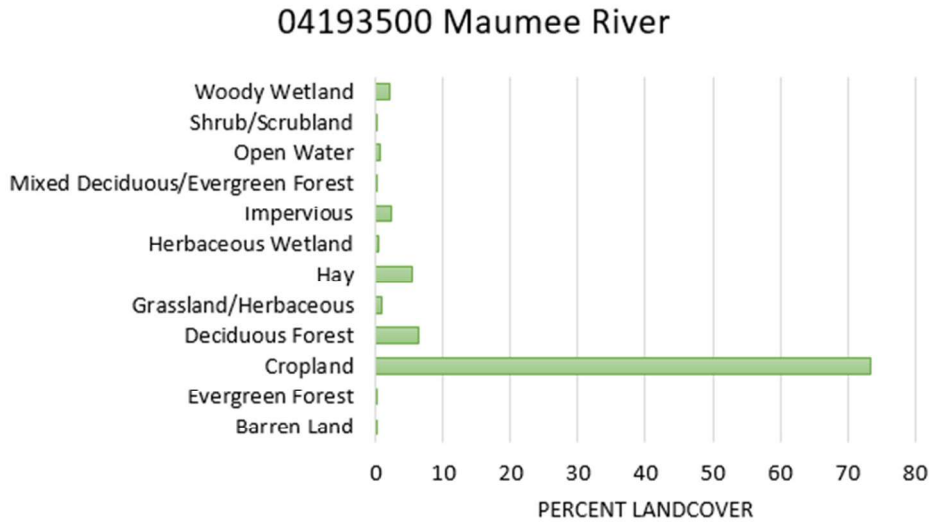

Figure 63. Watershed Landcover Characteristics of Sampling Site USGS-04193500

This site had a total of 29 detections out of 268 samples between 1996 and 2018 (**Table 45**)**. Table 45** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below. Data from NCWQR was not included with the USGS data download as the sampling frequency was much higher (near-daily) and detection frequency was much lower.

Table 45. USGS-04193500 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	13	9	69%	✓	0	✓
1997	17	5	29%	✓	0	✓
1998	14	0	0%	✓	0	✓
1999	13	0	0%	✓	0	✓
2000	14	2	14%	✓	0	✓
2001	11	2	18%	✓	0	✓
2002	8	0	0%	✓	0	✓
2003	8	1	13%	✓	0	✓
2004	8	1	13%	✓	0	✓
2005	7	2	29%	✓	0	✓
2006	16	3	19%	✓	0	✓
2007	16	4	25%	✓	0	✓
2008	0	—	—			
2009	0	—	—			
2010	1	0	0%			
2011	16	0	0%			
2012	3	0	0%			
2013	18	0	0%			
2014	18	0	0%			
2015	19	0	0%			
2016	18	0	0%			
2017	18	0	0%			
2018	12	0	0%			

SEAWAVE-QEX Analysis

While only 3 years of the USGS data have 12 or more samples and a detection frequency greater than 25% (Table 45), these were able to be modeled. Data from the NCWQR was not included as no years of data met the minimum SEAWAVE-QEX criteria. The data for 1996-2007 were input into SEAWAVE-QEX as they encompassed the 3 years meeting the minimum requirements. Since the empirical correlogram did not overlap with the fitted exponential correlation function using SEAWAVE-QEX default parameters, several small constants were added to improve fit (i.e., 0.0004, 0.0008, 0.0012). Fitting with the addition of 0.0012 resulted in the best model fit with low confidence.

For many years in the simulation, the 80% confidence bounds on the estimated maximum for each year span roughly an order of magnitude. There is a broad, shallow wave with a season from early May to early January and all measured concentrations fitting within the 2SSD bounds. Adjusted concentration is significantly (α=0.05) positively correlated with both MTFA and STFA. There is not much trend in the concentration data over the years. The normalized residuals are somewhat negatively skewed by season; viewing normalized residuals by year shows that residuals in 1996 are skewed positive while 1998-2001 are skewed negative. However, these negatively skewed residuals include many censored values, meaning that the exact location of the residuals will change in each conditional simulation. The

empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 19.9 days.

Table 46 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. In the year 2007, the mean estimated annual maximum (blue line) is high in the error bounds (blue box), indicating that the mean for that year is much higher than the median and the concentration data for 2007 may be skewed (**Figure 64**) and therefore may be overestimates.

Table 46. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-04193500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1996	0.36	0.17
1997	0.31	0.14
1998	0.18	0.08
1999	0.11	0.05
2000	0.08	0.05
2001	0.18	0.12
2002	0.13	0.07
2003	0.70	0.27
2004	0.20	0.12
2005	0.47	0.19
2006	0.20	0.13
2007	2.08	1.44

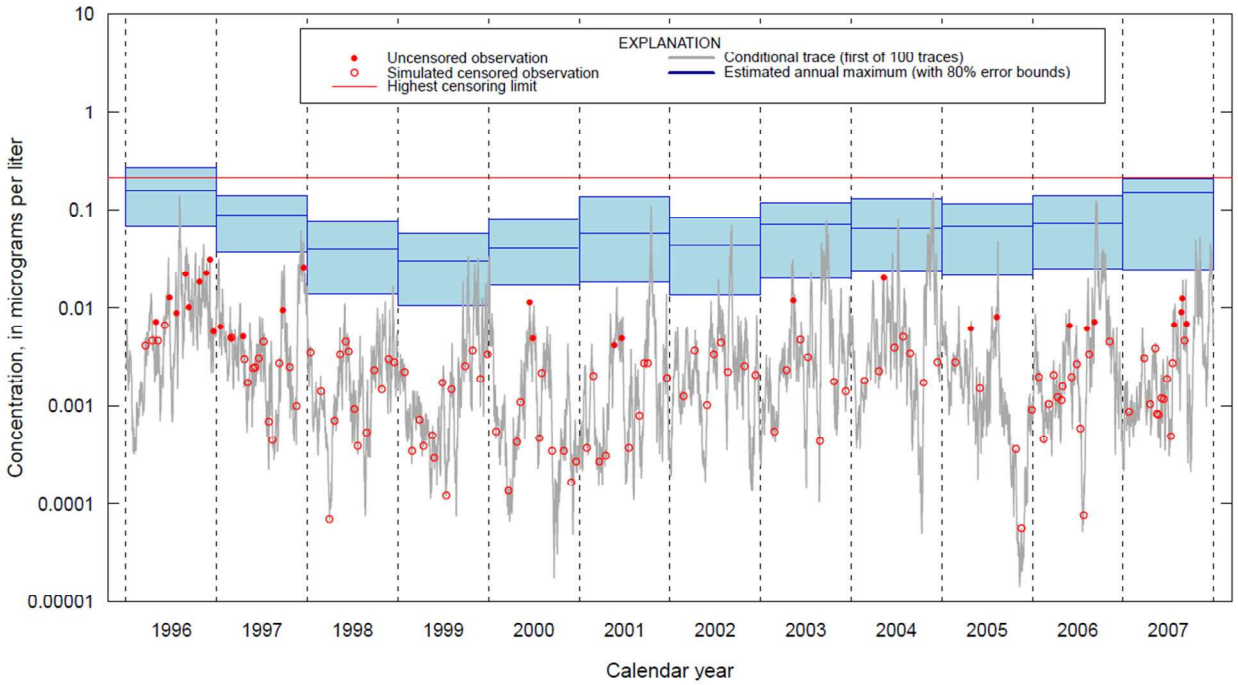

Figure 64. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-04193500 with High Mean in 2007

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 61** and **Figure 62** respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

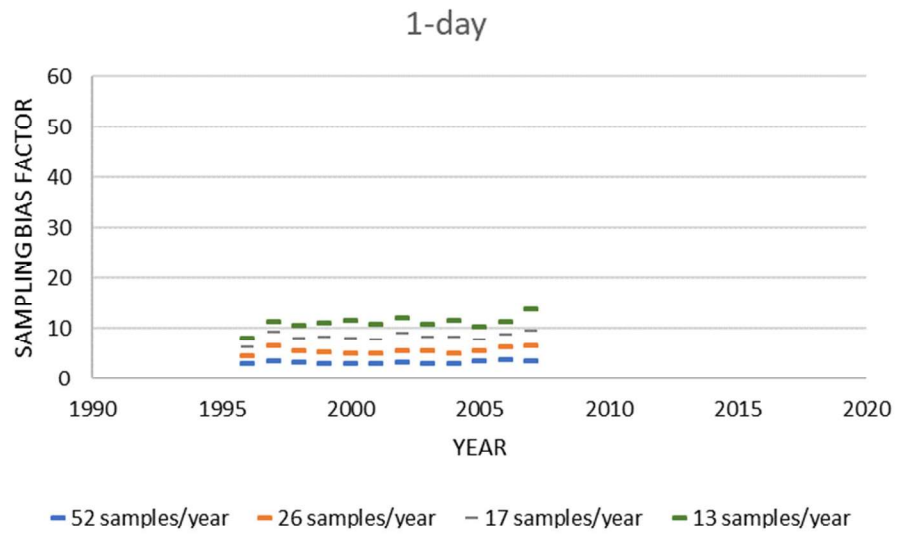

Figure 65. USGS Site 04193500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

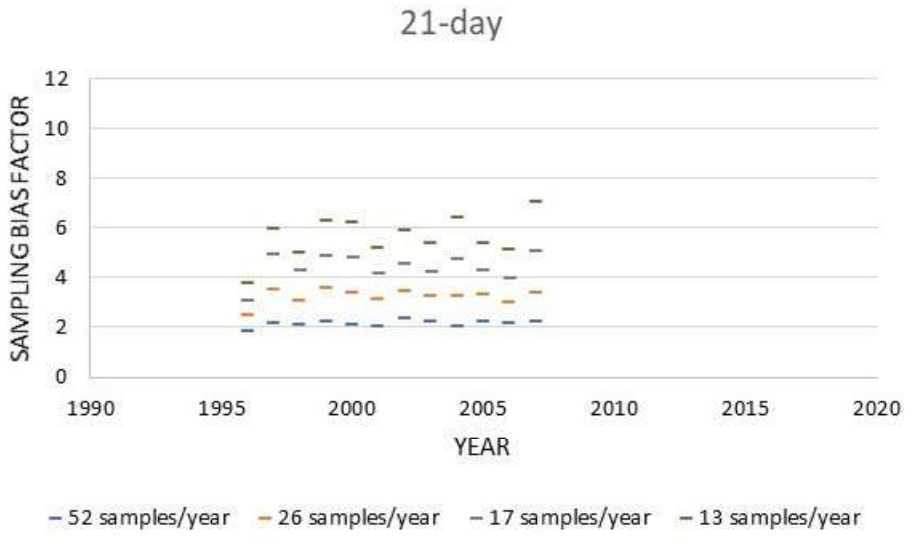

Figure 66. USGS Site 04193500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

SBFs for estimating the upper confidence interval on the 1-day and 21-day average concentration for all sampling intervals were below 11.5 and 8, respectively. The values were generally consistent across the years with the last year (2007) having the highest SBFs.

10. USGS-11274538

Site and Sampling Characterization

USGS site 11274538 (Orestimba Creek near Crows Landing, California) falls within a 180 mi^2 (465.2 km^2) watershed. The percent agriculture in 2006 in the sample site watershed was only 5% cropland and included a combined 74% of grassland and shrubs (**Figure 67.** Watershed Landcover Characteristics of Sampling Site USGS-11274538). This site is upstream of three community water system intakes, with two either on or receiving water through diversion of the San Joaquin River. These are the same three CWSs that the USGS site 11303500 is also upstream meaning water flow or pesticide loading from these sites would both likely occur at the downstream intake. The time of travel between the sample site on Orestimba Creek and each community water system intake is 1 day.

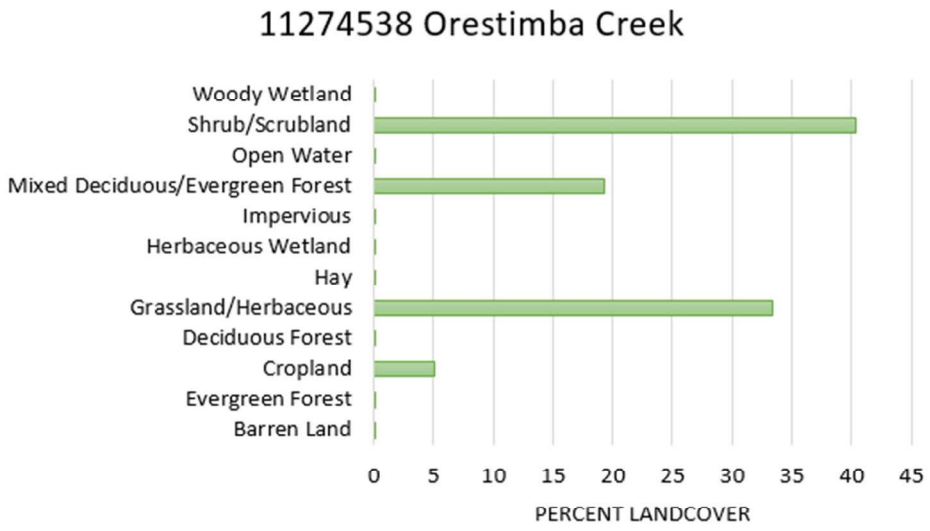

Figure 67. Watershed Landcover Characteristics of Sampling Site USGS-11274538

Based on available USGS data this site had a total of 163 detections out of 284 samples over 22 years between 1992 and 2017 (**Table 47**). Dow Agrosciences, currently known as Corteva Agriscience, also conducted a surface monitoring program in California on Orestimba Creek with daily and weekly sample collection (MRID 44711601). This program is described in more detail in the 2016 DWA (USEPA, 2016). USGS site 11274538 is "immediately above sampling location L1" where weekly samples were collected in 1996 and 1997 by Dow (Corteva Agriscience) for analysis of chlorpyrifos. **Table 47** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 47. USGS-11274538 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	44	40	91%	✓	21	✓
1993	40	22	55%	✓	4	✓
1994	1	1	100%	✓	0	✓
1995	1	1	100%	✓	0	✓
1996[2]	35	7	20%	✓	0	✓
1997[2]	26	15	58%	✓	0-3	✓
1998	14	9	64%	✓	0	✓
1999	16	5	31%	✓	0	✓
2000	20	15	75%	✓	2	✓
2001	43	24	56%	✓	8	✓
2002	18	8	44%	✓	0	✓
2003	16	8	50%	✓	0	✓
2004	8	5	63%	✓	0	✓
2005	6	4	67%	✓	0	✓
2006	4	3	75%	✓	0	✓
2007	0	—	—	✓	0	✓
2008	0	—	—	✓	0	✓
2009	1	1	100%	✓	0	✓
2010	15	5	33%	✓	0	✓
2011	0	—	—			
2012	2	0	0%			
2013	12	1	8%			
2014	3	0	0%			
2015	1	0	0%			
2016	4	2	50%			
2017	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

[2] 1996-1997 include additional data. Without additional data, 1996 has no samples and 1997 has 10 with 90% detection rate. No samples excluded without addition of data in 1997 and 3 samples excluded with extra data.

SEAWAVE-QEX Analysis

Initial SEAWAVE-QEX trials used chlorpyrifos concentration data from USGS. Nine years of data have 12 or more samples and a detection frequency greater than 25%, as shown in **Table 47**. The maximum measured concentration at this site is 0.3 μg/L (April 24, 1992). Several iterations of inputs to SEAWAVE-QEX were attempted to find the best fit to the data, such as including only the years 1998-2003 or 1998-2010. Ultimately, using data from the years 1998-2010 had the best model fit for USGS data although 1992-2010 also had an acceptable, low confidence fit and encompassed more years of data.

Given that additional data, from Dow Agrosciences (referred to Dow in this section, and is now Corteva Agriscience), was available with high frequency sampling directly downstream of the site, SEAWAVE-QEX output from the USGS data model run was compared to unadjusted measured chlorpyrifos data for

1996 and 1997 from Dow at site L1. These data added 51 samples with 13 detections (**Table 47**). The maximum measured concentration at L1 in 1996 and 1997 was 1.126 µg/L and 1.066 µg/L, respectively. Since the model fit by SEAWAVE-QEX is dependent on the input data, and the USGS data from 1992-2010 produced a poorer model fit than the data from 1998-2010, the latter was used for comparison to the more robust data set of USGS and supplemental Dow data from 1992-2010. Both the USGS (1998-2010) and USGS with Dow (1992-2010) data produced SEAWAVE-QEX results with medium confidence based on the diagnostic plots.

The data from USGS alone encompassed the highest measured concentration in the Dow data from the site (1.126 µg/L), however, the summary statistics used as point estimates of concentration (i.e., the maximum of the 99th 1- and 21-day average concentrations) did not reflect the maximum measured in the other data set. This can be seen in **Figure 68**, which shows the upper centiles (> 95 percentile) of all conditional simulations overlaid in blue, the maximum measured concentration as a red line, and each of the annual point estimates encircled along the top. Conversely, the USGS with Dow data in green has enough estimates beyond the measured maximum that the concentration is captured by the point estimates and better reflect the expected concentrations at that site. The full distributions of estimated concentrations from both runs, shown in **Figure 69**, shows that the addition of the Dow data increased the percentage of concentrations at the lower tail of the distribution. Overall, this comparison suggests that SEAWAVE-QEX may underestimate chlorpyrifos concentrations at the upper tail if run for datasets with high censorship and infrequent sampling (≥7-day sampling). Therefore, the USGS data along with the more frequent (i.e., weekly) sampling collected by Dow were combined and analyzed using SEAWAVE-QEX for the years 1992-2010 and used in the development of SBFs.

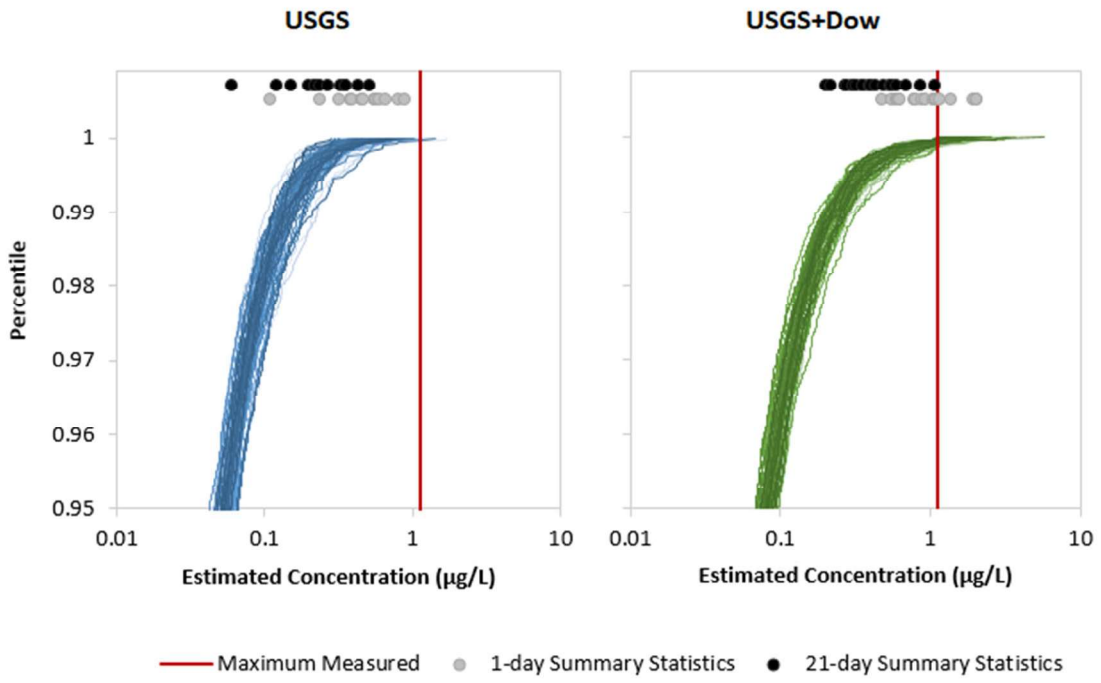

Figure 68. Upper Tail of Distribution of Estimated Concentrations from SEAWAVE-QEX and Associated Summary Statistics for USGS-11274538 With and Without Dow Monitoring Data

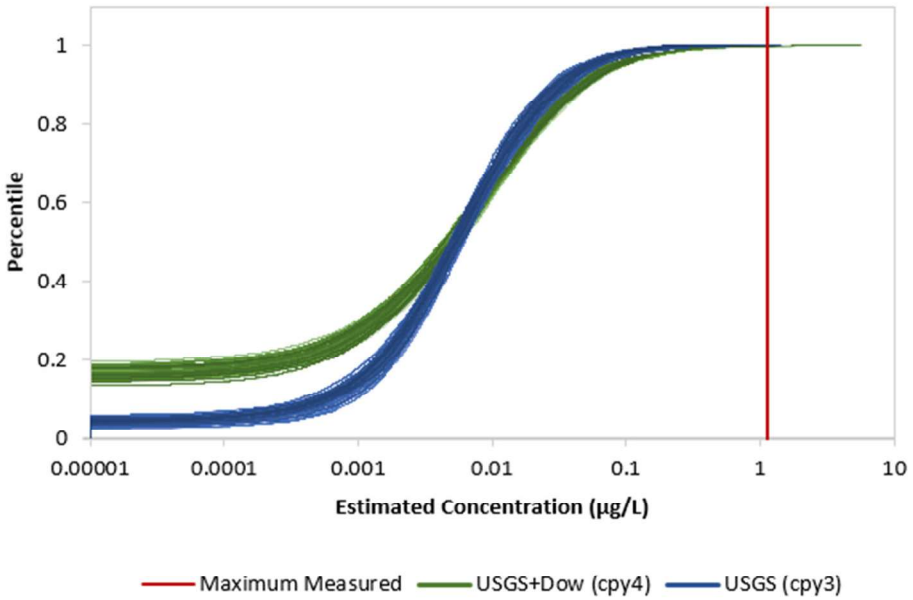

Figure 69. Distribution of Estimated Concentrations from SEAWAVE-QEX for USGS-11274538 With and Without Dow Monitoring Data Compared to Maximum Measured Concentration in 1996

SEAWAVE-QEX fit a shallow, long seasonal wave to the data and the 2xSSD on the model are approximately one order of magnitude. The season extends first of February to mid-October. The shape and season of the wave are very similar to that produced for the USGS data alone. The measured data are mostly within the 2xSSD lines and other model assumptions are satisfied (all diagnostic plots are provided in **ATTACHMENT 4**).

For just the USGS data from 1998-2010 (file name cpy3), the 80% confidence bounds on the estimated maximum for each year span up to an order of magnitude and all are below 1 µg/L. SEAWAVE-QEX fit a broad, shallow wave with a season from early April to early October and most measured concentrations fitting within the 2SSD bounds. Adjusted concentration is generally not correlated with MTFA but has a slight negative weak correlation with STFA. Concentration data trends somewhat upward over the years. The normalized residuals are somewhat positively skewed viewed across season and seem to be particularly skewed positive in 2000, 2006, and 2010. The empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 9.3 days.

When including the daily sampling data taken from another sample location on Orestimba Creek from 1996-1997 (file name cpy4), the 80% confidence bounds on the estimated maximum for each year similarly span up to an order of magnitude but include concentrations above 1 µg/L. The 80% error bounds for the two years with weekly samples added (i.e., 1996-1997) are much tighter (i.e., low uncertainty) than for the years of USGS data only, though the upper bound (i.e., top of the blue box) is not substantially higher than those of other years. SEAWAVE-QEX fits a single broad wave for these data as well, with an extended season from late January to mid-October and several measured data points falling outside the 2SSD bounds. Adjusted concentration is weakly negatively correlated with both MTFA and STFA; the negative correlation with STFA is present in both SEAWAVE-QEX runs but does not significantly impact the model. Measured concentrations trend somewhat downward from 1992-2010 and normalized residuals are still positively skewed in this run. There are several data points in season

that have the maximum residual value (+3); these are all from the extra measured data in 1996-1997 that are at higher concentrations. Additionally, 2006 and 2010 remain skewed positive relative to other years. The empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 7.7 days.

Table 48 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 48. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-11274538

Year	USGS		USGS+Dow	
	1-day Conc. (µg/L)	21-day Conc. (µg/L)	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	—	—	1.11	0.54
1993	—	—	0.48	0.20
1994	—	—	1.95	1.09
1995	—	—	1.04	0.56
1996	—	—	1.39	0.59
1997	—	—	2.05	0.69
1998	0.38	0.20	0.63	0.27
1999	0.32	0.15	0.88	0.43
2000	0.47	0.22	0.61	0.31
2001	0.11	0.06	0.61	0.22
2002	0.24	0.12	0.59	0.31
2003	0.45	0.27	0.94	0.40
2004	0.39	0.22	0.79	0.36
2005	0.60	0.24	1.07	0.39
2006	0.57	0.33	1.17	0.49
2007	0.80	0.51	2.06	0.87
2008	0.66	0.35	0.61	0.32
2009	0.55	0.35	0.55	0.36
2010	0.90	0.43	0.81	0.28

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 70** and **Figure 71**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

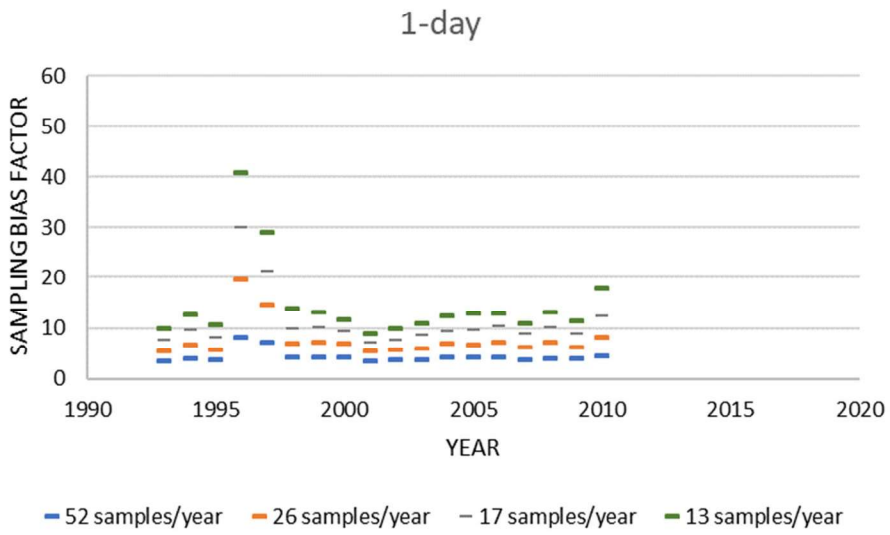

Figure 70. USGS Site 11274538: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

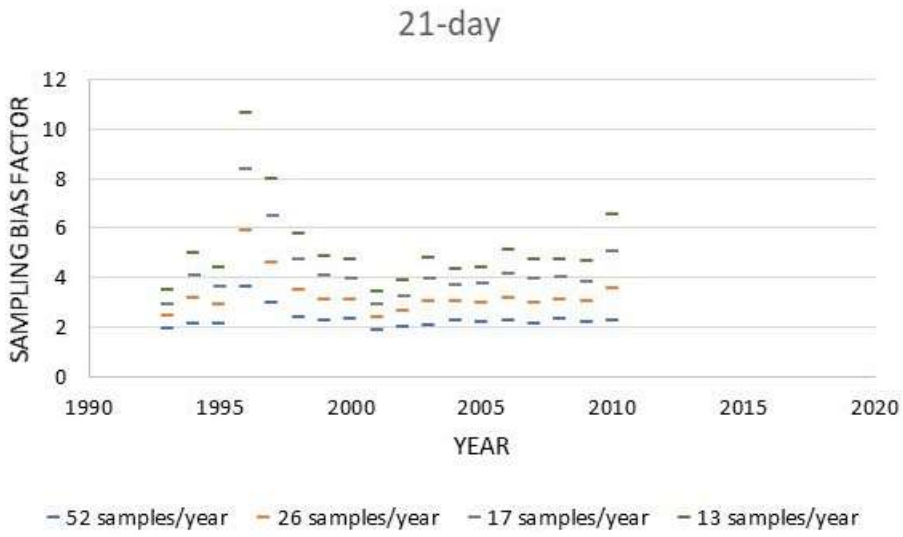

Figure 71. USGS Site 04193500: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

SBFs varied across years. The highest SBFs were estimated for the years (1996 and 1997) with the most monitoring data (i.e., daily). Like USGS-02174250, the highest SBFs are driven by measured concentrations. Again, this calls into question the ability to estimate accurate SBFs when infrequent sampling (i.e., non-daily) is conducted or misses peak occurrence concentrations.

11. USGS-03612500

Site and Sampling Characterization

USGS site 03612500 (Ohio River at Dam 53 near Grand Chain, IL) is in HUC-06 in a 203,100 mi^2 (526,000 km^2) drainage area. The watershed has roughly 20% cropland, 15% hay, and 46% deciduous forests (**Fig**).

The sampling location is upstream of several drinking water intakes serving community water systems, pulling from the Ohio River. Travel times from the sampling site to each intake is less than a day, making the site very relevant for source drinking water.

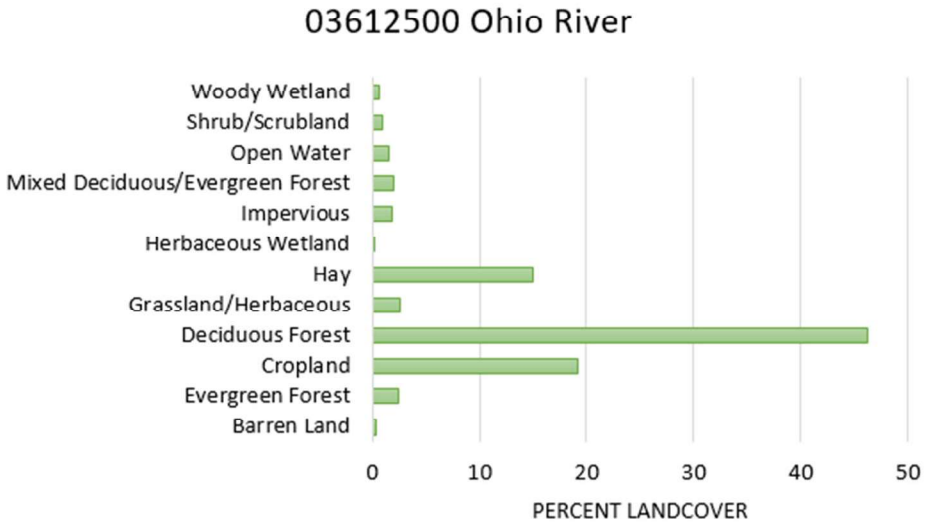

Figure 72. Watershed Landcover Characteristics of Sampling Site USGS-11274538

The site has 42 chlorpyrifos detections out of 262 samples from 1992-2014 (**Table 49**). **Table 49** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 49. USGS-03612500 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	10	10	100%	✓	0	✓
1993	1	1	100%	✓	0	✓
1994	0	—	—	✓		✓
1995	0	—	—	✓		✓
1996	12	10	83%	✓	0	✓
1997	15	6	40%	✓	0	✓
1998	13	3	23%	✓	0	✓
1999	11	3	27%	✓	0	✓
2000	13	7	54%	✓	0	✓
2001	15	1	7%			
2002	15	0	0%			
2003	13	0	0%			
2004	15	0	0%			
2005	14	0	0%			
2006	12	0	0%			
2007	13	0	0%			
2008	12	0	0%			
2009	12	0	0%			
2010	12	0	0%			
2011	15	1	7%			
2012	12	0	0%			
2013	14	0	0%			
2014	13	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The site has 42 chlorpyrifos detections out of 262 samples from 1992-2014, with only 3 years meeting the minimum criteria for SEAWAVE-QEX as outlined earlier (**Table 49**). The site does not have daily streamflow measurements to use as a covariate in SEAWAVE-QEX. However, in a USGS study (Aulenbach et al., 2007), streamflow from a nearby site is used in conjunction with water quality data from this site. Therefore, streamflow from USGS-03611500 (Ohio River at Metropolis, IL) is also used in this analysis as a surrogate for USGS-03612500. The site was run in SEAWAVE-QEX unsuccessfully using years 1996-2000 with and without adding a constant (0.004 and 0.012). The analysis was repeated with a start date of 1992, since 1992 has 10 samples with 100% detection frequency. Including 1992 improved the fit and was considered acceptable after subtracting a constant of 0.012 within the model.

The 80% confidence bounds on the estimated maximum for each year span less than an order of magnitude. The estimated concentrations have a clear downward trend from 1992 to 2000 of nearly an order of magnitude. Similarly, the adjusted concentrations trend significantly downward over the timeframe analyzed. However, it is notable that several measured concentrations from 1996-1998 are in

the mid-range of the measured concentrations from 1992, implying that the estimated concentrations for 1992 continue to be relevant for peak values throughout the time period. There are two shallow seasonal waves of similar amplitude; one season spanning early February to late June and the second from late October to late December. All but one measured concentration is within the 2SSD bounds. There is a significant (α=0.05) negative correlation of adjusted concentration with MTFA and weakly negative correlation with STFA. The normalized residuals are mostly centered on zero with slightly positive skew seeming to result from data in 2000. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 20.5 days.

Table 50 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 50. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-03612500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	0.35	0.23
1993	0.20	0.14
1994	0.32	0.21
1995	0.10	0.068
1996	0.059	0.042
1997	0.036	0.023
1998	0.046	0.033
1999	0.031	0.023
2000	0.040	0.021

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 73** and **Figure 74**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

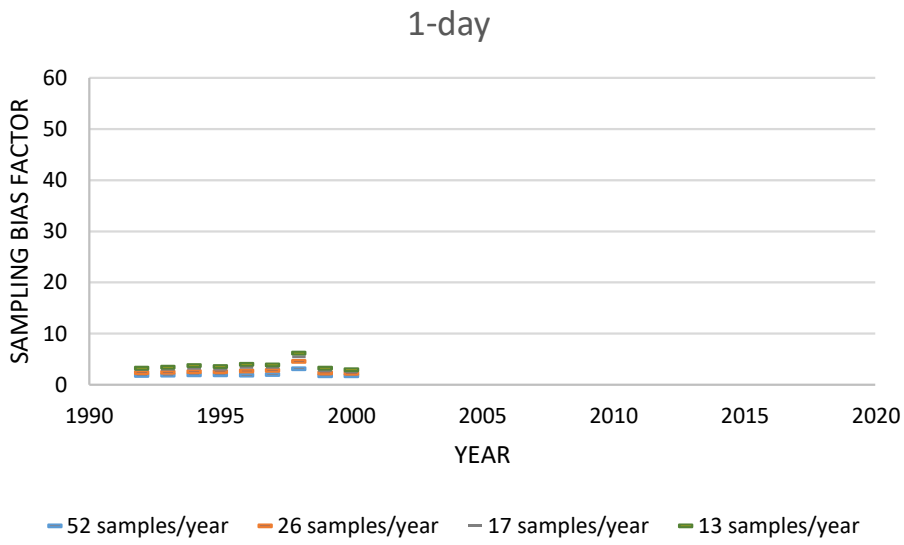

Figure 73. USGS Site 03612500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

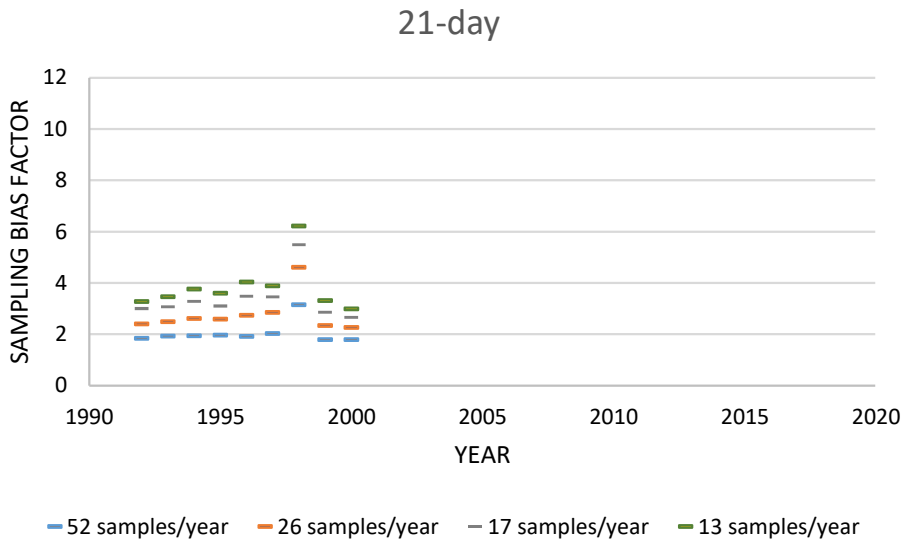

Figure 74. USGS Site 03612500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

SBFs are consistent across years except 1998. There is nothing notable about the diagnostic plots that would suggest that the estimated concentrations from SEAWAVE-QEX would be out of line for 1998. Like USGS site 03612500, the highest bias factors are driven by measured concentrations. The confidence bounds on the 1998 simulation are tight around the measured concentration. Giving confidence in the estimated SBFs. Again, this calls into question the ability to estimate accurate SBFs using SEAWAVE-QEX when infrequent (i.e., non-daily) sampling is conducted or misses peak occurrence concentrations.

12. USGS-11447360

Site and Sampling Characterization

USGS site 11447360 (Arcade Creek near Del Paso Heights, CA) falls has a 38 mi^2 (98.5 km^2) urban watershed in HUC 18, with 42% impervious surfaces and no cropland (**Figure 75.** Watershed Landcover Characteristics of Sampling Site USGS-11447360). The water travel time is noted to be less than a day to a community water system intake.

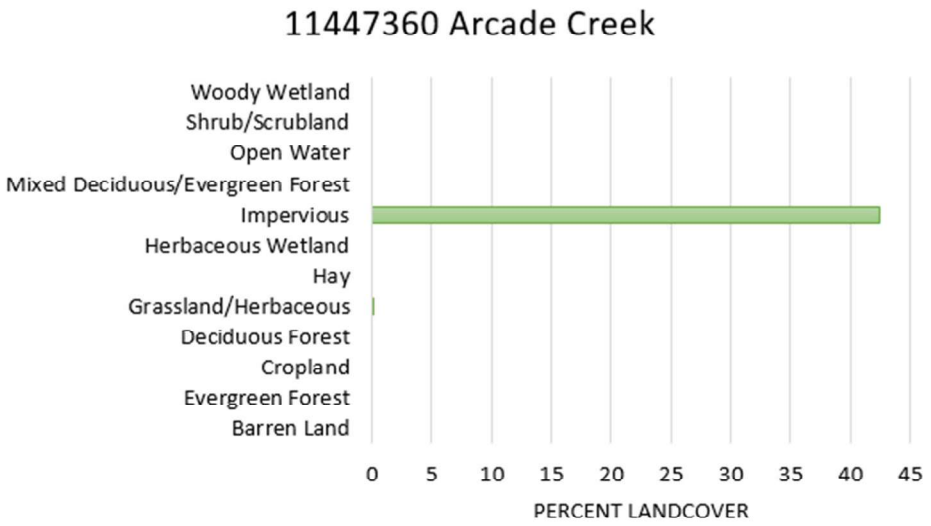

Figure 75. Watershed Landcover Characteristics of Sampling Site USGS-11447360

This site had a total of 57 detections out of 128 samples between 1996 and 2012. Four years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 51**. SEAWAVE-QEX analysis is described in the subsection below.

Table 51. USGS-11447360 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	2	2	100%			
1997	24	18	75%	✓	0	✓
1998	4	2	50%	✓	0	✓
1999	0	—	—	✓	0	✓
2000	0	—	—	✓	0	✓
2001	10	6	60%	✓	0	✓
2002	9	2	22%	✓	0	✓
2003	9	4	44%	✓	0	✓
2004	13	6	46%	✓	0	✓
2005	20	8	40%	✓	0	✓
2006	4	3	75%	✓	0	✓
2007	4	0	0%	✓	0	✓
2008	13	6	46%	✓	0	✓
2011	5	0	0%			
2012	11	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1997-2008 were input into SEAWAVE-QEX. Other subsets of years were explored; however, the best fit was determined to be for the period from 1997 to 2008 with the addition of a small constant (0.0012), which resulted in an acceptable model fit of low confidence. The maximum measured concentration at this site is 0.04 μg/L (January 13, 1997).

The 80% error bounds on the estimated maximum are <1 μg/L for each year and span much less than 1 order of magnitude. The seasonal wave is very shallow in an extended season from September to early May, which is the wetter time of year in California, with few measured concentrations outside of the 2SSD bounds. Adjusted concentration has a significant positive correlation with MTFA and weakly positive correlation with STFA. The adjusted concentrations decrease over time (1997 to 2008) and the residuals are centered on zero. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function at time intervals less than the average. However, there is more uncertainty at the shortest time intervals (large 95% confidence limits without much overlap). The CTS is 22.6 days and all other model assumptions are satisfied (diagnostic plots are provided in **ATTACHMENT 4**).

Further analysis of the streamflow data indicates that results from SEAWAVE-QEX for this site may not be appropriate to use quantitatively, based on feedback from the SAP. This is because 6.5% of the streamflow values are zero for this site (see **Figure 76**). Therefore, SEAWAVE-QEX chemographs from this site were not used for the development of SBFs.

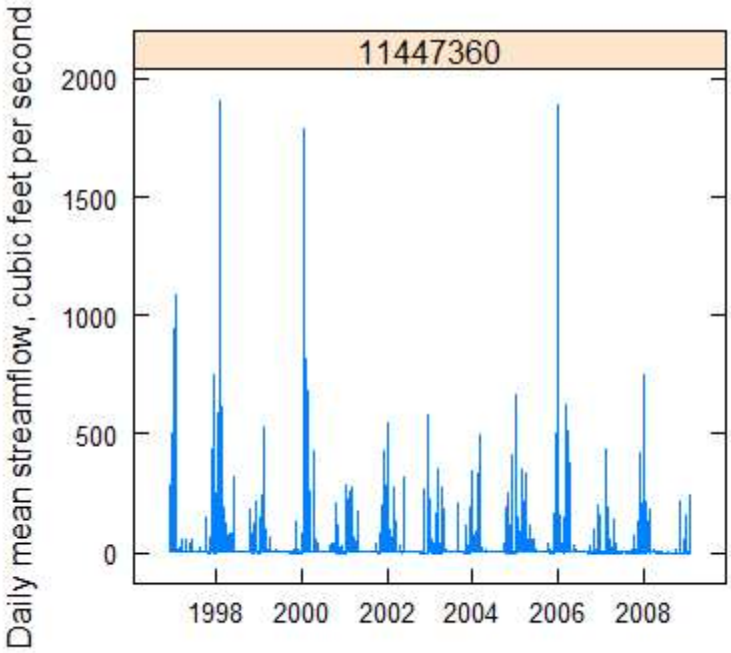

Figure 76. USGS-04193500 Streamflow Data

13. USGS-14201300

Site and Sampling Characterization

USGS site 14201300 (Zollner Creek near Mount Angel, OR) is in a 15.7 mi^2 (40.6 km^2) watershed in HUC 17 with 53% cropland and 35% hay landcover (**Figure 77.** Watershed Landcover Characteristics of Sampling Site USGS-14201300). The time of travel of water from the sampling site to a community water system intake is one day.

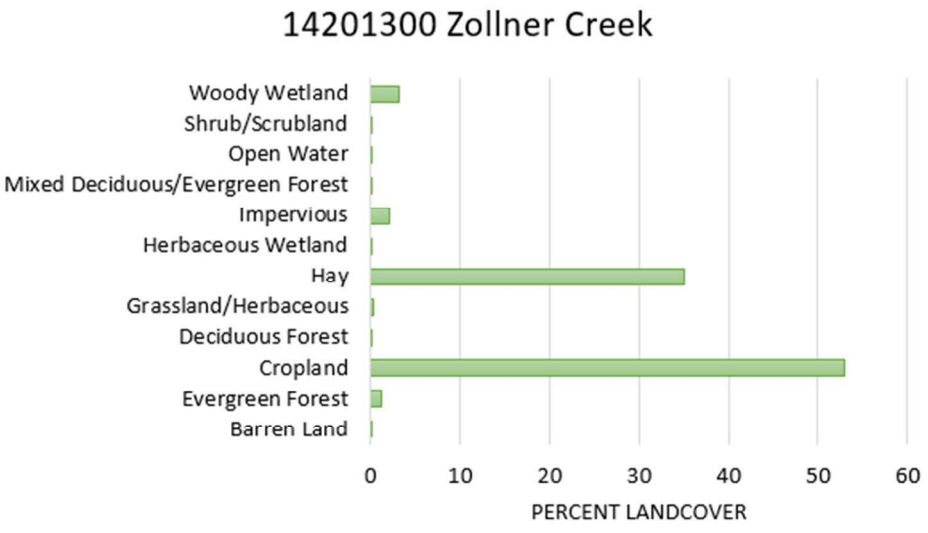

Figure 77. Watershed Landcover Characteristics of Sampling Site USGS-14201300

This site had a total of 205 detections out of 354 samples over 25 years between 1993 and 2019. Twelve years of data have 12 or more samples and a detection frequency greater than 25% (**Table 52**) spanning from 1993-2018.

Table 52. USGS-14201300 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	14	9	64%	✓	8	
1994	11	8	73%	✓	0	
1995	5	3	60%	✓	0	
1996	3	2	67%	✓	0	
1997	9	7	78%	✓	0	
1998	11	5	45%	✓	0	
1999	12	5	42%	✓	0	
2000	11	9	82%	✓	0	
2001	19	14	74%	✓	0	
2002	24	20	83%	✓	0	
2003	13	4	31%	✓	0	
2004	9	8	89%	✓	0	
2005	6	6	100%	✓	0	
2006	4	4	100%	✓	0	
2007	5	5	100%	✓	0	
2008	17	14	82%	✓	0	
2009	0	—	—	✓	n/a	
2010	0	—	—	✓	n/a	
2011	5	5	100%	✓	0	
2012	23	19	83%	✓	0	
2013	24	6	25%	✓	0	
2014	24	9	38%	✓	0	
2015	31	7	23%	✓	0	
2016	24	11	46%	✓	0	
2017	24	13	54%	✓	0	
2018	23	11	48%	✓	0	
2019	3	1	33%		n/a	

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The years 1993-2018 were included in the SEAWAVE-QEX modeling with default parameters, resulting in a low confidence fit. Due to the limitations of site relevance due to intermittent flow, additional fits were not pursued further.

The 80% error bounds on the estimated maximum vary in size by year, but all are <1 µg/L and appear to span less than 1 order of magnitude. The seasonal wave is very shallow in an extended season from late September to late June, with few measured concentrations outside of the 2SSD bounds. Adjusted concentration has a weakly positive correlation with MTFA and significantly

positive correlation with STFA; however, both diagnostic plots indicate that there are a number of flow days where the flow anomaly does not correlate with concentration at all, typically observed for sites with zeros in the flow data (see **Figure 78**).

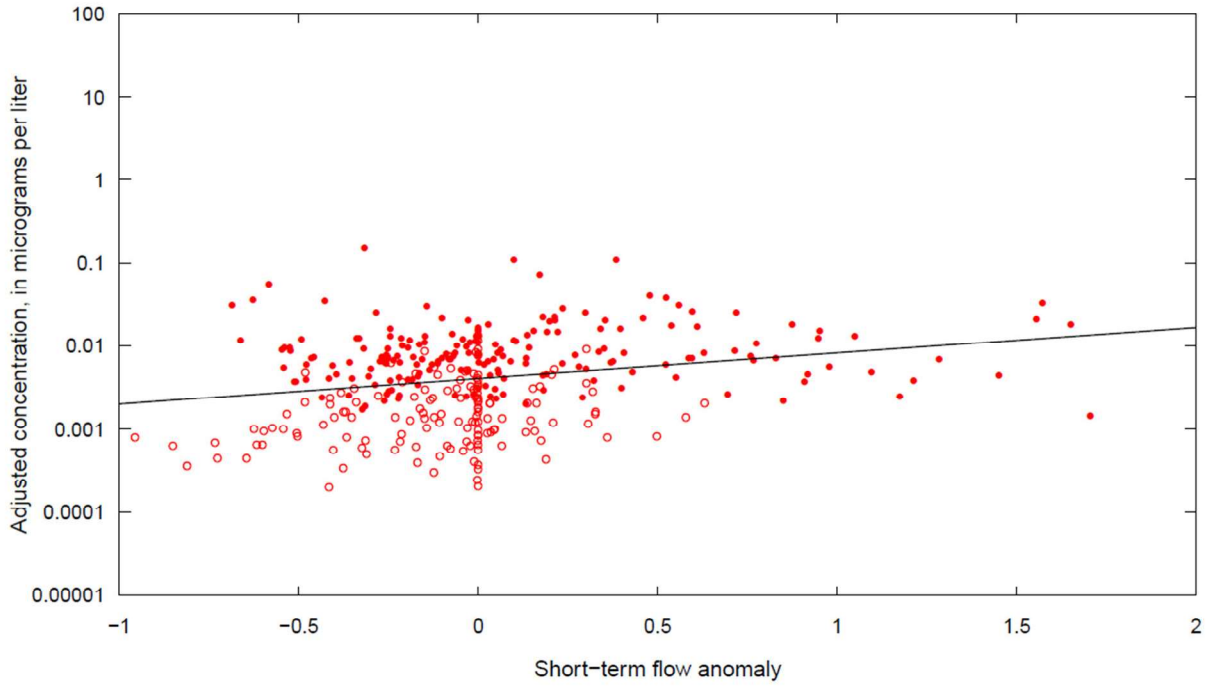

Figure 78. Correlation Between Adjusted Concentration and Short-term Flow Anomaly for USGS-14201300

The adjusted concentrations decrease over time (1993 to 2018) and the residuals are centered on zero with a few individual residuals skewing positive. By year, the residuals skew positive from roughly 2001 to 2008, suggesting that further subsets of the data (e.g., 2012 to 2018) may produce improved results. The 95% confidence limits on the empirical correlogram does not always overlap with the fitted exponential correlation function at time intervals less than the average; when there is not overlap, the empirical correlogram is lower, indicating the potential to overestimate concentrations. The CTS is 43.9 days.

While the flow data for the site does not have measurements of zero, the seasonality of flow (**Figure 79**) and unusual diagnostic plots have decreased confidence in quantitative use of the SEAWAVE-QEX output to an unacceptable level. Therefore, SEAWAVE-QEX chemographs from this site were not used for the development of SBFs.

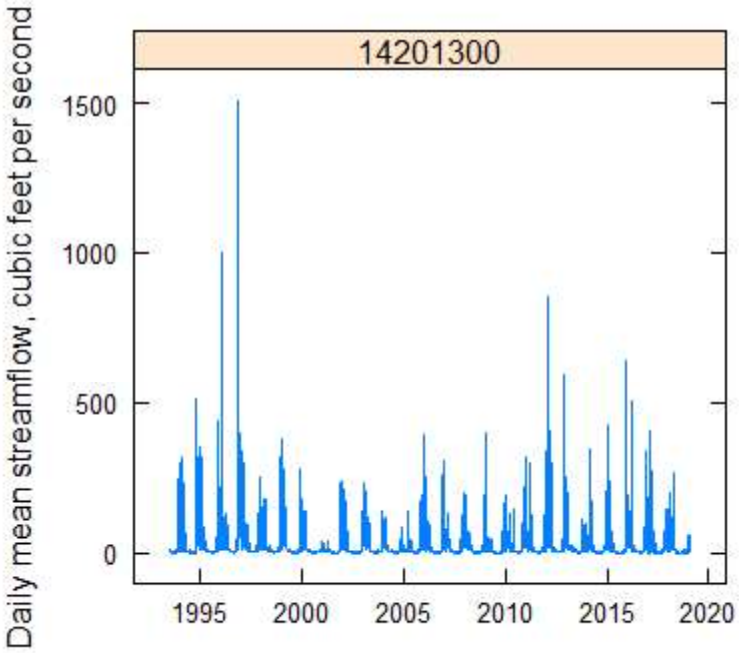

Figure 79. USGS-14201300 Streamflow Data

14. OREGONDEQ-32010-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32010-ORDEQ sampling site (West Prong Little Walla Walla River south of Stateline Road, OR) is in a 24.1 mi^2 (62.3 km^2) watershed in HUC 17 with 55% evergreen forest, 14.5% grassland, 12% cropland and <1% hay landcover (**Figure 80.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32010-ORDEQ). This sample site is located upstream of two community water system intakes. Based on flow data, this site is within a 2-day travel time of one community water system intake and within in a 3-day travel time of a second community water system intake.

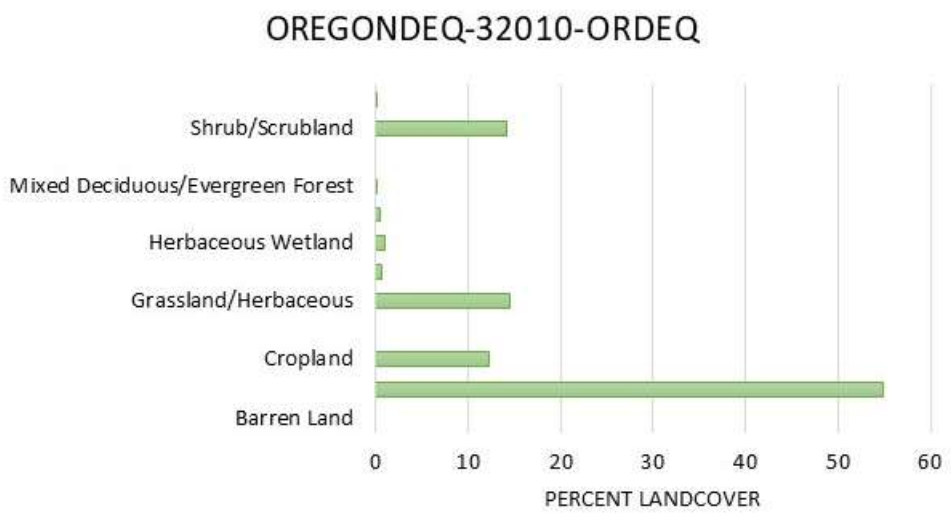

Figure 80. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32010-ORDEQ

A summary of the data collected for OREGONDEQ-32010-ORDEQ is provided in **Table 53**. Sample collection began in 2005 and continues today. Between 9 and 15 samples have been collected each year. Detection frequencies at this site are high in most years. All quantifiable detections at this site occurred in the months of March or April (**Figure 81**).

Table 53. OREGONDEQ-32010-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	15	6	40%
2006	14	5	36%
2007	10	3	30%
2008	12	6	50%
2009	14	3	21%
2010	10	2	20%
2011	10	1	10%
2012	10	3	30%
2013	11	1	9%
2014	11	2	18%
2015	13	1	8%
2016	12	2	17%
2017	12	2	17%
2018	10	4	40%
2019	9	0	0%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

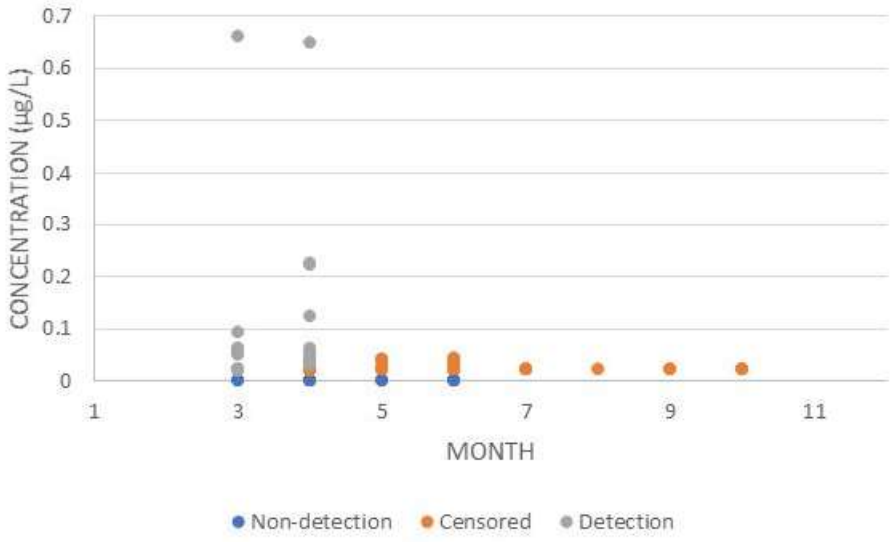

Figure 81. OREGONDEQ-32069-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linear interpolated) 21-day average concentration. The results are shown in **Table 57**.

Table 54. Sampling Bias Factor Analysis Summary for OREGONDEQ-32010-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2009	14	0.65	0.14	54.8 (22.2)	11.5 (8.9)	35.6 (14.41)	1.6 (1.2)
Bracketed values are for sub-set of SBFs for years 2005-2015							

15. OREGONDEQ-32068-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32068-ORDEQ sampling site (Noyer Creek at Hwy 212, St. Paul Lutheran Church (North Fork, Deep Creek, Clackamas, OR) is in a 33.3 mi^2 (86.3 km^2) watershed in HUC 17 with 7.1% evergreen forest, 8.4% cropland, 39.3% hay landcover and 9.7% impervious (**Figure 82.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32068-ORDEQ). This sample site is located upstream of 5 community water system intakes. Based on flow data, all 5 of these community water system intakes are located within a day's travel time from the monitoring site.

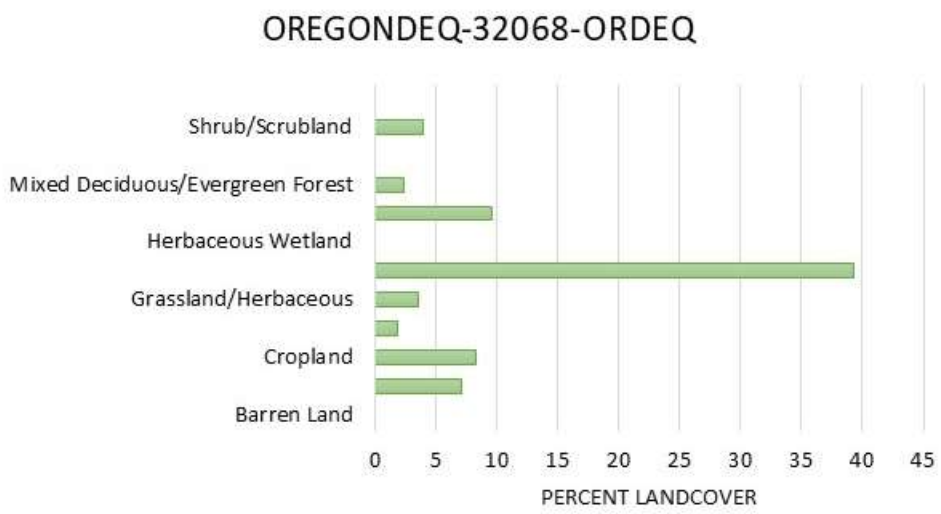

Figure 82. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32068-ORDEQ

A summary of the data collected for OREGONDEQ-32068-ORDEQ is provided in **Table 55**. Sample collection at this site began in 2005 and is ongoing. Detection frequencies are high with between 6 and 16 samples collected per year. With the highest detection frequency occurring in 2016. Quantifiable detections at this site occur throughout the year, mainly March through December with peak measured concentrations occurring in May and October.

Table 55. OREGONDEQ-32068-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	12	5	42%
2006	16	6	38%
2007	14	5	36%
2008	10	1	10%
2009	9	4	44%
2010	6	2	33%
2011	8	2	25%
2012	11	2	18%
2013	15	4	27%
2014	13	0	0%
2015	15	2	13%
2016	13	9	69%
2017	14	4	26%
2018	13	4	31%
2019	8	1	13%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

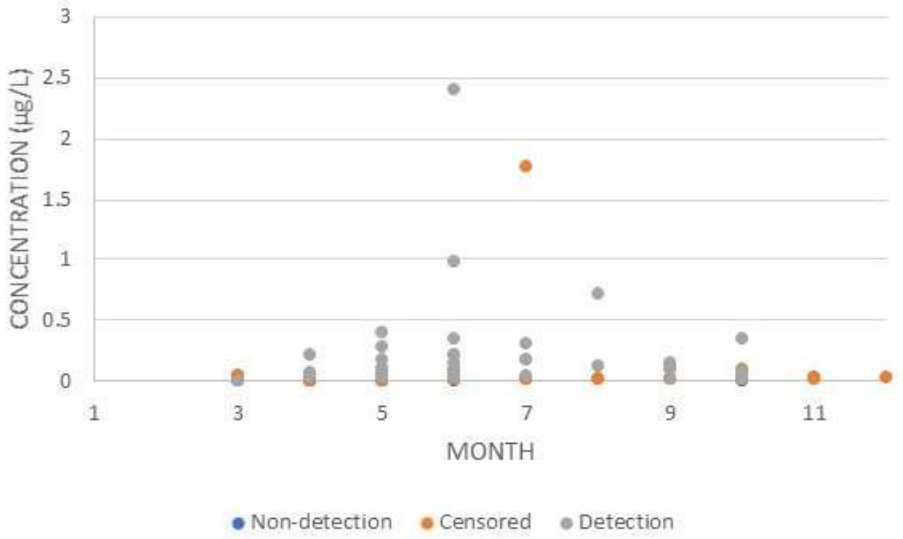

Figure 83. OREGONDEQ-32068-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linear interpolated) 21-day average concentration. The results are shown in **Table 56**.

Table 56. Sampling Bias Factor Analysis Summary for OREGONDEQ-32068-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2007	14	2.4	1.7	54.8 (22.2)	11.5 (8.9)	131.5 (53.3)	19.3 (14.9)
2015	15	1.8	0.7	54.8 (22.2)	11.5 (8.9)	97.0 (39.3)	7.6 (5.6)
2016	13	0.7	0.6	54.8 (22.2)	11.5 (8.9)	39.6 (16.0)	6.5 (5.0)
Bracketed values are for sub-set of SBFs for years 2005-2015							

16. OREGONDEQ-32069-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32069-ORDEQ sampling site (NF Deep Creek at Springwater trail, Boring, between 2nd and 3rd towers from trailhead (Clackamas, OR)) is in a 19.5 mi^2 (50.6 km^2) watershed in HUC 17 with 7.1% evergreen forest, 27.3% cropland and 30.3% hay landcover (**Figure 84.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32069-ORDEQ). This sample site is located upstream of 5 community water system intakes. All community water system intakes are located within a day's travel time of the monitoring site. These are the same community water system intakes downstream of OREGONDEQ-32068-ORDEQ.

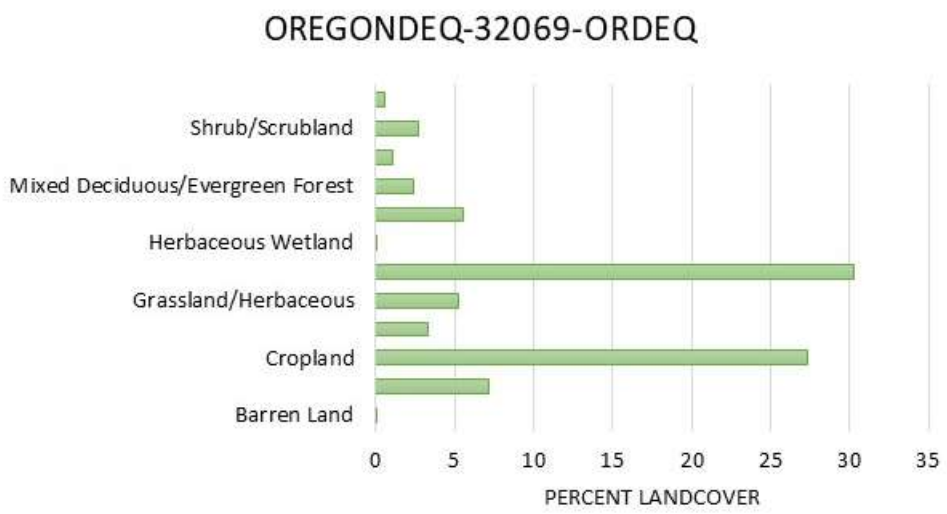

Figure 84. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32069-ORDEQ

A summary of the data collected for OREGONDEQ-32069-ORDEQ is provided in **Table 57**. Sample collection began in 2005; however, the last year of sampling collection at this site ended in 2011. Sample frequency ranged from 5 to 16 per year. Detection frequency was high in those years with the most samples collected. Quantifiable detections at this site occur throughout the year except for January and February. The maximum measured concentrations occurred in May and October (**Figure 85**).

Table 57. OREGONDEQ-32069-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	12	8	67%
2006	16	1	6%
2007	13	7	54%
2008	9	1	11%
2009	9	0	0%
2010	5	1	20%
2011	8	0	0%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

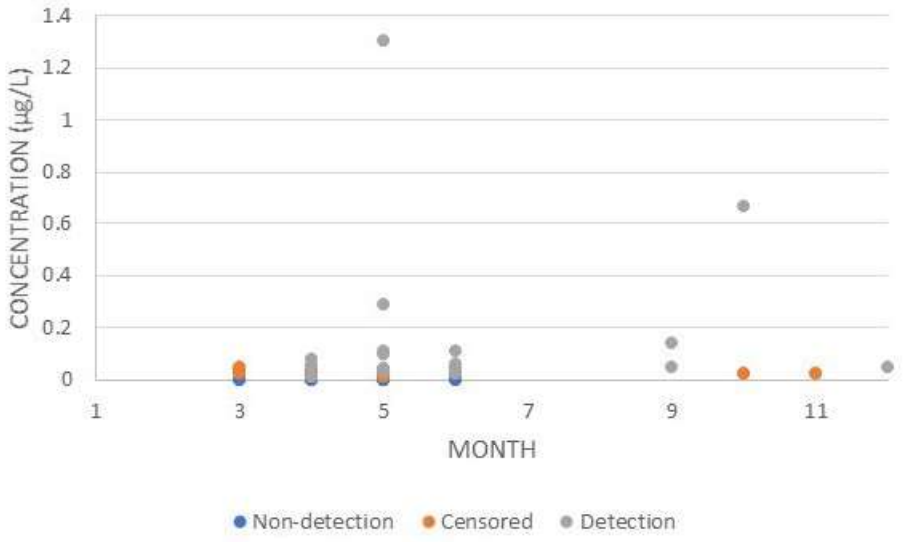

Figure 85. OREGONDEQ-32069-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. The results are shown in **Table 58**.

Table 58. Sampling Bias Factor Analysis Summary for OREGONDEQ-32069-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2007	13	1.3	0.4	54.8 (22.2)	11.5 (8.9)	71.2 (28.9)	4.8 (3.7)
Bracketed values are for sub-set of SBFs for years 2005-2015							

17. OREGONDEQ-34235-ORDEQ

Site and Sampling Characterization

OREGONDEQ-34235-ORDEQ sampling site (Middle Cozine at Old Sheridan Road (McMinnville, OR)) is in a 73.5 mi^2 (190.3 km^2) watershed in HUC 17 with 2.8% evergreen forest, 35.7% cropland, 9.4% hay landcover and 11.1% impervious (**Figure 86.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-34235-ORDEQ). This sample site is located upstream of 2 community water system intakes. Both community water system intakes have a 1-day travel time between the sampling site and the intake.

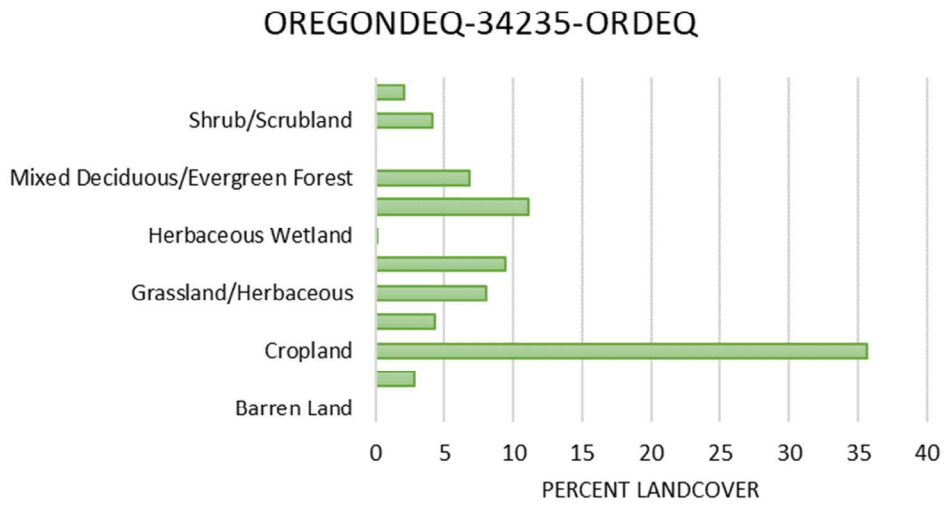

Figure 86. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-34235-ORDEQ

A summary of the data collected for OREGONDEQ-34235-ORDEQ is provided in **Table 59**. Sample collection at this site began in 2007 and is ongoing. Detection frequencies are much lower at this site compared to other Oregon sites. Sample collection ranged between 7 and 15 samples per year. With the highest detection frequency occurring in 2017. Quantifiable detections at this site occur throughout the growing season (**Figure 87)**. The highest sample value for this site is for a censored sample collected on August 10, 2018. Additional information on these reported values was solicited but not additional information became available as of the writing of this assessment.

Table 59. OREGONDEQ-34235-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2007	14	0	0%
2008	10	0	0%
2009	7	0	0%
2010	6	0	0%
2011	8	0	0%
2012	12	2	17%
2013	15	0	0%
2014	14	0	0%
2015	15	0	0%
2016	14	0	0%
2017	13	3	23%
2018	13	1	8%
2019	8	0	0%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%

[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

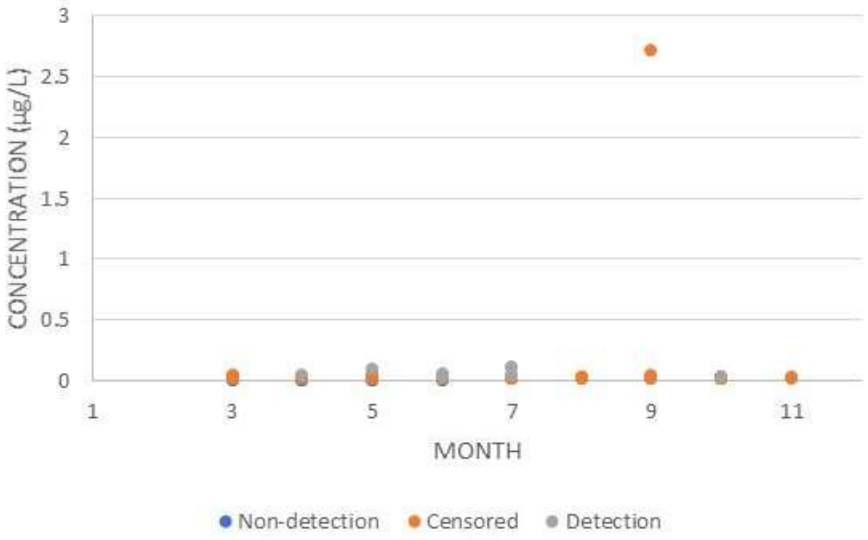

Figure 87. OREGONDEQ-34235-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFS for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. The results are shown in **Table 60**.

Table 60. Sampling Bias Factor Analysis Summary for OREGONDEQ-34235-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2018	13	2.72[1]	1.4	54.8 (22.2)	11.5 (8.9)	74.5 (30.2)	16.4 (12.7)

Bracketed values are for sub-set of SBFs for years 2005-2015
[1] value is a censored concentration.

18. OREGONDEQ-37639-ORDEQ

Site and Sampling Characterization

OREGONDEQ-37639-ORDEQ sampling site (West Fork Palmer Creek at SE Palmer Creek Road) is in a 73.5 mi^2 (465.2 km^2) watershed in HUC 17 with 56.8% cropland, and 26.3% hay landcover (**Figure 88.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-37639-ORDEQ). This sample site is located upstream of 2 community water system intakes. Based on flow data, both community water system intakes are within a 1-day travel time from the monitoring site. These community water systems are the same systems in line with OREGONDEQ-34235-ORDEQ.

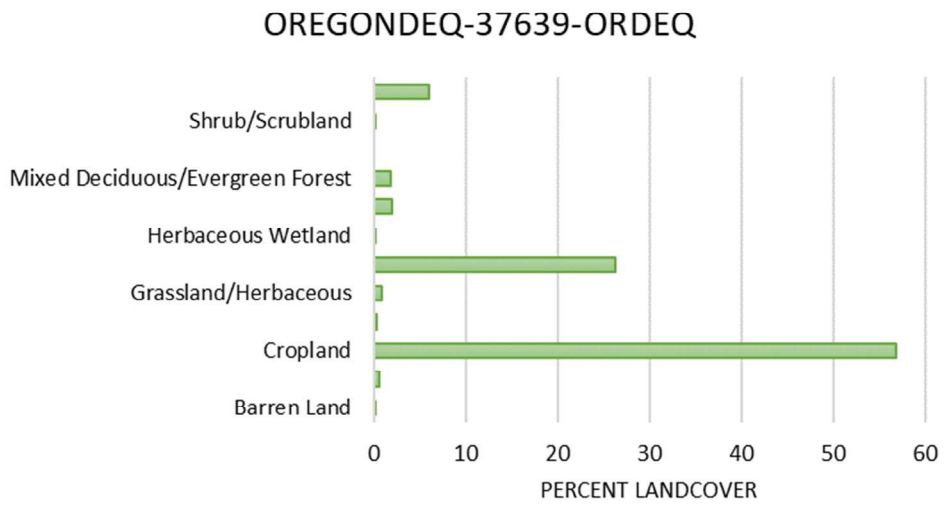

Figure 88. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-37639-ORDEQ

A summary of the data collected for OREGONDEQ-34235-ORDEQ is provided in **Table 61**. Sample collection occurred between 2014 and 2018. Samples number ranged between 13 and 15 while detection frequencies ranged between 7 and 46 percent. With the highest detection frequency occurring in 2017.The highest quantifiable detections at this site occur in April (**Figure 89**).

Table 61. OREGONDEQ-37639-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2014	14	4	29%
2015	15	1	7%
2016	14	2	14%
2017	13	6	46%
2018	13	1	8%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

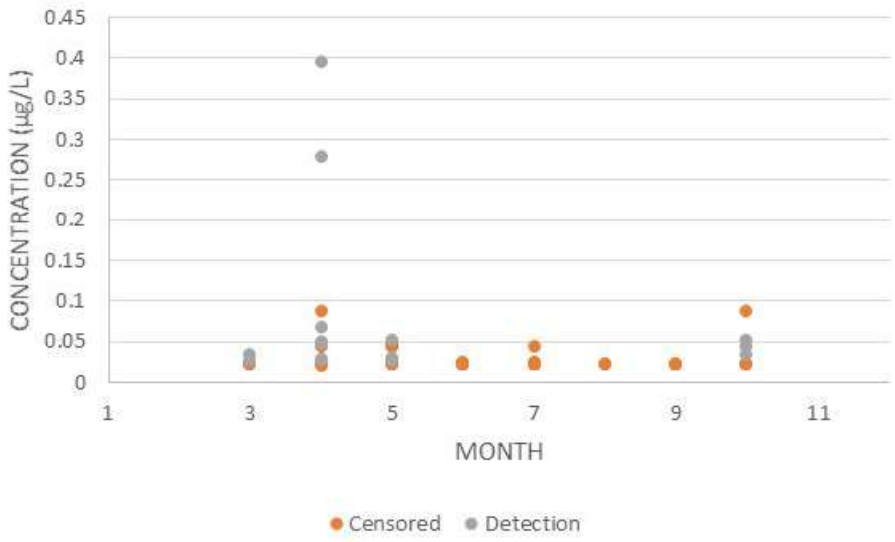

Figure 89. OREGONDEQ-37639-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. This site was identified for additional analysis using the 1-day maximum measured concentration when estimating upper confidence bound for the 21-day average. Estimation on the 21-day average concentration for estimation of the upper bound are shown in **Table 62**.

Table 62. Sampling Bias Factor Analysis Summary for OREGONDEQ-34235-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2014	14	0.09	0.22 (0.20)	-	2.5 (2.3)	-	23. (1.8)
Bracketed values are for sub-set of SBFs for years 2005-2015							