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' Opposition to Petitioners' Motion for Stay Pending Review

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INTRODUCTION

Petitioners' motion to stay EPA's August 2021 Final Rule under the Federal Food, Drug, and Cosmetic Act ("FFDCA") revoking chlorpyrifos tolerances it found unsafe should be denied.

To begin, the Court lacks subject-matter jurisdiction over the petition, and therefore lacks jurisdiction to grant a stay. As explained in EPA's motion to dismiss, the Final Rule, which was issued under 21 U.S.C. § 346a(d)(4)(A)(i) is not an action subject to immediate judicial review under the FFDCA judicial review provision, 21 U.S.C. § 346a(h)(1). *See* Respondents' Mot. to Dismiss.

Even if jurisdiction were not a bar, Petitioners are not entitled to a stay. *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 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. EPA never formally 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, Petitioners ask this Court to stay EPA's revocation of tolerances for *all* uses of chlorpyrifos, not just the 11 so-called "designated safe uses."

Second, Petitioners' allegations of harm 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 risk of harm from chlorpyrifos exposures, EPA found the existing tolerances of chlorpyrifos 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 take action within 60 days to grant a revocation petition pending since 2007. Petitioners' motion for a stay of the revocation is contrary to the FFDCA and the public interest, and stands in at least significant 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

The FFDCA regulates pesticide residues on food under a strict safety standard. Under that Act, 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). Pursuant to 1996 amendments to 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). In addition, 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 their 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." In contrast to the risk-only safety standard in the FFDCA, FIFRA's "unreasonable adverse effects" standard requires consideration of both risks and benefits when evaluating whether to register pesticidal uses. *Id.* §§ 136a(c)(5), 136(bb).

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years. *Id.* § 136a(g)(1)(A)(iii)-(iv). During "registration review," EPA must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account any new relevant scientific information, and any 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(c)(1), (5). EPA may propose measures to mitigate such 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 EPA can initiate cancellation proceedings under § 136d(b).

B. Factual background

1. Prior Ninth Circuit litigation

In 2007, public interest groups petitioned EPA to revoke all existing chlorpyrifos tolerances. EPA failed to issue a formal response to the petition, and on August 10, 2015, the U.S. Circuit Court of Appeals for the Ninth Circuit 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). EPA published a proposed rule revoking all chlorpyrifos tolerances and "encourage[d] interested parties to comment." Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080 (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 North America v. EPA,* 840 F.3d 1014, 1015 (9th Cir. 2016). On March 29, 2017, EPA denied the petition, departing from its proposal and leaving the tolerances in effect. 82 Fed. Reg. 16,581 (Apr. 5, 2017). On July 18, 2019, in response to another Ninth Circuit order, EPA issued a final order denying all objections. 84 Fed. Reg. 35,555 (July 24, 2019); *League of United Latin Am. Citizens v. EPA*, 922 F.3d 443 (9th Cir. 2019) (en banc).

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the original petition and the objection petition, 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 remanded the matter to EPA expressly precluding further 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. *Id.* at 703. "That response must be a final regulation 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.* The Ninth Circuit also directed EPA to "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 704.

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 Interim Decision for the Registration Review of Chlorpyrifos (PID) (Ex. A). 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, in only specific geographic areas and with restricted application rates: alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and spring and winter wheat. *Id.* at 40-41. EPA proposed that all other existing uses of chlorpyrifos be cancelled under FIFRA. *Id.* at 40. Multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses. *See* Decl. of Dr. M. E. Reaves (Ex. B) ¶ 23. Carrying out the modifications proposed in the PID would require use cancellations and label amendments. *Id.* ¶ 20. No registrants have submitted voluntary cancellation requests for their chlorpyrifos registrations. *Id.* EPA intends to issue a final interim decision on or before the October 1, 2022 statutory deadline for registration review. *Id.* ¶ 9.

3. EPA's revocation of all chlorpyrifos tolerances

In response to the Ninth Circuit's April 2021 order, on August 30, 2021 EPA published the Final Rule at issue here, revoking all tolerances for chlorpyrifos. 86 Fed. Reg. 48,315 (Aug. 30, 2021). EPA set an expiration date of February 28, 2022 for the tolerances. *See id.*

Chlorpyrifos affects the nervous system by inhibiting acetylcholinesterase ("AChE"), an enzyme necessary for the proper functioning of the nervous system. *Id.* at 48,320. 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 48,317. EPA considered aggregate exposures that would occur in or on food, in drinking water, and in residential settings due to currently registered uses. *Id.* 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.* at 48,330-31. Because EPA concluded that aggregate exposures to chlorpyrifos exceeded safe levels, EPA revoked all chlorpyrifos tolerances. *Id.* at 48,333.

Some Petitioners submitted objections to the Final Rule and requested a hearing on those objections, and also requested an administrative stay of the Final

Rule. *See* Pet. Exs. A-B. EPA intends to finalize its response to those filings by February 28, 2022. Reaves Decl. ¶ 25. After EPA responds to those filings, EPA intends to commence involuntary cancellation proceedings, if necessary, for all registrations for which voluntary cancellation requests are not submitted. *Id.* ¶ 25. Those proceedings will address existing stocks. *Id.*

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. The court lacks jurisdiction.

The Court should deny the stay motion because it lacks subject-matter jurisdiction. Absent jurisdiction, the Court cannot proceed to grant Petitioners relief. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998) (jurisdiction must "be established as a threshold matter," and "[w]ithout jurisdiction the court cannot proceed at all in any cause") (internal quotation marks and citation omitted). As explained in EPA's Motion to Dismiss, under the FFDCA, Petitioners cannot challenge the Final Rule until EPA issues a final order under § 346a(g)(2)(C) responding to their objections to the Final Rule, which it has not

done. *Id.* § 346a(h)(1) (authorizing review of regulations "that are the subject of an order" under § 346a(g)(2)(C)); *see In re Pesticide Action Network N. Am.*, 863 F.3d 1131, 1132-33. A stay is unwarranted.

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

Even if this Court had jurisdiction, Petitioners are unlikely to succeed on the merits because EPA's action was required by the statute.

1. EPA cannot conclude that chlorpyrifos is safe.

EPA's *sole* statutory criteria for establishing or revoking a tolerance is whether the residue is "safe." *Id.* § 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 cause neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. 86 Fed. Reg. at 48,320. There is a large body of evidence showing an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* at 48,323-25. 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, as EPA's discretion under the FFDCA is circumscribed "by 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.

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

First, EPA was not required to make a "tolerance-by-tolerance examination." Petitioners' contention to the contrary (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. C) 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. Reaves Decl. ¶ 5. None of the registrants, including Gharda, has submitted requests to voluntarily cancel their registrations. *Id.* ¶¶ 21-23. Thus, at the time of the Final Rule, EPA could not conclude that exposures associated with those registered products would not be anticipated. *Id.* ¶ 24.

Third, Petitioner's 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 has conducted a tolerance-by-tolerance analysis "countless times before" is wrong. Mot. at 16 (citing McLean Decl. Ex. D, 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 approach to assessing whether existing tolerances are safe under the FFDCA: "when one tolerance is unsafe, *all* tolerances are equally unsafe . . ." Carbofuran; Order

Denying FMC's Objections and Requests for Rehearing, 74 Fed. Reg. 59,608, 59,675 (Nov. 18, 2009) (emphasis added); *see also* Ex. C at 44-45. Moreover, 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, a final "finding that EPA's Designated Safe Uses are safe for everyone." *See supra* at 7; Mot. at 1. Multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses, subject to geographic and application rate restrictions. Some, 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 EPA's safety determination supporting even those limited 11 uses was not supported by the available science. Reaves Decl. ¶ 23. EPA is still evaluating these comments and will not issue a final interim decision until later this year, consistent with the decoupling of EPA's registration review and consideration of tolerances. *Id.* ¶ 9; *see also LULAC II*, 996 F.3d at 678 (denial of petition on the basis of ongoing registration review was a "total abdication of the EPA's statutory duty under the FFDCA"). Contrary to Petitioners' claim (at 11), EPA did not make a final safety finding in the Final Rule for the subset of 11 uses or designate any particular uses as "safe." *See* 86 Fed.

Reg. at 48,333 (EPA's "ability to make the safety finding for any remaining uses would be contingent upon significant changes to the existing registrations. . .").

Sixth, EPA could not have completed a final safety analysis on the subset of 11 uses within the Ninth Circuit's 60-day deadline without, at a minimum, any submissions of voluntary cancellation requests by all registrants of the other uses. Reaves Decl. ¶¶ 24-25 (noting involuntary cancellations can take up to two years). 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. EPA did enter into good-faith negotiations with each of the technical registrants,[1] including Gharda, but none of them ever submitted a voluntary cancellation request under FIFRA to cancel food uses. *Id.* ¶ 23. Nor did any registrants submit proposed revised labels enabling EPA to amend labels to reflect the cancelled uses and to restrict the remaining uses to certain geographic areas and reduce application rates consistent with EPA's assessed usage rates. *Id.*

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

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

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. McLean Decl. Ex. A at PDF pp. 60-61. 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.* at PDF pp. 64-65. 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, or two additional growing seasons. *Id.* at PDF pp. 82-83. Given that EPA could not make a safety finding for chlorpyrifos, it had concerns about these proposed terms and ultimately did not agree to them. Reaves Decl. ¶¶ 16-17. Without voluntary cancellation requests in-hand from any registrants and the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision based upon an assessment of the registrations that actually existed. *Id.* ¶ 24.

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. It has requested a stay of the Final Rule and submitted objections to the Final Rule, along with a request for hearing on those objections. EPA intends to finalize its response to those filings by February 28, 2022. Gharda may seek judicial review of that decision, if necessary, pursuant to 21 U.S.C. § 346a(h)(1). Additionally, Gharda and the other registrants may at any time request voluntary cancellation or modification of its registrations and petition EPA to establish new tolerances. Instead, Gharda is pursuing a stay of the revocation of tolerances for all uses.

3. 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, 13.

In support, 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' quotation is incomplete: Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1). 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. Consistent with that direction and 21 U.S.C. § 346a(*l*)(1), EPA plans to commence involuntary cancellation proceedings, if necessary, for any registrations that are not voluntarily cancelled after EPA issues its response to the objections by February 28, 2022. Reaves Decl. ¶ 25. Those involuntary cancellation proceedings will address the treatment of existing stocks as appropriate. *Id.* Contrary to Petitioners' contention (at 21), neither FIFRA nor the FFDCA requires EPA to address existing stocks before the revocation of a tolerance goes into effect.

In sum, Petitioners have not demonstrated that they are likely to succeed on the merits.

B. 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). Demonstrating only monetary loss is insufficient, unless the loss threatens the very existence of 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.

1. Growers have not demonstrated irreparable harm.

While Petitioners advance arguments 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 dramatically overstate possible costs to growers. Decl. of Neil Anderson (Ex. D) ¶ 20. For example, Petitioners estimate losses of around $82 million for sugarbeet grower members alone. Mot. at 23. This figure is wrong. *See* Anderson Decl. ¶ 20. EPA's rigorous economic assessment of the impact of revocation yielded an estimate of total losses to all sugarbeet growers—taking into account both additional costs of alternatives and reductions in yield—of approximately $2.2 to $31.5 million, with likely costs of $8.6 million. *Id.*; EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos (Nov. 18, 2020) (Ex. E) at 7.

The total estimated losses from reduced yield or increased costs of alternatives across the subset of 11 uses is between $9.2 and $96.6 million per year. Ex. E at 6-7; Anderson Decl. ¶ 15. There is a wide range in these estimates because pest pressure varies from year to year, but total likely losses are around $53 million. Anderson Decl. ¶ 15.

Petitioners do not claim, nor could they, that their expected losses would threaten the very existence of large numbers of farms. Chlorpyrifos is applied to just 4.4% of all acreage of the subset of 11 uses, and annual revenue for the subset of 11 uses exceeds $82 billion, meaning that anticipated losses account for just under .1% of growers' expected revenue. *Id.* ¶ 16. Moreover, EPA analyzed the impacts of revoking the tolerance on U.S. farmers, with a particular emphasis on small farms. On the vast majority of farms, including small farms, that typically apply chlorpyrifos, losses due to the revocation are expected 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, in the event that 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. ¶ 26. And, even in heavily infested peach orchards in the southeastern United States, only about 20% of trees are affected by borers. *Id.* ¶ 25; Ex. E 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. ¶ 22. 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.").

2. 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. *See* McLean Decl., Ex. B at 6. That its gamble did not pay off does not constitute the type of harm that can form the basis for a stay.

Petitioners do not articulate a basis for Gharda's claim of reputational harm. *See* Mot. at 25. Regardless, Gharda could not distinguish reputational harm from the effectiveness of the Final Rule and reputational harm from Gharda's decision to seek to continue to sell chlorpyrifos for all uses despite EPA's and the Ninth Circuit's conclusions that exposures from those uses are associated with brain damage in infants and children.

For these reasons, Petitioners have not shown irreparable harm in the absence of a stay.

C. 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 that are not safe. *See* H.R. Rep. No. 104-669(II) (July 23, 1996) (Ex. F) 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" in establishing tolerances with a pure safety standard). Excusing Petitioners from complying with the revocation of chlorpyrifos tolerances during the upcoming growing season not only would contravene Congressional intent but also could result in harm to those exposed to chlorpyrifos through its continued use on currently registered 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 at least stand in considerable tension with the Ninth Circuit's order to revoke or modify the tolerances.

CONCLUSION

For the foregoing reasons, Petitioner's stay request should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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EXHIBIT A

Chlorpyrifos

Proposed Interim Registration Review Decision
Case Number 0100

December 2020

Approved by: _____

Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

Date: 12-03-2020

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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Proposed Interim Registration Review Decision (PID) for chlorpyrifos (PC Code 059101, case 0100), and is being issued pursuant to 40 CFR §155.56 and §155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on chlorpyrifos, can be found in the EPA's public docket (EPA-HQ-OPP-2008-0850) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing a PID for chlorpyrifos so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendix A). EPA is currently working with the National Marine Fisheries Service (NMFS) under a reinitiated Endangered Species Act (ESA) consultation, and NMFS plans to issue a revised biological opinion for chlorpyrifos in June 2022. The U.S. Fish and Wildlife Service (FWS) has not yet completed a biological opinion for chlorpyrifos. EPA will complete any necessary consultation with NMFS and FWS for chlorpyrifos prior to completing the chlorpyrifos registration review. See section I. B. and Appendix B for more information. See Appendix C for additional information on the endocrine screening for the chlorpyrifos registration review.

Chlorpyrifos (O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate) is a broad-spectrum, chlorinated organophosphate insecticide used to control a variety of foliar and soil-borne insects. Pesticide products containing chlorpyrifos are registered for use on many agricultural crops, with the highest uses on corn, soybeans, alfalfa, oranges, wheat, and walnuts in terms of pounds of chlorpyrifos applied per year. Additionally, chlorpyrifos products are registered for use on non-food sites such as ornamental plants in nurseries, golf course turf, as wood treatment, and as an ear tag for cattle. 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 Reregistration Eligibility Document for chlorpyrifos was issued July 31, 2006.[1] In 1996, the Food Quality Protection Act set a more stringent safety standard to be especially protective of infants and children. After finalizing the chlorpyrifos risk assessments for reregistration, EPA identified the need to modify certain chlorpyrifos uses to meet the revised standard of safety, and to address health and environmental risks from chlorpyrifos exposure. In 1997, the registrant, Dow AgroSciences (now known as Corteva), voluntarily agreed to cancel chlorpyrifos registrations for indoor broadcast use and direct pet treatments, except pet collars. In December 2001, the majority of the remaining chlorpyrifos residential products were subject to voluntary phase out/cancellation. Further changes included label revisions such as buffer zones to ensure environmental and worker safety in 2002. Additional spray drift mitigation and reduced application rates were added in 2012 to be protective of bystanders in sensitive areas including schools and recreational areas. Current chlorpyrifos residential uses are limited to granular ant mound use (commercial applicator only) and roach bait in child-resistant packaging (for homeowner use). Chlorpyrifos can be applied as a seed treatment, by chemigation, airblast, and other ground applications (e.g., groundboom, tractor-drawn spreader), aerial applications, handheld applications (e.g., handwand, handgun, backpack sprayer, rotary spreader), and as an impregnated ear tag for some types of cattle. Products containing chlorpyrifos have almost every type of formulation including wettable powder, emulsifiable concentrate, flowable concentrate, water-soluble packets (WSP), and granules. There are currently four technical registrants. The first product containing chlorpyrifos was registered in 1965 and the Tolerance Reassessment and Risk Management Decision (TRED) was published in 2002. Reregistration was completed with the 2006 update to the Organophosphate Cumulative Risk Assessment.

This document is organized in five sections: the *Introduction*, which includes this summary; *Use and Usage*, which describes how and why chlorpyrifos is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA's PID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

[1] https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-059101_1-Jul-06.pdf

A. Summary of Chlorpyrifos Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for chlorpyrifos with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of chlorpyrifos.

- March 2009 – The *Chlorpyrifos. Human Health Assessment Scoping Document in Support of Registration Review* and *Chlorpyrifos Summary Document* were posted to the docket for a 60-day public comment period.

- May 2009 – The *Preliminary Problem Formulation for the Ecological Risk and Environmental Fate, Endangered Species, and Drinking Water Assessments for Chlorpyrifos* was posted to the docket.

- October 2009 – The *Chlorpyrifos Final Work Plan* (FWP) was issued. The agency received nine comments on the *Chlorpyrifos Summary Document.* The comments received did not change the data and risk assessment needs or schedule for the chlorpyrifos registration review. The agency also published:
  - *Response to Comments on Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessments for Chlorpyrifos*
  - *Chlorpyrifos. Health Effects Division Response to Comments on the Registration Review Preliminary Work Plan*
  - *BEAD Response to Comments on Chlorpyrifos Preliminary Work Plan*

- September 2010 – The *Chlorpyrifos Generic Data Call (GDCI-059101-967)* was issued. There are no studies outstanding from the DCI that are needed to complete the registration review of chlorpyrifos.

- July 6, 2011 – The agency published the *Chlorpyrifos Preliminary Human Health Assessment for Registration Review,* as well as the following supporting materials, to the public docket for a 90-day comment period:
  - *Chlorpyrifos: Occupational and Residential Exposure Assessment*
  - *Revised Chlorpyrifos Acute and Chronic Dietary Exposure and Risk Assessments*
  - *Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment*
  - *Chlorpyrifos. Registration Review Action for Chlorpyrifos. Summary of Analytical Chemistry and Residue Data.*
  - *Chlorpyrifos Carcinogenicity: Review of Evidence from the U.S. Agricultural Health Study (AHS) Epidemiologic Evaluations 2003-2009*
  - *Reader's Guide to the Preliminary Human Health Risk Assessment for Chlorpyrifos*
  - *Chlorpyrifos: Tier II Incident Report*

- July 15, 2011 – The agency published the *Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment - Appendix D - Typical Use Data for Chlorpyrifos and Spray Drift Mitigation Decision for Chlorpyrifos* and *Occupational and Residential Appendices A* through *H*.

- July 2012 – The agency published *Chlorpyrifos – Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures, Spray Drift Mitigation Decision for Chlorpyrifos*, Appendices E, F, and G of the *Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures,* and the *Evaluation of Columbia University Epidemiology Study Claims Related to Brain Abnormalities and Pre-Natal Exposures to Chlorpyrifos.*

- February 2013 – The *Chlorpyrifos Preliminary Evaluation of the Potential Risks from Volatilization* was published for a 30-day public comment period.

- July 2014 – The agency published the *Chlorpyrifos: Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies.*

- December 2014 – The agency published the *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* and the following:
    - *Chlorpyrifos: Updated Drinking Water Assessment for Registration Review*
    - *Chlorpyrifos Updated DWA Attachment 12/23/2014*
    - *Chlorpyrifos Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review*
    - *Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review*

- June 2015 – The agency published the *Chlorpyrifos: Quality Assurance Assessment of the Chlorpyrifos Physiologically Based Pharmacokinetic/Pharmacodynamic Model for Human Health Risk Assessment Applications.*

- April 2016 – The *Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion* were published for a 60-day comment period.[2]

- November 2016 – EPA issued the *Chlorpyrifos: Revised Human Health Assessment for Registration Review* along with the *Chlorpyrifos Refined Drinking Water Assessment for Registration Review.*

- January 2017 – The agency announced the availability of the following:
    - *Endangered Species Act Section 7 Formal Consultation Letter for Chlorpyrifos, Diazinon, and Malathion*
    - *Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion*

[2] https://www3.epa.gov/pesticides/nas/chlorpyrifos/draft-chlorpyrifos.pdf

- *Final Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion*[3]

- September 2020 – The agency issued the *Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review* and *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review* in addition to the following:
  - *Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review*
  - *Evaluating the Impact of Removal of the 10X FQPA Safety Factor on Chlorpyrifos Drinking Water Concentrations*
  - *Usage of chlorpyrifos (PC# 059101) on alfalfa grown for alfalfa hay and seed, cotton, soybeans, sugar beets, spring and winter wheat, Michigan asparagus, Florida and Texas citrus, and Oregon strawberries by hydrologic region (two-digit HUC)*

- December 2020 – The agency is completing the PID for chlorpyrifos, in preparation for publication in the docket for a 60-day public comment period. The agency is also taking comments on the *Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review* and *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review* issued September 21, 2020. In addition, the agency is also issuing:
  - *Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)*
  - *Chlorpyrifos (PC# 059101) Usage and Benefits Assessment for Non-crop Uses*
  - *Average and maximum application rates and average number of applications of chlorpyrifos (PC# 059101) used in cherries, corn, peaches, pecans, and peppers by hydrologic region (two-digit HUC)*
  - Chlorpyrifos (059101) National and State Summary Use and Usage Summary Matrix

B. Endangered Species Consultation

Chlorpyrifos was one of the first three pilot chemicals that EPA conducted a nationwide ESA consultation. EPA completed a biological evaluation and initiated consultation with the FWS and NMFS in January 2017. [4] Pursuant to a consent decree, at the end of December 2017, NMFS issued its Biological Opinion (BiOp) on chlorpyrifos, diazinon, and malathion.[5] In July 2019, EPA re-initiated formal consultation with NMFS on the December 2017 BiOp.[6] EPA re-initiated consultation because new information on how the pesticides were actually being used may show that the extent of the effects of the actions may be different than what was previously considered. As part of this re-initiation, EPA provided additional usage data it believes may be relevant to the consultation. In its transmittal of this information to NMFS, EPA also referenced usage data and information that had been recently submitted by the registrants of pesticide products containing chlorpyrifos, malathion, and diazinon. After reviewing information EPA provided to NMFS on the 2017 BiOp, NMFS determined that it was appropriate to revise the chlorpyrifos,

[3] https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
[4] https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
[5] https://www.fisheries.noaa.gov/resource/document/biological-opinion-pesticides-chlorpyrifos-diazinon-and-malathion
[6] https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0141-0136

malathion, and diazinon BiOp. NMFS plans to issue a revised final BiOp for chlorpyrifos, diazinon, and malathion by June 2022. FWS has not yet issued a BiOp on chlorpyrifos. EPA plans to address risks to listed species and critical habitats from use of chlorpyrifos as part of the final registration review decision, pending completion of the nationwide consultation process.

C. Other Chlorpyrifos Actions

In September 2007, the Pesticide Action Network North America (PANNA) and Natural Resources Defense Council (NRDC) filed a Petition requesting that the EPA revoke all tolerances for chlorpyrifos under section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA) and cancel all chlorpyrifos registrations under FIFRA. Public dockets were opened for the transmittal of public documents pertaining to this petition in EPA-HQ-OPP-2007-1005 and EPA-HQ-OPP-2015-0653.

The registration review of chlorpyrifos and the organophosphates (OPs) has presented EPA with numerous novel scientific issues that the agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings.[7] Many of these complex scientific issues formed the basis of the 2007 petition filed by PANNA and NRDC and EPA therefore decided to address the Petition on a similar timeframe to EPA's registration review schedule.

Throughout the development and revisions to the human health draft risk assessment, and after seeking the expertise of the SAP in 2016, the EPA issued the order to deny the petition in March 2017. The agency concluded that the science addressing neurodevelopmental effects remained unresolved and further evaluation of the science during the remaining time for completion of registration review was warranted. The agency specified it would continue to review the science addressing pre- and postnatal neurodevelopmental effects of chlorpyrifos, and those actions are described in further detail in this PID.

Petitioners and other parties filed objections to directly challenge the denial order. In July 2019, the EPA issued a final order denying objections to EPA's March 2017 order denying PANNA and NRDC's 2007 Petition to revoke all tolerances and cancel all registrations for chlorpyrifos.[8] That 2019 order has been challenged by the Petitioners in the Ninth Circuit, which heard oral arguments in that case in July 2020. *LULAC v. Wheeler*, No. 19-71979 (9th Cir.). To date, the Court had not yet issued a decision on the agency's decision to deny the petition to revoke chlorpyrifos tolerances.

Documents pertaining to the chlorpyrifos Petition to revoke all tolerances and cancel all registrations for chlorpyrifos (docket EPA-HQ-OPP-2007-1005) and chlorpyrifos tolerance rulemaking (docket EPA-HQ-OPP-2015-0653) may be found at www.regulations.gov.[9]

[7] https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings
[8] https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0527
[9] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2007-1005 and https://www.regulations.gov/docket?D=EPA-HQ-OPP-2015-0653, respectively

D. Approach for Presenting Risk Estimates and Uncertainty Factors

As noted in the previous section, the registration review of chlorpyrifos and the OPs has presented EPA with numerous novel scientific issues, notably the potential for neurodevelopmental effects on the young (pre-natal, infants and children), that the agency has taken to multiple FIFRA SAP meetings since the completion of reregistration.[10] The agency completed a weight-of-the-evidence (WOE) analysis for neurodevelopmental effects using the "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment."[11] The WOE analysis integrated quantitative and qualitative findings from experimental toxicology studies, epidemiology studies, and physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) modeling. [12] EPA has also considered the emerging new information from laboratory animal and mechanistic studies in addition to epidemiology studies that identified potential concern for increased sensitivity and susceptibility for the young from neurodevelopmental effects in the development of this PID. Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Due to this uncertainty, EPA has retained the FQPA 10X safety factor in its human health risk assessment in order "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." FFDCA § 408(b)(2)(C). For consistency, EPA has also applied an additional 10X database uncertainty factor (UF_{DB}) in its assessment of occupational risks.

Notwithstanding, EPA recognizes that the science is evolving on this topic, and that there may be new information available prior to the completion of registration review that may impact the agency's conclusions about these effects. Most recently, EPA held a FIFRA SAP meeting from September 15 to September 18, 2020 to assess new approach methodologies that might be used to evaluate developmental neurotoxicity in EPA's assessment of risks to human health. EPA will consider the input and recommendations from the September 2020 FIFRA SAP once the SAP report is released in December 2020. In order to provide a fuller picture of the potential risk estimates and the evolving understanding of the potential for neurodevelopmental effects, EPA has also assessed the potential risks assuming a reduction to 1X of the FQPA SF and the UF_{DB}.

This PID presents the risk estimates as reflected in the 2020 human health risk assessment. EPA is proposing mitigation measures to mitigate risks estimated based on the retention of the 10X FQPA SF and $UF_{DB.}$ EPA is also presenting measures to mitigate risks assuming a reduction to 1X. Depending on the recommendations of the SAP, EPA's conclusions about risk, and thus proposed mitigation measures, may be revised.

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[10] https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings

[11] U.S. Environmental Protection Agency. 2016. Framework for Incorporating Human Epidemiologic and Incident Data in Health Risk Assessment, December 28, 2016. Available at https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.

[12] The PBPK-PD model was used to derive toxicological points of departure (PoDs) and to determine the appropriate intra-species and inter-species uncertainty factors. https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0941.

II. USE AND USAGE

Chlorpyrifos is a broad-spectrum insecticide and miticide registered for use for control of numerous insect pests and some mite pests. Products containing chlorpyrifos are registered for over 50 agricultural uses including fruit and vegetable crops, tree nuts, sorghum, wheat, and other food uses. Chlorpyrifos is also used to treat non-food uses such as cotton, nursery and landscape ornamentals, Christmas trees, golf course turf, greenhouse plants, as well as non-structural wood treatments such as utility poles and fence posts, cockroach bait stations, and as a mosquito adulticide. Many commercially-applied pesticide products containing chlorpyrifos are classified as restricted use products (RUPs), which can only be applied by certified applicators or those under their supervision. There is only one product currently registered for homeowner use which is formulated as a child-resistant bait station for cockroach control (EPA Reg. No. 9688-67). There are over 60 FIFRA Section 3 registrations, including eight technical registrations, and over 30 FIFRA Section 24(c) Special Local Need registrations for products containing chlorpyrifos, which include co-formulated products (i.e., those with multiple active ingredients in addition to chlorpyrifos). Overall usage has declined in the past decade but increased for some specific uses, such as sorghum, sweet corn, sunflowers, tobacco and pears. Since 2019, several states, including California, Hawaii, New York, Maryland, and Oregon, have initiated state-level actions to phase out all or most uses of chlorpyrifos.

Chlorpyrifos products are available in a variety of formulations, including wettable powders, granules, emulsifiable concentrates, WSPs, cattle ear tags, and bait stations. Chlorpyrifos products may be applied via groundboom sprayer, aircraft, tractor-drawn spreader, hand-wand, backpack sprayer, mechanically-pressurized handgun, and belly grinder. Application may take place throughout the agricultural season or throughout the year for non-agricultural applications.

Approximately 5.1 million pounds of chlorpyrifos were used each year for agricultural purposes in the United States between 2014 and 2018. Soybeans, alfalfa and corn make up nearly 50% of the total volume of chlorpyrifos used in the United States each year, with soybeans alone accounting for nearly 25% of total pounds applied. Less than 6% of each crop (i.e., soybeans, alfalfa and corn), however, is treated with chlorpyrifos. In addition to soybeans, alfalfa, and corn, crops with relatively high usage of chlorpyrifos (i.e., those with 100,000 lbs applied per year or more) include almonds, apples, grapes (wine, table, and raisins combined), oranges, peanuts, pecans, sugar beets, walnuts, spring wheat, and winter wheat. At least 40%, of the total acreage planted with apples, grapefruit, and asparagus is treated with chlorpyrifos. There has been a general trend of decreased usage in terms of pounds applied per year from 1998-2018, although acres treated has remained relatively stable (Kynetec, 2019.)[13]

Chlorpyrifos is registered for a number of non-crop uses including turf and ornamentals, tree farms and forest trees, cattle ear tags, livestock housing, rights of way, building perimeters, wood protection treatments, general outdoor treatments for ants and other pests, and wide area mosquito adulticide treatments. The majority of chlorpyrifos products registered for residential treatments were voluntarily cancelled or phased out by the registrants between 1997 and 2001. While usage data is not available for all non-agricultural use sites, available data indicate that the

[13] Kynetec USA, Inc. 2019. “The AgroTrak® Study from Kynetec USA, Inc.” Database Subset: 1998-2018.

majority of non-agricultural chlorpyrifos usage in terms of pounds of active ingredient were applied to ornamental lawns and turf. Within this market segment, turf farms account for the majority of usage, with 70,000 pounds of chlorpyrifos applied to approximately 64,000 acres. Nursery and greenhouse use on ornamentals are a close second, with 50,000 pounds applied to approximately 67,000 acres (Kline, 2012).[14] Far fewer pounds of chlorpyrifos were applied for wide area mosquito treatment, with only 10,000 pounds applied annually. However, due to very low application rates typically used for mosquito adulticides, treatments for mosquitos account for the vast majority of non-crop acres treated with chlorpyrifos, with over 1,000,000 acres reported to be treated for this purpose (Kline, 2017).[15] Chlorpyrifos is also registered for use on the following additional surveyed non-crop sites: wide area/general outdoor treatment (for ants and other miscellaneous pests), buildings/premises, rights of way/utilities, and trees. However, while Kline and Company does survey these sites, the surveys did not report any usage for these sites, indicating that chlorpyrifos is not widely used in these sectors (Kline, 2016[16] and Kline, 2017). Chlorpyrifos is also registered for use on livestock areas and animal quarters, but usage data on pounds applied are unavailable for these sites.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of chlorpyrifos. For additional details on the human health assessment for chlorpyrifos, see the *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review*, which is available in the public docket.

1. Hazard Characterization

Chlorpyrifos is known to form chlorpyrifos-oxon, 3,5,6-trichloro-2-pyridinol (TCP), and 3,5,6-trichloro-2-methoxypyridine (TMP). Chlorpyrifos undergoes desulfuration, reacting in bioactivation to degrade to the more toxic and potent acetylcholinesterase (AChE) inhibitor, chlorpyrifos oxon. Due to rapid deactivation through hydrolytic cleavage by a process called diarylation, the oxon is highly unstable and breaks down to release TCP, which is not a U.S residue of concern.

The hazard characterization for chlorpyrifos and its oxon degradate is based on adverse health effects in animals and humans related to AChE inhibition, and potential for neurodevelopmental effects. Guideline animal toxicity studies have historically been used in support of the 10% red

[14] Kline and Company. 2012. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2012: U.S. Market Analysis and Opportunities. [Accessed April 2020.]
[15] Kline and Company. 2017. Professional Pest Management Markets for Pesticides 2016: United States Market Analysis and Opportunities 2016. [Accessed April 2020.]
[16] Kline and Company. 2016. Mosquito Control Markets 2015: U.S. Market Analysis and Opportunities. [Accessed April 2020.]

blood cell (RBC) AChE inhibition point of departure (POD) for chlorpyrifos in EPA risk assessments.

Since the agency has used the PBPK-PD model for chlorpyrifos to simulate human RBC AChE inhibition, the default 10X inter-species uncertainty factor (to account for uncertainty in relying on animal toxicity data to estimate a human toxicity endpoint) is not warranted and is reduced to 1X. The PBPK-PD model also 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, meaning a data derived extrapolation factor (DDEF) can be applied in lieu of the default intraspecies uncertainty factor. The agency has selected the 99th percentile of the distribution to account for variation of sensitivity. The intra-species DDEF is 4X for chlorpyrifos and 5X for the oxon for all groups except females of reproductive age for whom the 10X intra-species factor was retained.

The 2020 revised human health risk assessment presents potential risks with the 10X FQPA Safety Factor (SF), reflecting the uncertainties around doses that may cause pre- and postnatal neurodevelopmental effects, as well as 1X to demonstrate the range of potential risk estimates.

The uncertainty factors and total level of concern (LOC) for each subpopulation is as follows:

Table 1: Uncertainty Factor Summary

Uncertainty Factor	FQPA 10X			FQPA 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 LOC	**100**	**40**	**50**	**10**	**4**	**5**

2. Risk Summary and Characterization

Steady State

As with other OPs, chlorpyrifos exhibits a phenomenon known as steady state AChE inhibition. Following repeated exposure at the same level, the degree of inhibition reaches equilibrium with production of new, uninhibited enzyme and the amount of AChE inhibition in a given dose remains consistent across exposure duration. After reaching steady state, the amount of AChE inhibition at a select dose remains constant across exposure duration. It generally takes approximately 2 to 3 weeks for this class of chemicals to reach steady state (U.S. EPA, 2002); however, this timeframe can vary with select chemicals. As such, the agency evaluated potential risks from steady state exposure in lieu of chronic exposure.

Dietary (Food + Water) Risks

FOOD

Both the acute and steady state dietary (food only) exposure analyses for chlorpyrifos were highly refined and incorporated monitoring data for almost all foods. Most of the food residues used were based upon USDA's Pesticide Data Program (PDP) monitoring data except in a few instances where no appropriate PDP data were available. Chlorpyrifos is routinely included in PDP monitoring.

The only residue of concern for the dietary (food only) assessment is chlorpyrifos. Food exposures do not incorporate potential exposure from food handling establishment (FHE) uses since the agency did not identify any registered FHE uses. Therefore, food exposures are based only upon field use of chlorpyrifos. At the 99.9th percentile of exposure the subgroup with the highest acute exposure was females (13-49 years old) at 3.2 % acute population adjusted dose for food ($aPAD_{food}$) with the 10X FQPA safety factor retained. For the steady state dietary (food only) exposure analyses, the population subgroup with the highest exposure was children (1 to <2 years old) at 9.7% of the $ssPAD_{food}$ at the 99.9th percentile of exposure. No potential risks of concern were identified from exposure to chlorpyrifos in food only. With the FQPA SF reduced to 1X, acute and steady state dietary risk estimates are <1% of the $aPAD_{food}$ and $ssPAD_{food}$ for all populations.

WATER

Drinking Water Assessment and Refinements

The *Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review* builds upon refinements from the 2014 and 2016 assessments at the Tier 3 assessment level, which included a screening-level approach at the national, regional, and watershed level as well as monitoring data and effects from water treatment systems. Based on regional screening, the incidence of high exposures is expected to be highly localized. However, assessing exposure on a local scale is difficult without regional-specific data and considering several local characteristics including soil type(s) and weather conditions. To further account for exposure on a local scale, EPA examined the potential geospatial concentration differences between two Hydrological Unit Code (HUC 2) Regions. This method was developed to identify use patterns that may result in estimated drinking water concentrations (EDWCs) that exceed the Drinking Water Level of Comparison (DWLOC) on a regional basis.

Moreover, the 2020 assessment incorporates the following additional refinements:

- New surface water model scenarios (i.e., soil, weather, and crop data);
- Use of community water system percent cropped area (PCA) adjustment factors and state level percent crop treated (PCT) data; and
- Quantitative use of surface water monitoring data.

Quantitative use of surface water monitoring data underwent external review in November 2019 from the FIFRA SAP and the remaining refinements were open to public comment and external

peer review. Utilization of the aforementioned factors and data elevates the drinking water assessment to a Tier 4 assessment level, the most highly refined assessment tier.[17] The *Framework for Conducting Pesticide Drinking Water Assessments for Surface Water (DWA Framework)* (USEPA, 2020) includes a description of how these methods fit into the overall tiered drinking water assessment process.

Drinking Water Level of Comparison (DWLOC) Approach

Given the potential drinking water risks of concern previously identified during the registration review of chlorpyrifos, the *Updated Chlorpyrifos Refined Drinking Water Assessment (DWA) for Registration Review* focuses on a subset of high-benefit[18] [19] and/or critical uses in defined areas of the country:

- Alfalfa
- Apple
- Asparagus
- Cherry
- Citrus
- Cotton
- Peach
- Soybean
- Sugar beet
- Strawberry
- Wheat (Spring and Winter)

For a drinking water assessment which utilizes a DWLOC, the calculated DWLOC is compared to the EDWC. When the EDWC is greater than the DWLOC, there may be a risk concern for exposures to chlorpyrifos and/or chlorpyrifos oxon. Conversely, when the EDWC is less than the DWLOC, there are no risks of concern.

Both chlorpyrifos and the chlorpyrifos oxon are residues of concern in drinking water. With the 10X FQPA safety factor, the lowest acute DWLOC and steady state DWLOC calculated were 23 ppb and 4 ppb, respectively, for the most sensitive population, infants (<1 year old). The DWLOCs are 230 ppb and 43 ppb, respectively, without retention of the 10X FQPA safety factor. Drinking water concentrations of chlorpyrifos oxon above the DWLOC indicate a potential risk concern.

Table 2: DWLOC Values for Chlorpyrifos-Oxon for Infants

DWLOC (ppb) for infants				
	Chlorpyrifos		Chlorpyrifos-oxon	
Safety Factor	10X	1X	10X	1X
Steady State	17	180	**4**	**43**
Acute	100	1000	23	230

[17] https://www.epa.gov/sap/meeting-information-november-19-22-2019-scientific-advisory-panel

[18] A high benefit indicates that there are no alternative pesticides for a pest on a specific crop or alternatives products are expensive or less efficacious. Target pests in these crops include alfalfa weevil, lygus bugs, scale, and two spotted spider mites. Additional details are provided in Section III.C. of this document.

[19] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0943

As noted earlier, several refinements were considered in the *Updated Chlorpyrifos Refined Drinking Water Assessment (DWA),* including usage data, percent cropped area aggregation, and percent cropped area-percent crop treated aggregation. These refinements are reflected in the below EDWCs and discussed in detail in the *Updated Chlorpyrifos Refined Drinking Water Assessment (DWA).*

Table 3: Surface Water Sourced Estimated Drinking Water Concentrations Resulting from Different Refinements for a Subset of 11 High-Benefit Chlorpyrifos Uses (Assuming Upper Bound Application Parameters)

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,	8.3	5.6	5.2[4]	3.3

	and Winter Wheat				
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 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.

Based on the most refined EDWCs, concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are not likely to exceed the drinking water level of comparison (DWLOC) for the subset of 11 uses considered with the retention of the 10X FQPA safety factor. The consideration of additional crops would likely result in exceedances of the DWLOC if the 10X FQPA SF is retained. Dietary risks of concern from public health uses, such as mosquito adulticide treatment, are not expected at either the 1X or 10X.

EDWCs from the 2016 drinking water assessment for agricultural uses were compared to the DWLOCs to assess currently labels uses at the 1X FQPA safety factor. With a 1X FQPA safety factor, most of the current labeled uses result in drinking water concentrations below the DWLOC. Uses with drinking water concentrations above the DWLOC include, peppers, trash storage bins, and wood treatment, in all areas of the country. Additionally, uses with 1-in-10 year

21-day average drinking water concentrations above the 21-day average DWLOC in certain HUCs include corn, tart cherries, citrus, pecan, and peach. For additional information on the chlorpyrifos EDWCs at the 1X, please see *Evaluating the Impact of Removal of the 10X FQPA Safety Factor on Chlorpyrifos Drinking Water Concentrations.*[20]

Cancer

Chlorpyrifos has also been evaluated for cancer and is classified as "not likely to be carcinogenic to humans." Guideline carcinogenicity studies and epidemiological data are available from the Agricultural Health Study (AHS). Preliminary associations with breast, lung, colorectal, and prostate cancer warrant monitoring follow-up and additional research. There is no compelling evidence of an association with other cancer sites (C. Christensen, 6/16/11, D388167). The AHS chlorpyrifos carcinogenicity studies have been summarized in the memorandum, *Chlorpyrifos Carcinogenicity: Review of Evidence from the U.S. Agricultural Health Study (AHS) Epidemiologic Evaluations 2003-2009* (Christensen, D388167, 6/16/2011).

Residential Exposure Risks

Currently, chlorpyrifos products registered for residential use are limited to roach bait products (EPA Reg. No. 9688-67) or ant mound treatments which may only be applied by commercial applicators. The active ingredient is contained within a bait station which eliminates the potential for human contact; therefore, residential exposure to chlorpyrifos via these products is considered negligible. The majority of products registered for residential treatment were voluntarily cancelled or phased out by the registrants between 1997 and 2001.

There is a potential for exposure to the general population from use on golf courses following treatment with chlorpyrifos products or from exposures which occur following aerial or ground-based ultra-low volume (ULV) mosquito applications made directly in residential areas. Risk estimates for dermal and inhalation exposure were combined since the toxicological endpoint, RBC AChE inhibition, is the same for each of these exposure routes. With retention of the 10X FQPA SF, the residential post-application LOC for children is 40 and the adult residential post-application LOC is 100. Regardless of 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. The assessment of steady state golfer post-application exposures (dermal only) to chlorpyrifos treated turf resulted in no risks of concern to children/youth 6 to <16 years old (Margin of Exposure (MOEs) = 1,200 to 9,900) or adults (MOE = 1,000 to 5,400). With minimum MOEs of 400, there were no combined risks of concern identified for children 1 to <2 years old (dermal, inhalation, and incidental) or adults (dermal and inhalation) from post-application exposures following public health mosquito applications.

Aggregate Risk Assessment

A DWLOC approach was used to calculate the amount of exposure that could occur without exceeding the level of concern for acute and steady state aggregate assessments. This was to

[20] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0942

account for the available space in the "total aggregate risk cup" for exposures to chlorpyrifos oxon in drinking water after accounting for exposures to parent chlorpyrifos from food and residential uses. The calculated DWLOCs were then compared to the EDWCs of chlorpyrifos and chlorpyrifos oxon modeled under a variety of conditions.

With residential exposures considered negligible, the acute aggregate assessment includes only food and drinking water. The steady state aggregate assessment includes exposures from food, drinking water, and residential uses (golf courses). As previously mentioned, the drinking water assessment is highly refined incorporating multiple screening exercises and comparing modeling results to monitoring data.

When 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.

Non-Occupational Spray Drift Risks

Spray drift from ground or aerial applications can be a potential source of non-occupational exposure to chlorpyrifos. The potential risks from spray drift exposure and the impact of potential risk reduction measures were assessed in a July 2012 memorandum.[21] To increase protection for children and other bystanders, chlorpyrifos technical registrants voluntarily agreed to spray drift mitigation measures including lower application rates, increased droplet sizes, and buffer zones.

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 with or without the 10X FQPA SF for aerial or groundboom applications. There were no combined (dermal + incidental oral) risks for children 1 to < 2 years old at the field edge from indirect spray drift exposure to chlorpyrifos and there were no dermal risk estimates of concern at the field edge for adults (females 13 - 49 years old). Aerial applications are not permitted at rates higher than 2.0 lb a.i./ except for treatment of Asian Citrus Psyllid (citrus use) at application rates up to 2.3 lbs a.i./A. For aerial applications at this highest rate, MOEs of concern were identified within 10 feet from the edge of the field. However, current buffer distances required on the label mitigate these potential risks of concern.

The EPA assessed post-application exposures to residential bystanders from spray drift and volatilization. This assessment focuses primarily on individuals who live on, work in, or frequent areas adjacent to chlorpyrifos-treated agricultural fields. In June 2014, a re-evaluation of the 2013 preliminary volatilization assessment was conducted to present the results of two new vapor studies and their impact (MRIDs 49119501 and 49210101). These studies demonstrated that no toxicity occurred even at the saturation concentration, which is the highest physically achievable concentration. As such, there are no anticipated risks of concern from exposure to the volatilization of either chlorpyrifos or chlorpyrifos oxon with or without retention of the 10X FQPA SF.

[21] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0103

Cumulative Risks

Chlorpyrifos is a member of the OP class of pesticides. EPA considers OPs to express toxicity through a common biochemical interaction with cholinesterase which may lead to several potential cholinergic effects and, consequently, the OPs should be considered as a group when performing cumulative risk assessments. The agency first completed a cumulative risk assessment for the OPs in 2001, a revised cumulative risk assessment for the OPs was completed in 2002[22], and an updated OP cumulative risk assessment was completed in 2006.[23] The cumulative effects of exposure to multiple OPs, including chlorpyrifos, are evaluated in those documents. Prior to the completion of registration review, the agency will update the OP cumulative risk assessment to incorporate any toxicity and exposure information available since 2006.

Occupational Handler Risks

Occupational handlers mixing, loading, and/or applying pesticide products containing chlorpyrifos may be exposed to chlorpyrifos dermally or by inhalation. PBPK-PD model-derived PODs (dermal and inhalation), which were specifically set up for occupational exposure scenarios, were used to estimate handler risks. The steady state approach accounts for short-term exposure duration, as well as for workers that are exposed over longer periods of time (i.e., intermediate-term exposures). The dermal and inhalation risk estimates were combined since the toxicological endpoint, RBC AChE inhibition, is the same for each of these exposure routes.

The human health risk assessment presents estimates assuming both that the database uncertainty factor (UF_{DB}) 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).

Two hundred eighty-eight steady state occupational handler scenarios were assessed for non-seed treatments. Assuming a 10X database uncertainty factor is retained (LOC = 100), 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and a protection factor (PF) 10 respirator) (MOEs < 100). Risks of concern for 45 additional exposure scenarios could potentially be mitigated if engineering controls are used. Without retention of the 10X database uncertainty factor (UF_{DB}) (LOC = 10), 19 non-seed treatment scenarios are of concern with baseline attire, chemical resistant gloves, coveralls, and an elastomeric half mask (PF 10) respirator (MOEs < 10). If

[22] US EPA, 2002. https://nepis.epa.gov/Exe/ZyNET.exe/9100BFLL.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2000+Thru+2005&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C00thru05%5CTxt%5C00000023%5C9100BFLL.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL

[23] US EPA, 2006. https://www regulations.gov/document?D=EPA-HQ-OPP-2006-0618-0002

engineering controls are used, risks of concern for 15 additional scenarios could potentially be mitigated. 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.[24]

A total of 93 commercial seed treatment scenarios were assessed for chlorpyrifos. The revised human health risk assessment identified 22 seed-treatment scenarios of concern with the assumption that the 10X UF_{DB} is retained. Seed treatment uses include corn, cotton (delinted), cucumber, pumpkin, sorghum grain, triticale (wheat), and a variety of beans. No potential risks of concern were identified with scenarios assessed for cucumber, pumpkin, sorghum grain and triticale or for planting seeds previously treated with chlorpyrifos. If the 10X UF_{DB} is reduced to 1X, there are no seed-treatment scenarios of concern for chlorpyrifos. Potential risks of concern were found for the following with retention of the 10X UF_{DB}:

Table 4: Occupational Risks of Concern from Seed Treatment at the 10X UF_{DB}[1]

Formulation and PPE	Loader/Applicator[2]	Sewer	Bagger	Multiple Activities Worker
Liquid (with double layer PPE (coveralls), gloves, and an elastomeric half mask respirator (PF 10)	Corn = 67 - 95 Cotton = 33 - 46	Cotton = 50-71	Corn = 96 - 140 Cotton = 46 - 65	Beans = 61 - 86 Corn = 50 - 71 Cotton = 24 - 34
Liquid (microencapsulated)	Beans only: 59 - 83	Beans only: 91 - 130	Beans only: 84 - 120	Beans only: 44 - 62
Wettable Powder via WSP	Beans = 75 – 110 Corn = 62 - 88	Corn = 96 - 140	Corn = 89 - 130	Beans 57 – 79 Corn = 47 - 66

[1] LOC with 10X = 100
[2] Maximum MOEs with listed PPE

NON-SEED TREATMENT

Aerial and/or Chemigation applications

Several chlorpyrifos formulations may be applied by aerial or chemigation application. These include liquids, wettable powders, granule formulations, and water dispersable granules. The maximum application rate for aerial application is 2.3 lbs a.i./A for use on citrus.

Even with the use of engineering controls (closed systems), mixing and loading resulted in risks of concern to workers at the 1X UF_{DB} for four uses: corn (pre-plant), peanut, sweet potato, and sunflower. These risks of concern were limited to granular formulations for these uses. The MOE for aerial application of granular formulations of chlorpyrifos on peanuts is 5. MOEs for other

[24] 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).

aerial granular applications are 9.4 (sweet potato), 9.5 (sunflower, tobacco), and 9.6 (corn). Without the 10X UF_{DB}, MOEs for mixing and loading for aerial applications ranges from 0.61 to 6.7 for uses with risks of concern with baseline PPE (long-sleeved shirt, long pants, socks and shoes). Use of the highest 2 tiers of refinement (double layer (coveralls), gloves, and an elastomeric half mask respirator or engineering controls result in MOEs of 4.7 to 66 for mixing and loading granular formulations.

For mixing/loading liquids and wettable powders (WP), nearly all scenarios resulted in MOEs below the LOC of 100 (with retention of the 10X UF_{DB}). With the exception of ornamental shade trees and herbaceous plants (MOE = 130 with engineering controls), the risk estimates for mixers and loaders for all remaining formulations were below the LOC of 100 with a range of 9.6 to 71 for citrus, tree nuts (almonds, filberts, hazelnuts), tree fruit (apple, cherries), cole crops (excludes Brussels sprouts and cauliflower), Christmas tree plantations, and nursery stock (pre-plant). Potential risks to aerial or chemigation applicators were found for all starting formulations of spray applications and granules for the following uses with MOEs from 5 to 94: peanut, sweet potato, sunflower, tobacco, sod farms (turf), corn (pre-plant and post-emergence), alfalfa, cotton (except Mississippi), soybean, wheat, sorghum, and Christmas tree plantations. All remaining aerial applications were above the LOC of 100 and, therefore, not of concern.

Airblast applications

Chlorpyrifos may be applied by airblast application at rates from 1.0 to 6.0 lbs a.i./acre to citrus, tree nuts, tree fruits, grapes, asparagus, and to shade trees, herbaceous plants, Christmas tree plantations, and ornamental woody shrubs and vines. Formulations that may be applied by airblast include liquid/soluble/emulsifiable concentrate (L/SC/EC), WP in WSP, and dry flowable/water dispersable granule (DF/WSG) in WSP. Risk estimates for mixing, loading, and applying airblast applications were mostly above the LOC of 100 with the use of engineering controls. At a rate of 6.0 lbs a.i./acre (California and Arizona citrus), MOEs ranged from 64 to 67 for mixing and loading WSP formulations. MOEs for mixing, loading, and applying citrus outside of California and Arizona were 98. Mixing, loading, and applying all formulations for tree nuts (pecans) ranged from 89 to 91. MOEs for remaining uses ranged from 98 to 390 with engineering controls. All airblast application scenarios without engineering controls, even those with use of chemical resistant headgear, resulted in potential risks of concern with MOEs from 0.55 to 4.2, which is below the LOC with or without retention of the 10X UF_{DB}.

There were no risks of concern for occupational handlers mixing and loading WSP formulations except and as mentioned above for citrus and tree nuts (pecans). However, with the use of double layer (coveralls), gloves, and an elastomeric half mask respirator, only the following uses resulted in MOEs above the agency's LOC of 100 for all other formulations (L/SC/EC):

- Cherries, tree fruits (pear, plum/prune (dormant, delayed dormant), tree nuts (almonds, filberts, hazelnuts, pecans, walnuts); MOE = 110
- Ornamental and/or shade trees, ornamental woody shrubs and vines, herbaceous plants, Christmas tree plantations, grapes; MOEs = 220

Risk estimates for all levels of PPE for the remaining uses were from 4.6 to 71 for mixers and loaders and were, therefore, of concern with retention of the 10X UF_{DB}.

Groundboom applications

Groundboom application is one of the most widely used application methods for chlorpyrifos. Nearly every use resulted in potential risks of concern from mixing, loading, or applying without the use of PPE above baseline levels (long-sleeved shirt, long pants, socks and shoes) for mixers, loaders, and applicators with retention of the 10X UF_{DB}. Risk estimates of concern were still identified for groundboom applicators with engineering controls on corn (pre-plant, MOE = 67) and cotton (except in Mississippi, MOE = 99) and mixers and loaders for the following uses:

Table 5: Groundboom Risk Estimates with MOEs < 100 with Engineering Controls

Formulation	Crop/Target Category	MOE with baseline PPE	MOEs with double layer (coveralls), gloves and respirator	MOE with engineering controls
Mixers and Loaders				
Liquid/Soluble Concentrate/Emulsifiable Concentrate (L/SC/EC)	Corn (pre-plant)	1.9	14	39
	Cotton (except MS)	2.7	22	58
	Tree nut orchard floors (pecans, almonds, walnuts)	3.2 - 3.5	25 - 26	68 - 73
	Ornamental lawns and turf, sod farms	3.7	28	77
	Radish (pre-plant)	4.6	35	96
Wettable powder in water-soluble packet (WSP)	Ornamental lawns and turf, sod farms	N/A	N/A	51
	Ornamental woody shrubs and vines (pre-transplant)	N/A	N/A	67
Dry flowable/water-soluble granule in WSP	Tree nut orchard floors (pecans, almonds, walnuts)	N/A	N/A	46 - 48
	Corn, sorghum grain, soybean	N/A	N/A	79
	Rutabaga	N/A	N/A	80
	Turnip	N/A	N/A	86
	Sweet potato	N/A	N/A	92
	Cole crops (excludes Brussels sprouts and cauliflower), mint (peppermint and	N/A	N/A	98

	spearmint), peanut, sunflower			
Applicator Risk Estimates with MOEs < 100 with Engineering Controls or Maximum PPE				
Spray (all starting formulations)	Corn (pre-plant), cotton (except Mississippi)	4.8 – 7.2	31 - 47	67 - 99
	Corn (post-emergence), tree nut orchard floors (pecans, almonds, walnuts), ornamental lawns and turf, sod farms (turf)	8.3 - 9.8	54 - 62	110 - 130
	Radish, alfalfa, cotton, sorghum grain, soybean, wheat,	12 - 15	78 - 94	170 - 210
	Rutabaga	15	94	210

Use of engineering controls resulted in mixer/loader risk estimates above the LOC of 100 for mixing and loading for the following uses (MOEs = 120 – 190):

- At a rate of 4.0 lbs a.i./acre: nursery stock (pre-plant)
- At a rate of 2.0 to 2.4 lbs a.i./acre: Brussels sprouts (at plant and post-emergence), cauliflower, cole crops, figs (only in California), grapes (foliar, dormant, delayed dormant), mint, peanut, pineapple, rutabaga, strawberries (pre-plant), sunflower (pre-plant) sweet potato (pre-plant and soil broadcast), and tobacco (preplant).
- At a rate of 1.9 lbs a.i./acre: beets (table, sugar, at plant), clover (grown for seed, foliar), hybrid cottonwood and polar plantations
- At a rate of 1.5 lbs a.i./acre: cranberry
- At a rate of 1.0 lbs a.i./acre: alfalfa, cotton, sorghum grain, soybean, and wheat

Mixer and loader risk estimates for these crops with double layer (coveralls), gloves, and an elastomeric half mask respirator range from 42 to 71. Applicator risks estimates with this level of PPE ranged from 31 to 470 with risks of concern identified for use on corn (pre-plant and post-emergence) and cotton (except MS), rutabaga, alfalfa, soybean, sorghum grain, wheat, radish (preplant), tree nut orchard floors (pecans, almonds, walnuts) and ornamental lawns and turf with MOEs up to 94.

With the exception of microencapsulated formulations for ornamental non-flowering plants and wettable powder for citrus orchard floors and cole crops (excluding Brussels sprouts and cauliflower), all remaining uses present potential risks of concern to mixers, loaders, and applicators with baseline PPE (long-sleeved shirt, long pants, socks, and shoes). MOEs for mixers and loaders range up to 27 and up to 72 for applicators. Use of double layer (coveralls), gloves, and an elastomeric half mask respirator results in risk estimates up to 220 for mixers and loaders and 470 for applicators and are not of concern.

Flaggers

Although the use of global positioning systems (GPS) has vastly replaced the use of flaggers to guide aerial applications, the agency continues to assess exposure as use of flaggers is not explicitly prohibited on pesticide products containing chlorpyrifos. At the 1X UF_{DB}, all risk estimates were above the LOC of 10 and, therefore, are not of concern. Nearly all applications of chlorpyrifos products results in potential risks of concern for flaggers with the maximum amount of PPE (double layer (coveralls), gloves, and PF10 respirator) at the 10X UF_{DB}; risk estimates of concern ranged from 15 to 88 with the maximum PPE (where the LOC with the 10X UF_{DB} is 100). No risks of concern were identified for flaggers with granule application to turf nor for applications to sweet potato, corn (pre-plant), sunflower, and tobacco with the maximum amount of PPE.

Handheld application methods[25]

Assessment of handheld application methods typically assumes mixer, loader, and applicator exposure to the same occupational handler.

Manually-pressurized handwand and handgun

Manually-pressurized handwand application is limited to mostly non-food uses such as ornamental plants, nursery stock, poultry litter, and industrial and commercial areas. Food uses include select tree nuts and tree fruits. With the use of single layer (long-sleeved shirt and long pants) and gloves, most uses are above the EPA's LOC of 10 at the 1X UF_{DB} (MOEs = 3.9 – 9,000) No risks of concern were identified at the 1X UF_{DB} from spot treatment applications (0.023 lbs a.i./Acre). Without gloves, MOEs ranged from 2.6 – 110 with risks of concern for use on applications that were not considered spot treatments (i.e., applications of 40 gallons or to 1,000 square feet). MOEs were below the LOC of 100 at the 10X UF_{DB} for the following handwand applications with maximum PPE (double layer (coveralls)) gloves, and an elastomeric half mask respirator:

- Wood protection treatment (MOE = 82)
- Nursery, pine seedlings (MOE = 90)
- Indoor commercial, institutional, industrial premises, food processing plant premises (MOE = 16)

Risks of concerns were found for nearly all scenarios with manually-pressurized handgun applications and formulations with the exception of:

- WSP application to ornamental woody shrubs and vines (MOEs = 440 to 2100); and
- All formulations registered for use on seed orchard tree (MOEs = 1800 – 8300).

Remaining risk estimates with use of double layer (coveralls), gloves, and an elastomeric half mask respirator ranged from 11 to 83. An MOE of 83 was determined for ornamental and/or shade trees, herbaceous plants, and grapes (WSP formulation only).

[25] Assessment assumes mixing, loading, and application are conducted by some the same individual and does not include use of engineering controls.

Tractor-drawn spreader

At the 10X UF_{DB}, no occupational handler risks of concern were identified with use of tractor-drawn spreaders. Nor were risks of concern found with use of a SmartBox®. SmartBox® systems are closed application systems that are considered to be protective as engineering controls. Retention of the 10X UF_{DB} resulted in risks of concern with use of only baseline PPE. MOEs range up to 71 except for use of golf course turf, rights of way, and road medians where the MOE is 120. Application to most uses are above the LOC of 100 with use of gloves, respirator, and coveralls or engineering controls. Even with engineering controls (excluding SmartBox systems), risk estimates are below 100 for application to soybean, corn, and ornamental woody shrubs and vines for mixers, loaders, and applicators (MOEs = 53 – 89).

Backpack Sprayers

Risks of concern from backpack sprayers without retention of the 10X UF_{DB} were limited to use on ornamental and/shade trees, herbaceous plants, ornamental woody shrubs and vines, wide-area general outdoor treatment, and outdoor commercial/institutional/industrial premises, non-agricultural outdoor buildings and structures.

MOEs for liquid concentrate application by backpack sprayer ranged from 1.5 – 76 and exceeded the agency's LOC of 100 for all levels of PPE except as follows:

Table 6: Risk Estimates for Backpack Sprayer Applications[1]

Formulation	Application type	Crop/Targeted Use	PPE	MOE
Dry flowable/water-dispersable granule in WSP	Broadcast (foliar)	Grapes (pre-bloom)	Double layer (coveralls), gloves, and an elastomeric half mask respirator	94
	Trunk spray/Drench	Tree fruits (apple)		100
	Drench/Soil-Ground-directed	Grapes (pre-bloom)		130
Liquid/soluble concentrate/emulsifiable concentrate	Broadcast (foliar)	Golf course turf		94
	Spot treatment applications (0.023 A treated)	Ornamental and/or Shade Trees, herbaceous plants	Baseline	320
		Ornamental lawns and turf, sod farms (turf)		350
		Outdoor commercial/institutional/industrial premises, non-agricultural buildings and structures, golf course turf		1300
Microencapsulated formula	Broadcast (foliar)	Ornamental woody shrubs and vines	Double layer	94

		Ornamental non-flowering plants	(coveralls), gloves, and an elastomeric half mask respirator	130
	Directed broadcast	Outdoor commercial/institutional/industrial premises	Baseline	230
	Broadcast	Agricultural farm premises	Baseline	400
	Broadcast	Poultry litter	Baseline	1100
WSP	Spot	Ornamental woody shrubs and vines (pre-transplant)	Baseline	330
	Spot	Outdoor lawns and turf, Sod Farms (turf)	Baseline	350
	Broadcast	Ornamental woody shrubs and vines	Baseline	930

[1]Select uses with risk estimates below the LOC of 100 were included if chlorpyrifos was considered a high benefit.

Granule formulations

Application of chlorpyrifos granule formulations by hand is limited to non-agricultural uses. Applications by spoon resulted is risk estimates from 1400 to 5700 and were not of concern. Regardless of PPE, all applications with a belly grinder with retention of the 10X UF_{DB} resulted in potential risks of concern with a maximum MOE of 43. Hand dispersal resulted in potential risks on concern with or without retention of the 10X UF_{DB} and regardless of PPE for treatment of commercial/institutional/industrial premises and utilities with MOEs from 0.49 to 1.4. Treatment of golf courses and sod farms by the same method were of concern with baseline PPE (MOE = 90; long-sleeved shirt, long pants, no gloves and no respirator). Hand dispersal and rotary spreader application resulted in MOEs below the LOC of 100 with retention of the 10X UF_{DB} for ornamental woody shrubs and vines regardless of PPE with MOEs up to 53. With baseline PPE, MOEs for all other remaining uses treated by rotary spreader were 63 to 70. Use of maximum PPE (double-layer (coveralls), gloves, and an elastomeric half mask respirator) results in MOEs of 290 to 320.

Non-Food and Other Application Methods:
Application of cattle eartags, bait stations, and total release foggers (greenhouses) are considered to have negligible exposure; therefore, there were no risks of concern identified to occupational handlers for these treatment methods. However, potential risks of concern were identified for all levels of personal protective equipment using paint brushes and rollers for wood protection treatment. Regardless of PPE, all applications with a brush roller resulted in potential risks of concern with retention of the 10X UF_{DB} with a maximum MOE of 45.

Wide-area Mosquito Abatement

With label required single layer (long-sleeved shirt and long pants) and gloves, MOEs for mixing and loading wide area mosquito applications were below the agency's LOC of 100 for aerial applications and above the LOC for ground applications. Aerial applications were assessed assuming only engineering control and were not of concern. With the retention of the 10X UF_{DB}, ground applications were only above the LOC of 100 with the use of engineering controls. Without engineering controls, ground applicator MOEs were of concern. Ultra-low volume (ULV) wide-area applications by airblast were below the LOC of 10 without retention of the 10X UF_{DB} with MOEs ranging from 4.4 to 5.6.

Occupational Post-Application Risks

Most crops and activities require a restricted entry interval (REI) of 24 hours on current chlorpyrifos labels. However, in some cases such as citrus fruits, REIs are up to 5 days after application. Occupational post-application risks have been updated to incorporate PBPK-derived steady state PODs based on 10% RBC AChE inhibition. Assuming the UF_{DB} is reduced to 1X, most post-application risk estimates are not of concern 1 day after application. Likewise, the majority of the post-applications scenarios are not of concern 1 day after application (REI = 24 hours) assuming the UF_{DB} of 10X is retained. However, for some activities 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.

The residue of concern for occupational post-application exposures is the chlorpyrifos parent compound, although it may be possible that the formation of chlorpyrifos oxon is greater and its degradation slower in greenhouses when compared to the outdoor environment. Dermal exposure to the oxon on foliar surfaces from reentry into an outdoor environment previously treated with chlorpyrifos is not anticipated and, therefore, has not been assessed.

The agency has numerous dislodgeable foliar residue (DFR) studies for several chlorpyrifos registered uses. Specifically, the DFR studies examined the use of 1) granular formulations on turf and sweet corn; 2) emulsifiable concentrate formulations on citrus, sugar beets, sweet corn, pecans, cotton, and turf; 3) a microencapsulated liquid formulation on ornamentals; 4) a total release aerosol formulation on ornamentals; and 5) wettable powder formulations on pecans, almonds, apples, tomato, cauliflower, and turf. These studies varied in location and calculations using each of these studies yield different risk estimates. The agency is presenting the full range of post-application risk estimates in Appendix D1 of this PID.

Dermal exposure assessment on outdoor foliar surfaces was limited to chlorpyrifos exposure only. Exposure to chlorpyrifos 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, was not assessed. Occupational post-application assessments were performed for: 1) exposures to the parent compound chlorpyrifos in outdoor environments (all uses), 2) exposures to the parent chlorpyrifos indoors (e.g., greenhouses) and 3) exposures to both the parent and chlorpyrifos oxon in greenhouses. Occupational dermal post-application exposures were assessed in greenhouses using conservative assumptions of oxon formation.

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. Post-application exposure from seed treatment is not expected.

The agency's LOC for occupational post-application risks is 100 at the 10X UF_{DB} and 10 at the 1X UF_{DB}. Post-application exposure to agricultural workers from commercial seed treatment is not expected. The agency has identified potential risks of concern for the following uses and activities. The comprehensive list of REIs by crop, post-application activity, and study location yielding those risk estimates are presented in Appendix D1.

Greenhouse

Chlorpyrifos may be applied to food and non-food uses in greenhouses. Chlorpyrifos formulations used in greenhouses include emulsifiable concentrate, microencapsulated liquid, wettable powder in WSP, and total release foggers. The chlorpyrifos parent compound is the residue of concern for occupational post-application dermal exposures; however, available exposure data indicate chlorpyrifos oxon may form in indoor environments.[26] It is uncertain if the formation of the oxon is greater and its deactivation slower in greenhouses when compared to the outdoor environment. Workers reentering indoor environments (i.e., greenhouses) previously treated with chlorpyrifos could potentially be exposed to the more toxic oxon as chlorpyrifos degrades. Risks for reentry into treated greenhouses for the parent chlorpyrifos plus chlorpyrifos oxon were estimated using a total toxic residue approach for all four formulations used in greenhouses.[27] A conservative assumption of 5% (0.05) of the total chlorpyrifos was estimated as present as DFR in greenhouses and available for contact during post-application activities. Five percent is the high-end value for the percent of parent that metabolized during the course of the residue studies. Risk estimates after treatment for total release fogger and liquid concentrate formulations were not of concern 0 to 6 days. 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.

3. Human Incidents

Chlorpyrifos incidents were previously reviewed in 2011.[28] The human incident databases that were reviewed are:

- Office of Pesticide Programs Incident Data System (OPP IDS);
- National Pesticide Information Center (NPIC);
- NIOSH's Sentinel Event Notification System for Occupational Risks (SENSOR);
- California Pesticide Illness Surveillance Program Incident Data (CA PISP).

Incident information from each of these databases follows.

[26] 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.
[27] Total DFR (µg/cm^2) = [Chlorpyrifos DFR (µg/cm^2) * TAF] + [Chlorpyrifos DFR (µg/cm^2)]
[28] Chlorpyrifos: Tier II Incident Report https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0032

IDS

The IDS consists of the Aggregate IDS and Main IDS. In Aggregate IDS, queried from January 1, 2002 to May 27, 2010, there are 745 incidents involving chlorpyrifos. Prior to 2011, there are 247 cases reported that involve the active ingredient chlorpyrifos for the Main IDS. Of these cases, 141 cases are reported for the single chemical chlorpyrifos in the database. Most of these incidents were categorized as Human Moderates (HCs); 12 were categorized as Human Majors (HBs); and one was categorized as fatality (HA). Fifteen of these incidents were reported as affecting children 6 years old or under (2 HBs and 13 HCs). These latter incidents appear to be due to accidental ingestion and post application exposure to cancelled products. Main IDS-reported chlorpyrifos incidents appear to have decreased substantially in this period from 43 incidents in 2002, to 2 incidents in 2010. The initial large reductions generally coincide with the dates for which regulatory actions were taken.

NPIC

Similar to Poison Control Centers, NPIC's primary purpose is to provide information on a variety of pesticide topics and direct callers for pesticide incident investigation and emergency treatment. While NPIC does collect information about incidents, it generally receives fewer reports than IDS. From 2002 to 2010, 178 cases were reported for chlorpyrifos in the NPIC database. Of these cases, 88 were reviewed because, in these cases, chlorpyrifos was used as a single chemical and had a certainty classification of probable, possible, or unclassified. Eight of the chlorpyrifos cases were associated with children six years old or younger.

NIOSH SENSOR

The NIOSH SENSOR database is not national in scope and is limited to participation of 13 states.[29][30] For the 2011 human incident report, the agency analyzed NIOSH SENSOR data from 1998-2007. SENSOR focuses on occupational pesticide incidents, although both occupational and non-occupational incidents are included in the database. For NIOSH SENSOR from 1998 to 2007, there were 635 cases reported for chlorpyrifos in the database. Of these cases, 348 involved chlorpyrifos use as a single chemical only and had a certainty classification of definite, probable, or possible. There was one death due to suicide. Eight cases were classified as high severity; 60 cases, as moderate severity; and 279 cases, as low severity. Of the 348 chlorpyrifos-only cases, 18 cases involved children six years old or younger. These latter incidents were mostly due to accidental ingestions, misapplications around the home, and drift from nearby properties. Generally, chlorpyrifos incidents involved workers in agricultural or professional application occupations, homeowners and individuals at work but their job was not related to pesticide application, and to individuals exposed through drift.

California PISP

One hundred and sixty-four cases are attributable to chlorpyrifos-only exposures were reported to the California PISP between 1999 and 2008. Of these cases, 87 were occupational incidents and 77 were non-occupational incidents. A number of these incidents appear to be due to accidents and misuse. Drift of chlorpyrifos from adjacent fields appears to be the cause of the

[29] https://www.cdc.gov/niosh/topics/pesticides/overview html
[30] Only twelve states had participated between 1998- 2007.

most incidents in PISP accounting for 56% of the cases reported to PISP from 1999 to 2008. In the NIOSH SENSOR database, chlorpyrifos application appears to lead to the most incidents, being responsible for 46% reported to NIOSH SENSOR from 1998 to 2007. The chlorpyrifos incidents reported have declined substantially (95%) among residential users from 2002 to May 27, 2010; however, the rate of occupational incidents reported remained the same during this reporting period.

Overall, the incident data suggest that incidents associated with chlorpyrifos are declining over time. IDS incident reports decreased by 95% from 2002 to 2010, and NPIC incident reports have decreased by 92% from 2002 to 2010. The decrease in the number of chlorpyrifos incidents can be temporally associated with the phase out/cancellation of most residential chlorpyrifos products.

Health effects reported include neurological (e.g., tremors, headaches, dizziness, seizures), gastrointestinal (e.g., nausea, abdominal pain), respiratory (e.g., choking, coughing, shortness of breath), ocular (e.g., pain, itchiness), dermal (e.g., rash, lesions), and cardiovascular symptoms. Patients could exhibit multiple symptoms. The incidents reported have been reviewed and the agency will continue to monitor these incidents and remain alert for any changes in trend or patterns.

4. Tolerances

The 2020 revised chlorpyrifos human health risk assessment recommended changes to various tolerance levels to conform with the agency's rounding practice (*i.e.*, adding a trailing zero) at that time. Since the 2020 risk assessment was issued, the agency has decided to follow the Organization for Economic Coordination and Development (OECD) rounding class practice, which does not recommend adding a trailing zero. The EPA notes that the tolerance expression for chlorpyrifos in the 40 CFR§180.342 will be updated to comply with the S. Knizner 5/27/09 memo as follows:

> 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.

Based on data indicating that residues of chlorpyrifos may be present, EPA is recommending that tolerances be established 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 (OECD rounding class practice, commodity definition revisions, crop group conversions/revisions, and harmonization with Codex, are presented in Tables 7 and 8.

Table 7: 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 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	--	15	Recommended tolerance based on

byproducts			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. Corrected values to be consistent with OECD Rounding Class Practice.
Milk, fat	--	0.3	
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	
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 8: 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.

The agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority. The agency will consider the input and recommendations from the September 2020 FIFRA Scientific Advisory Panel (SAP) on new approach methodologies for neurodevelopmental toxicity once the SAP report is released. After receiving the SAP's conclusions, EPA will examine the need for further tolerance actions.

5. Human Health Data Needs

The following residue chemistry data deficiencies were identified for chlorpyrifos. These data are not required to support this PID.

- 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.

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. As stated earlier in this document, as part of the EPA's responsibility under the ESA, the agency completed a nationwide biological evaluation for chlorpyrifos initiated consultation with the NMFS in January 2017. In July 2019, EPA re-initiated formal consultation. NMFS is planning to issue a revised final BiOp for chlorpyrifos, diazinon, and malathion by June 2022. FWS has not yet issued a BiOp on chlorpyrifos.

Because the EPA's assessment of listed species is contained in its biological evaluation mentioned above, only the potential risks for non-listed species are described below.

The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of chlorpyrifos. The agency has compiled an evaluation of risks to non-listed species for registration review in the document *Chlorpyrifos Draft Ecological Risk Assessment for Registration Review*. That document is based in part on the agency's biological evaluation for chlorpyrifos.[31] For additional details on the ecological assessment for chlorpyrifos, see the *Chlorpyrifos Draft Ecological Risk Assessment for Registration Review* (September 15, 2020), which is available in the public docket.

1. Risk Summary and Characterization

Chlorpyrifos prevents the natural breakdown of various cholines by inhibiting cholinesterase activity and ultimately causing the neuromuscular system to seize. Chlorpyrifos will initially enter the environment via direct application and may move off-site via runoff, spray drift, or volatilization. As it degrades, chlorpyrifos forms chlorpyrifos-oxon, TCP, and TMP. Further discussion on the consideration of residues of concern, the fate of chlorpyrifos, and study

[31] https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment

information may be found in the biological evaluation[32] and the previously issued drinking water assessments.[33] [34]

Terrestrial Risks

Mammals

The streamlined ecological risk assessment identified acute and chronic risks of concern from most uses for chlorpyrifos. Acute risk estimates for mammals from chlorpyrifos exposure ranged from 0.01 to 10. Half of the uses assessed resulted in acute RQs of 5 or greater (LOC = 0.5). Chronic risks in animals based on reproductive effects, a 30% loss of pups, ranged from 0.66 to 625. All chronic RQs based on a 4 to 5% decrease in body weight resulted in potential exceedances to the agency's LOC of 1 with a range of 2.01 to 1900. Fifty percent of uses resulted in RQs greater than 148 based on a reproductive endpoint and over 450 based on body weight loss.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Acute RQs ranged from 0.07 to 380 with over half of all uses resulting in RQs greater than 93 (LOC = 0.5). Risk estimates for birds were based on significant reproductive effects, an 83% reduction in eggs laid. More than half of uses assessed resulted in chronic RQs above 14 with a total range of 0.60 to 58 (LOC = 1). As a result, there may be adverse effects to birds, as well as to terrestrial-phase amphibians and reptiles for which birds serve as surrogates.

Terrestrial Invertebrates (honeybees)

Consistent with its use as an insecticide, chlorpyrifos is highly toxic to adult honeybees on an acute exposure basis. The 2017 biological evaluation did not include the review of one acute larval honeybee study from Corteva. MRID 49960301 was submitted on the effects of chlorpyrifos to honeybee larvae after acute *in vitro* exposure. This study resulted in an LD_{50} of 0.0165 µg a.i./larva. This represented the most sensitive endpoint available for effects to honeybee larvae and was used as the endpoint for risk estimation. Acute RQs range from 820 to 4900 with exceedances for all uses (LOC = 0.4). Chronic toxicity data is not available for chlorpyrifos; therefore, the risk picture for terrestrial invertebrates is incomplete.

After EPA issued the problem formulation and registration review DCI for chlorpyrifos, EPA released its June 2014 *Guidance for Assessing Pesticide Risks to Bees*[35]. This 2014 guidance lists additional pollinator studies that were not included in the chlorpyrifos registration review DCI. Due to the timing of the chlorpyrifos DCI being issued before the guidance came out, EPA is not requiring any additional studies for assessing pollinators as part of registration review, although EPA continues to consider whether additional pollinator data are needed for chlorpyrifos. If the

[32] https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
[33] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0198
[34] https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0437
[35] Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

agency determines that additional pollinator exposure and effects data are necessary for chlorpyrifos, then the EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 9 below.

Table 9: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline	Honey bee adult chronic oral toxicity
Non-Guideline	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

Terrestrial and Aquatic Plants

Risk quotients for aquatic vascular, non-vascular, and terrestrial plants did not exceed EPA's LOC of 1 with a total range of < 0.01 to 0.42. In addition, there were no vegetative vigor effects seen for either monocots or dicots and no seedling emergence effects were observed for monocots. There are some incidents involving plants from chlorpyrifos exposure, but potential risks to terrestrial or aquatic plants from chlorpyrifos exposure is considered limited.

Aquatic Risks

Fish and Aquatic-Phase Amphibians

The acute and chronic effects of chlorpyrifos exposure have been studied extensively in aquatic organisms. The acute LC_{50} for estuarine/marine and freshwater fish were 0.37 and 1.7 µg a.i./L, respectively. The chronic NOAEC was 0.28 µg a.i./L for estuarine fish but was not determined for freshwater fish which had a LOAEC of 0.251 µg a.i./L. Endpoints for fish were based on a 52% in fecundity for freshwater fish with a LOAEC of 0.251 µg a.i./L, lower than that of 0.48 µg a.i./L, for estuarine fish with 32% reduction in fecundity.

As with mammals, the majority of acute and all chronic RQs exceeded EPA's LOC of 0.5 for acute risks and 1 for chronic risks. Over 50% of uses assessed resulted in acute RQs above 33 with a range of .42 to 160. Chronic RQs reached a maximum of 135. Given the many use patterns affiliated with chlorpyrifos use, potential risks to fish and aquatic-phase amphibians from chlorpyrifos exposure can be expected.

Aquatic Invertebrates

All RQs for aquatic invertebrates were well above the agency's LOC of 0.5 for acute risks and 1 for chronic risks. Maximum acute and chronic RQs were 4300 and 8600, respectively, with 50% of all uses having RQs over 880 and 1540, respectively. Since chlorpyrifos is registered for a number of uses patterns across the United States, there exists the potential for risks to aquatic invertebrates.

2. Ecological Incidents

Numerous notable ecological incidents (e.g., significant fish kills, bee kills, large number of bird deaths) have been reported for all taxa for chlorpyrifos, including plants. These incidents summarized herein are based on the incidents reported for the chlorpyrifos Biological Evaluation and were reported with a high certainty level that chlorpyrifos was the associated causative agent. The biological evaluation on chlorpyrifos provided an extensive analysis of reported incidents broken down by individual taxa. Chlorpyrifos was reported as the 'possible,' 'probable,' or 'highly probable' causative agent for 110 adverse aquatic incidents (e.g., fish kills), 64 incidents involving birds, and 43 terrestrial plant incident reports. Some of the terrestrial plant incident reports were associated with spray drift, but most involved damage to the crop treated.

Additionally, 36 bee incidents were classified with a certainty index of 'possible', 'probable' or 'highly probable'. All of the terrestrial invertebrate incident reports involve honeybees, with bees being exposed via foraging on treated plants or by spray drift.

On August 14, 2020, an updated incident report was generated from the Incident Data System (IDS) for the time period from approximately January 1, 2015 to August 14, 2020. There were 20 unique incidents reported associated with nontarget organism in IDS. All of these incidents were associated with bee kills, except for one where the organism impacted was not specified. Two aggregate incidents, one presumed to involve bees, and one involving non-specified wildlife, were additionally reported.

EPA will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

No additional ecological or environmental fate data are required to support this registration review decision. EPA will consider requiring submission of pollinator data as a separate action.

C. Benefits Assessment

Based on a recent analysis[36] conducted by the agency for agricultural uses of chlorpyrifos, the total annual economic benefit of chlorpyrifos to crop production is estimated to be $19 - $130 million. These estimates are based on the additional costs of alternative pest control strategies likely to be used in the absence of chlorpyrifos or reduced revenue for some crops that do not have effective alternatives to chlorpyrifos for some pests. In some cases, effective alternatives could not be found; for those crops, the benefit of chlorpyrifos was estimated by yield or quality losses if chlorpyrifos were no longer available for use.

The high benefits are reflected in the wide use of chlorpyrifos on many different crops. However, despite this widespread usage, the majority of the benefits are concentrated in specific crops and regions that rely on chlorpyrifos without available effective alternatives to control pests. In particular, there are potentially high total benefits of chlorpyrifos usage in the production of sugar beets in Minnesota and North Dakota, oranges in California, peaches in the Southeastern U.S., and soybeans and apples throughout the U.S. The high-end total benefit for each of these crops is estimated to be in excess of $7 million per year. High total benefits are driven by high per-acre cost of production without chlorpyrifos in the case of sugar beets, orange, apple, and peach, and by the extent of acres treated in the case of large field crops like soybean despite relatively low benefits per acre.

For most non-crop uses, the agency's assessment[37] concluded that, chlorpyrifos is no longer recommended or heavily used for critically important insect pests. However, there a few exceptions to this overall conclusion. For pests of public health concern, such as mosquitoes and certain ticks, chlorpyrifos is one of a limited set of effective options available for wide area or broadcast use in specific use settings, such as government agency mosquito control districts (when suppressing adult mosquitoes), and golf courses (for ticks). For mosquitoes, chlorpyrifos also has value as one of a few insecticides that can be used against pyrethroid-resistant populations or to delay the onset of such resistance. While effective alternatives are available, due to the consequences to public health posed by the serious diseases transmitted by these pests, chlorpyrifos provides an important resistance management tool to sustain the effectiveness of non-organophosphate alternatives.

Similarly, for the protection of certain types of cattle livestock from horn flies, chlorpyrifos confers a benefit to control fly populations that have developed tolerance to pyrethroids, a widely used class of insecticides. In addition, for horn fly populations that have not yet developed pyrethroid resistance, chlorpyrifos is an active ingredient that, when used in rotation with pyrethroids, could mitigate, delay or even avoid insecticide resistance. Finally, for producers of outdoor-grown nursery plant stock, chlorpyrifos is one of a very limited set of insecticide options that qualify producers' products for pest-free certification in southeastern U.S. states that are currently under a USDA quarantine intended to prevent the spread of imported fire ants.

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[36] Mallampalli, N., Waterworth, R., and Berwald, D. 2020. Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101). Biological and Economic Analysis Division memorandum to the Pesticide Re-Evaluation Division. Official record available through the chlorpyrifos docket at www.regulations.gov.

[37] Mallampalli, N. and C. Paisley-Jones. 2020. Chlorpyrifos Benefits Assessment for Non-crop Uses. Biological and Economic Analysis Division memorandum to the Pesticide Re-Evaluation Division. Official record available through the chlorpyrifos docket at www.regulations.gov.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed and Considered Risk Mitigation and Regulatory Rationale

Chlorpyrifos poses potential dietary and aggregate risks associated with drinking water exposure for currently labelled uses with and without the 10X FQPA safety factor, and mitigation is being proposed to reflect the range of potential risks. With the exception of seed-treatment uses, both occupational handler and post-application risks of concern were identified with and without the 10X UF_{DB}. PPE, use restrictions, and REI extensions are being considered to address these potential risks. The agency is also proposing spray drift management label language, pesticide resistance management label language, and other labeling updates consistent with those which are being required for other pesticides in registration review.

The agency will consider the input and recommendations from the September 2020 FIFRA Scientific Advisory Panel (SAP) on new approach methodologies for neurodevelopmental toxicity once the SAP report is released. After receiving the SAP's conclusions, EPA may further revise the human health risk assessment and proposed/considered mitigation. The agency is currently in discussions with the registrants regarding the proposed/considered mitigation measures.

1. Use Cancellations

To mitigate potential dietary exposure to chlorpyrifos, the agency is proposing to limit application to select uses in certain regions of the U.S. where the EDWCs for those uses are lower than the DWLOCs. Table 10 provides a list of the high-benefit agricultural uses that the agency has determined will not pose potential risks of concerns with an FQPA safety factor of 10X and may be considered for retention. In addition to the agricultural uses listed below, the agency may also retain use on public health pests such as mosquitos, ticks, and fire ants. The 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.

Table 10: Agricultural Uses Proposed for Retention in Chlorpyrifos Labels with an FQPA Safety Factor of 10X

Use Site	State for retention at the 10X[1]
Alfalfa	AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WY
Apple	AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV
Asparagus	MI
Cherry (tart)	MI
Citrus	AL, FL, GA, NC, SC, TX
Cotton	AL, FL, GA, NC, SC, VA
Peach	AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV

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
Strawberry	OR
Sugar beet	IA, ID, IL, MI, MN, ND, OR, WA, WI
Wheat (spring)	CO, KS, MO, MT, ND, NE, SD, WY
Wheat (winter)	CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY
[1]Only specific uses in specific 2-digit HUCs were assessed as described in the 2020 drinking water assessment. These specific uses are based on usage data and may not reflect maximum label rates on current labels.	

With a 1X FQPA safety factor, the majority of labeled chlorpyrifos uses result in drinking water concentrations below the DWLOC. Uses with drinking water concentrations above the DWLOC include, 1) peppers, 2) trash storage bins, and 3) wood treatment. In addition, six uses as noted in Table 11 below, can only be retained in certain states. Otherwise, all labeled chlorpyrifos uses can be retained nationwide.

Table 11: Regional Restrictions for Corn, Tart Cherries, Citrus, Pecan, and Peach with an FQPA Safety Factor of 1X

Use Site	State for retention at the 1X[1]
Corn	AL, AR, FL, GA, IA, IL, IN, KS, KY, LA, MN, MO, MS, MT, NC, ND, NE, NY, OH, OK, PA, SC, SD, VA, VA, WI, WV, WY
Cherries (tart) 3 lb a.i./A	WA, OR, ID, MT (Deer Lodge, Flathead, Granite, Lake, Lincoln, Mineral, Missoula, Powell, Ravalli, Sanders, and Silver Bow counties)
Cherries (tart) 2 lb a.i./A	MI, WA, OR, ID, MT (Deer Lodge, Flathead, Granite, Lake, Lincoln, Mineral, Missoula, Powell, Ravalli, Sanders, and Silver Bow counties)
Citrus	AL, FL, GA, NC, SC, TX
Pecan	AL, FL, GA, NC, NM, OK, SC, TX
Peach	AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV
[1]Only specific uses in specific states listed above were assessed as described in the 2020 supplemental document. These specific uses were assessed based on actual application rates from reported usage data and may not reflect maximum label rates on current labels. If usage data were not available no additional refinement was possible, therefore, the state would not be listed.	

Stakeholders and registrants identified to EPA particular crops they considered to be important chlorpyrifos uses.[38] EPA estimated the benefits of chlorpyrifos in these, and many other crops

[38] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0938

with chlorpyrifos use.[39] Uses that were identified by stakeholders and registrants as important were alfalfa, citrus, cotton, soybean, sugar beet, and wheat. The estimated per acre benefits for alfalfa were low, at around $1 per acre, but over 1 million acres are treated annually, so total benefits were over $1 million. For citrus, there are potential high benefits for California lemons in some cases, with benefits of $290 per acre. The high-end benefit estimate for California oranges was similar. However, chlorpyrifos use is already restricted in California, with almost all uses banned after 2020.[40] Estimated benefits of chlorpyrifos in cotton are up to $14 per acre, with total benefits of up to $6.1 million annually. The benefit of chlorpyrifos in soybean is up to $4 per acre, and with over 3 million acres treated annually, the total benefit could be about $12 million. Sugar beets had potentially very high per acre benefits of almost $500 per acre in parts of Minnesota and North Dakota, leading to high-end estimated benefits over $30 million overall. Per acre benefits in wheat are estimated to be low, about $1 per acre in both spring and winter wheat, with a total benefit for both crops of about $1.3 million. In addition to these crops, EPA estimated high per-acre economic benefits to growers.

Crops that EPA concluded have potentially high benefits per-acre were: apples (nationwide), where alternatives for some pests could cost up to $51 per acre more than chlorpyrifos; asparagus, where the lack of alternatives in Michigan specifically could lead to yield losses of up to $450 per-acre; tart cherries in Michigan, where uncontrolled pest pressure could lead to yield losses of up to $201 per-acre; peaches in the southeastern U.S., where uncontrolled pest pressure could lead to yield losses of up to $430 per acre in Georgia and South Carolina; strawberries in Oregon, where uncontrolled soil pests (garden symphylans) could lead to abandonment of strawberry acreage, with a loss that corresponds to over $7,800 per acre.

2. PPE

The agency is providing the details for all currently labelled uses that would require additional PPE should those uses be retained. Given the current proposal in Section IV.A.1., should cancellation of uses be pursued, only the subset of remaining uses will be identified as requiring the additional PPE described below.

As specified in Section III.A.2., of the 288 steady state occupational handler scenarios assessed for non-seed treatments, 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and an elastomeric half mask respirator) assuming the 10X UF_{DB} (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 (MOEs < 10). Risks of concern for 15 additional scenarios could potentially be mitigated if engineering controls are used.

[39] Mallampalli, N., Waterworth, R., and Berwald, D. 2020. Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101). Biological and Economic Analysis Division memorandum to the Pesticide Re-Evaluation Division. Official record available through the chlorpyrifos docket at www.regulations.gov.
[40] https://www.cdpr.ca.gov/docs/chlorpyrifos/pdf/chlorpyrifos_action_plan.pdf

a. PPE Requirements – potential risks with the 10X UF_{DB}

Airblast applications

With the exception of citrus and tree nuts (pecans), risk estimates for mixing and loading formulations in WSP were above the LOC of 100. The agency is considering reducing the rate of citrus from 6.0 lbs a.i./Acre to 4.0 lbs a.i./Acre due to occupational risks identified to airblast applicators. Although the MOEs for tree nuts (pecans) and citrus at the lower rate do not meet the LOC of 100, chlorpyrifos is regarded as a high benefit to these uses.

For the remaining formulations (L/SC/EC), risk estimates for mixers and loaders are below the LOC with the following PPE:

Table 12: Considered engineering controls and PPE for risks of concern from airblast applications

Crop/Use	PPE/Engineering controls	MOE
Citrus, Non-bearing Fruit and Nut Trees (Nursery)	Engineering controls	140
Tree Fruits (Nectarine, Peach - Dormant, Delayed Dormant)		190
Cherries, tree fruits (pear, plum/prune (dormant, delayed dormant), tree nuts (almonds, filberts, hazelnuts, pecans, walnuts)	Double layer (coveralls), gloves, and either a particulate filtering facepiece (PF5)	110
Ornamental and/or shade trees, ornamental woody shrubs and vines, herbaceous plants, Christmas tree plantations, grapes	Single layer (long pants and long sleeve shirt), gloves	150

To address potential risks of concerns from mixing and loading L/SC/EC formulations for airblast application, the agency is considering engineering controls or PPE as listed for the uses in Table 12.

MOEs for mixing and loading airblast applications for citrus at an application rate of 6.0 lbs a.i./acre (CA and AZ) are 67 for WSP formulations and 96 for L/SC/EC formulations. Given other risks of concern from this rate, the agency is considering reducing this application rate for Arizona to 4 lbs a.i./acre. Exposures in California are considered negligible after 2020. See Section IV.3. below for additional details regarding proposed application rate reductions.

All airblast application scenarios without engineering controls (i.e., enclosed cabs) resulted in risk estimates of concern without retention of the 10X UF_{DB}. MOEs for these scenarios ranged from 0.55 to 4.2. With engineering controls, MOEs were below the LOC of 100 for tree nuts (pecans) and citrus at 89 and 98, respectively, however, chlorpyrifos provides high benefits for use on these food crops. EPA, as a result, is considering requiring engineering controls for all airblast applications.

Groundboom applications

With the retention of the 10X UF_{DB}, EPA is considering requiring engineering controls (closed systems) to address potential risks of concerns to occupational handlers mixing and loading L/SC/EC chlorpyrifos formulations for groundboom applications for the following uses:

- Nursery stock (pre-plant)
- Brussels sprouts (at plant and post-emergence), cauliflower, cole crops, grapes (foliar, dormant, delayed dormant), mint (peppermint, spearmint), peanut, pineapple, rutabaga, strawberries (pre-plant), sunflower (pre-plant) sweet potato (pre-plant and soil broadcast), and tobacco (pre-plant).
- Beets (table, sugar, at plant), clover (grown for seed, foliar), hybrid cottonwood and polar plantations
- Cranberry
- Alfalfa, cotton, sorghum grain, soybean, and wheat
- Radishes (pre-plant).

Addition of engineering controls (closed systems) for mixing and loading L/SC/EC formulations for radishes is 96 and below the LOC of 100. Chlorpyrifos, however, is considered a high benefit for this use.

For the remaining groundboom applications that may be mitigated with additional PPE, EPA is considering the following measures for mixers and loaders in Table 13 and measures for applicators in Table 14:

Table 13: Considered PPE for Mixing and Loading Groundboom applications: L/SC/EC

Crop/Use	Proposed PPE	MOE[1]
Carrots	Double layer (coveralls), gloves, and a particulate filtering facepiece (PF 5)	110
Carrots	Double layer (coveralls), and gloves	92
Ornamental and/or shade trees, herbaceous plants, ornamental woody shrubs and vines		91
Asparagus, beets (table, sugar; at plant), citrus orchard floors, forest plantings (reforestation, plantation, tree farm), grass (forage/fodder/hay), legume vegetables, nonagricultural outdoor buildings and structures, onions		91
Conifers and deciduous trees, seed orchard trees		96

Golf course (fairways, tees, greens)	Single layer (long-sleeved shirt and long pants) and gloves	150

[1]MOE < LOC; however, chlorpyrifos is considered to be a high benefit to this use.

Table 14: Considered PPE or Engineering Controls for Groundboom Applicators		
Crop/Use	**Considered PPE or considered engineering controls**	**MOE[1]**
Alfalfa, sorghum grain, soybean, and wheat	Engineering controls	200
Ornamental lawns and turf, sod farms (turf)		130
Radish (pre-plant)		170
Turnip		86
Alfalfa, sorghum grain, soybean, and wheat	Double layer (coveralls), gloves, and an elastomeric half mask respirator	92
Nursery stock (pre-plant)	Double layer (coveralls), gloves, and a particulate filtering facepiece respirator	110
Brussels sprouts (at plant and post-emergence), cauliflower, cole crops, grapes (foliar, dormant, delayed dormant), mint (peppermint, spearmint), peanut, pineapple, strawberries (pre-plant), sunflower (pre-plant) and tobacco (pre-plant		110
Brussels sprouts (post-plant), grapes (foliar)		96
Clover (grown for seed, foliar), hybrid cottonwood and polar plantations		110
Rutabaga		88
Alfalfa, Sorghum Grain, Soybean, Wheat		87
Sweet potato (pre-plant and soil broadcast)	Single layer, gloves, and an elastomeric half mask respirator	88
Cranberry	Single layer, gloves, and a particulate filtering facepiece respirator	120
Beets (table, sugar; at plant), clover (grown for seed; foliar), hybrid cottonwood/poplar plantations		90

Asparagus, beets (table, sugar; at plant), citrus orchard floors, cole crops (excludes Brussels sprouts and cauliflower), cotton, forest plantings (reforestation, plantation, tree farm), grapes (dormant, delayed dormant), grass (forage/fodder/hay), legume vegetables, nonagricultural outdoor buildings and structures, onions, peppers, and strawberries	Single layer (long-sleeved shirt and long pants) and gloves	120
Ornamental and/or shade trees, herbaceous plants, ornamental woody shrubs and vines		120
Carrots		130
Conifers and deciduous trees, seed orchard trees		170
Forest trees (softwoods and conifers)		200
Golf course (fairways, tees, greens)		250

[1]MOE < LOC; however, chlorpyrifos is considered to be a high benefit to this use.

Handheld and Tractor-drawn Spreader applications

The agency is considering requiring the use of double layer PPE (coveralls), gloves, and an elastomeric half mask respirator, for mixers, loaders, and applicators applying chlorpyrifos liquid concentrate formulations via manually-pressurized handwand for wood protection treatment and to pine seedlings in a nursery. Although the MOEs are 82 and 90, respectively, and therefore are of concern at the 10X UF_{DB}, the agency considers chlorpyrifos to be of high benefit for these uses.

To increase MOEs to the LOC of 100, the agency is considering requiring additional PPE for manually-pressurized handwand application on the following uses:

- Single layer (long-sleeved shirt, long pants, socks, and shoes), gloves, and a particulate filtering facepiece for wide area/general outdoor treatment
- Single layer (long-sleeved shirt, long pants, socks, and shoes) and gloves for: Christmas tree plantations, conifers and deciduous trees; plantation nurseries, grapes, seed orchard trees, forest trees (softwoods, conifers), golf course turf, mounds/nests, non-agricultural outdoor buildings and structures, ornamental woody shrubs and vines, ornamental non-flowering plants, outdoor commercial/institutional/industrial premises (see master label description), agricultural farm premises, poultry litter, tree fruits (cherries, nectarines, peaches, plum/prunes), tree nuts (almonds) - pre-plant, tree nuts (apple) - pre-plant, and fruits and nuts (non-bearing, see master label description).

Regardless of PPE, risk estimates for application with mechanically pressurized handgun were below EPA's LOC of 100 for all uses except ornamental woody shrubs and vines and seed orchard trees (MOEs = 440 to 8,300); MOEs of concern ranged from 2.1 to 83 for all other uses and were therefore of concern.

For the following backpack sprayer applications and formulations, the PPE listed below is being proposed in Table 15:

Table 15: Considered Mitigation for Backpack Sprayer Applications

Formulation	Application type	Crop/Targeted Use	PPE[1]	MOE
Dry flowable/water-dispersable granule in WSP	Broadcast (foliar)	Grapes (pre-bloom)	Double layer (coveralls), gloves, and an elastomeric half mask respirator	94[2]
	Trunk spray/Drench	Tree fruits (apple)		100
	Drench/Soil-Ground-directed	Grapes (pre-bloom)		150
L/SC/EC	Broadcast (foliar)	Golf course turf		94[2]
	Spot treatment applications (0.023 A treated)	Ornamental and/or Shade Trees, herbaceous plants	Baseline	320
		Ornamental lawns and turf, sod farms (turf)		350
		Outdoor commercial/institutional/industrial premises, non-agricultural buildings and structures, golf course turf		1300
Microencapsulated formula	Broadcast (foliar)	Ornamental woody shrubs and vines	Double layer (coveralls), gloves, and an elastomeric half mask respirator	94[2]
		Ornamental non-flowering plants		130
	Directed broadcast	Outdoor commercial/institutional/industrial premises	Baseline	230
	Broadcast	Agricultural farm premises	Baseline	400
	Broadcast	Poultry litter	Baseline	1100
WSP	Spot	Ornamental woody shrubs and vines (pre-transplant)	Baseline	330
	Spot	Outdoor lawns and turf, Sod Farms (turf)	Baseline	350

	Broadcast (foliar)	Ornamental woody shrubs and vines	Baseline	930

[1]Baseline PPE includes long-sleeved shirt, long pants, shoes, no gloves, and no respirator.
[2] Although additional PPE does not result in MOEs above the LOC of 100 with the retention of the 10X UF_{DB}, chlorpyrifos is considered a high benefit for these uses.

The above-mentioned uses are the only uses which meet the agency's LOC of 100 with retention of the 10X UF_{DB}. All remaining uses treated by backpack sprayer applications are considered below in section IV.A.3 for possible application method prohibitions.

Tractor-drawn spreader applications

To address risks of concern to occupational handlers applying chlorpyrifos by tractor-drawn spreader, EPA is considering use of additional PPE. Most MOEs for mixers, loaders, and applicators are above the LOC of 100 with use of a SmartBox®, which is considered an engineering control. The EPA is considering additional PPE as follows for the uses in Table 16:

Table 16: Considered mitigation for tractor-drawn applications

Crop/Targeted Use	PPE	MOE[1]
Mixers/Loaders		
Ornamental woody shrubs and vines	Double layer (coveralls), gloves, and an elastomeric half mask respirator	91
Alfalfa	Single layer (long-sleeved shirt and long pants) and an elastomeric half mask respirator	98
Rutabaga	Single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece	100
Sweet potato		120
Brussels	Single layer (long-sleeved shirt and long pants) and a particulate filtering facepiece	92
Asparagus		120
Nursery stock		220
Citrus orchard floors, onions, ornamental lawns and turf, sod farms (turf)		180
Applicators		
Peanut	Double layer (coveralls), gloves, and an elastomeric half mask respirator	110
Sorghum grain		110
Ornamental woody shrubs and vines		96
Radish		85

Rutabaga	Single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece	97
Alfalfa		92
Cauliflower (post-plant), Turnip	Single layer (long-sleeved shirt and long pants) and a particulate filtering facepiece	86
Brussels Sprouts (post-plant)		86
Sweet potato		92
Cole crops (except cauliflower), ginseng, sugar beets, sunflower, tobacco		98
Asparagus		130
Nursery stock	Single layer (long-sleeved shirt and long pants), gloves	98
Citrus orchard floors, onions, ornamental lawns and turf, sod farms (turf)	Double layer (coveralls), gloves	87

[1] Although additional PPE does not result in MOEs above the LOC of 100 with the retention of the 10X UF_{DB}, chlorpyrifos is considered a high benefit for these uses.

Hand dispersal application

At baseline PPE, MOEs for the following uses are below the EPA's LOC of 100 when treated by rotary spreader or hand dispersal application. Therefore, the agency is considering requiring the following PPE:

Table 17: Considered Mitigation for Applications by Rotary Spreader or Hand Dispersal

Crop/Target Category	Application Equipment	Application Type	PPE	MOEs
Nursery stock	Rotary spreader	Broadcast	Double layer (coveralls) and gloves	110
Golf course turf, ornamental and/or shade trees, herbaceous plants, ornamental lawns and turf, sod farms (turfs)			Single layer (long sleeved shirt, long pants) and gloves	100
Golf course (turf) sod farms (turf)	Hand dispersal	Spot		130

Risk estimates for all other uses (ornamental woody shrubs and vines, commercial/institutional/industrial premises, utilities (pad)) fall below the LOC of 100 with maximum PPE (double layer (coveralls), gloves, and an elastomeric half mask respirator) and with retention of the 10X UF_{DB}. Therefore, the remaining uses are considered for possible application method prohibitions as addressed below in section IV.A.3.

Wide Area Mosquito Abatement

Risk estimates of concern were found for occupational handlers mixing, loading, and applying for wide-area mosquito treatment. Chlorpyrifos is not the primary pesticide used for the majority of wide-area mosquito treatment programs. However, given the public health concern for mosquito as vectors for a number of pathogens, there are high benefits for maintaining chlorpyrifos to treat adult mosquitos, particularly in areas with high pest pressure.

Without engineering controls, MOEs for applying wide area treatments of mosquito adulticide by ground are of concern. Thus, EPA is considering requiring engineering controls (enclosed cab) for airblast and aerial application of wide area mosquito treatment and double layer (coveralls), gloves, and an elastomeric half mask respirator for mixing and loading airblast and aerial applications.

b. PPE Requirements – potential risks without the 10X UF_{DB}

Aerial and Chemigation Application

Due to potential risks of concern to mixers and loaders for aerial application even without retention of the 10X UF_{DB}, EPA is considering requiring the following:

Table 18: Considered Mitigation for Mixing and Loading for Aerial and Chemigation Applications at the 1X FQPA Safety Factor

Crop/Target Category	Formula	Considered Engineering Controls or PPE	MOE
Aerial, Chemigation			
Citrus	L/SC/EC	Double layer (coveralls), gloves, and either a particulate filtering facepiece or an elastomeric half mask respirator	11
Non-bearing fruit and nut trees (nursery), radish (pre-plant), turfgrass (sod or seed)			12
Cherries, hybrid cottonwood/poplar plantations, mint (peppermint and spearmint), peanut, rutabaga, strawberries			12

(pre-plant), sunflower (pre-plant), sweet potato, tobacco, tree fruits (apple,), nectarine, peach, pear, plum/prune), tree nuts (almonds, filberts, hazelnuts, pecans, walnuts), turfgrass (ornamental and sod farms)			
Clover (grown for seed), cranberry, sunflower (post-emergence/ foliar)			13
Asparagus, Brussels sprouts, cauliflower, cole crops, strawberries, sugar beets, radish	L/SC/EC	Single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece	13
Aerial Application			
Corn (post-emergence)	L/SC/EC	Engineering Controls	13
Corn (pre-plant)	Granule	Double layer (coveralls), gloves, and either a particulate filtering facepiece or an elastomeric half mask respirator	13
Alfalfa, corn (pre-plant), cotton (except Mississippi), sorghum, soybean, wheat	L/SC/EC	Single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece	13
Christmas tree plantations			18
Carrots			19
Peanut	Granule		10
Sweet potato			20
Chemigation Application			
Tree nuts, orchard floors, (pecans)	L/SC/EC	Engineering controls	15
Tree nut orchard floors (almonds, walnuts)			17

Corn (pre-plant)			22
Corn (post-emergence)		Single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece	13
Alfalfa, corn (pre-plant), cotton (except Mississippi), sorghum, soybean, wheat			18

Groundboom Application

Mixing and loading all formulations in WSP resulted in MOEs above 10 and are not of concern at the UF_{DB} of 1X. Mixing and loading most L/SC/EC formulations with single layer (long-sleeved shirt, long pants) and a particulate filtering facepiece results in risks of concern for most uses. MOEs ranged from 1.9 to 28 with risks of concerns for the following uses: Corn (pre-plant and post-emergence), radish (pre-plant), rutabaga, Brussels sprouts (at-plant, post-plant), grapes (foliar, dormant, delayed dormant), sweet potato (pre-plant, soil broadcast), cotton (except Mississippi), cole crops, cauliflower, mint (peppermint, spearmint), peanut, pineapple, strawberries (pre-plant), sunflower (pre-plant), tobacco (pre-plant), cranberry, alfalfa, cotton, sorghum grain, soybean, wheat, beets (table, sugar; at plant), clover (grown for seed; foliar), hybrid cottonwood/poplar plantations, tree nut orchard floors (pecans, almonds, walnuts), nursery stock (pre-plant), ornamental lawns and turf, and sod farms.

With the addition of gloves for these uses, the range of MOEs increases to 11 – 56 and are no longer of concern at the UF_{DB} of 1X.

Groundboom application risks of concern were identified for corn (pre-plant), tree nut orchard floors (pecans, almonds, walnuts), and cotton (except Mississippi) (MOEs = 5.3 – 9.9). With the use of single layer (long-sleeved shirt, long pants) and gloves, all risk estimates for groundboom applicators are greater than 10 are not of concern at the UF_{DB} of 1X.

Airblast and Handheld Applications

For mixing and loading L/SC/EC for airblast applications, EPA is considering single layer (long-sleeved shirt and long pants) and gloves for the following uses:

- Citrus (CA and AZ); MOE = 24
- Citrus, Non-bearing Fruit and Nut Trees (Nursery); MOE = 36
- Tree Fruits (Nectarine, Peach - Dormant, Delayed Dormant); MOE = 48

EPA is also considering requiring double layer (coveralls) and gloves for backpack application on wide-area general outdoor treatment, and outdoor commercial/institutional/industrial premises, non-agricultural outdoor buildings and structures. The MOEs with this additional PPE range from 12 to 19.

For handheld applications, EPA is considering requiring single layer (long-sleeved and long pants) and gloves for:

- Brush roller application to wood protection treatment (MOE = 16) and structural (e.g., warehouses, food handling establishments, and home bathrooms (MOE = 33)).
- Manually-pressurized handwand application to: Wood protection treatment, nursery (pine seedlings), wide area/ general outdoor treatment, Christmas tree plantations, conifers and deciduous trees; plantation nurseries, grapes, seed orchard trees, forest trees (softwoods, conifers), golf course turf, mounds/nests, non-agricultural outdoor buildings and structures, indoor commercial/institutional/industrial premises (see master label description), food processing plant premises, ornamental woody shrubs and vines, ornamental non-flowering plants, tree fruits (cherries, nectarines, peaches, plum/prunes), tree nuts (almonds) - pre-plant, and tree nuts (apple) - pre-plant.

c. Additional PPE Labeling Updates and Requirements

PPE Label Consistency Updates

In addition, the agency is considering updating the glove and respirator statements currently on labels. The proposed new glove and respirator language does not fundamentally change the PPE that workers need to use, and therefore should impose no impacts on users.

For gloves in particular, all statements that refer to the chemical resistance category selection chart are proposed to be removed from chlorpyrifos labels, as they might cause confusion for users. These statements are proposed to be replaced with specific chemical-resistant glove types, consistent with the Label Review Manual.[41]

Respirator Requirement for Chlorpyrifos Handlers

To mitigate potential inhalation risk to occupational handlers, the agency is considering requiring a respirator and, for pesticides covered by the Worker Protection Standard[42] (WPS), the associated fit test, training, and medical evaluation for the aforementioned formulations and uses.

The EPA has recently required fit testing, training, and medical evaluations[43] for all handlers who are required to wear respirators and whose work falls within the scope of the WPS.[44] If a chlorpyrifos handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer, which includes the cost of the respirator plus, for WPS-covered products, the cost for a respirator fit test, training, and medical exam.

[41] https://www.epa.gov/pesticide-registration/label-review-manual
[42] 40 CFR 170
[43] Fit testing, training, and medical evaluations must be conducted according to OSHA regulations 29 CFR § 1910.134, 29 CFR § 1910.134(k)(1)(i) through(vi), and 29 CFR § 1910.134, respectively.
[44] 40 CFR 170 (see also Appendix A of Chapter 10 of the Label Review Manual, available at https://www.epa.gov/pesticide-registration/label-review-manual). [45] Economic Analysis of the Agricultural Worker Protection Standard Revisions. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 2015. p. 205. Available at www regulations.gov, docket number EPA-HQ-OPP-2011-0184-2522.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on available information that the EPA has, the cost of the respirators (whether disposable or reusable) is relatively minor in comparison to the fit-test requirement under the Worker Protection Standard. The agency expects that the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. The estimated cost of a respirator fit test, training and medical exam is about $180 annually.[45] The impact of the proposed respirator requirement is likely to be substantially lower for a chlorpyrifos handler who is already using a respirator because the handler or handler's employer uses other chemicals requiring a respirator in the production system or as part of the business (*i.e.*, the handler or employer will only incur the cost of purchasing filters for the respirator on a more frequent basis). Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection.[46]

The EPA acknowledges that requiring a respirator and the associated fit testing, training, and medical evaluation places a burden on handlers or employers. However, the proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. In estimating the inhalation risks, and the risk reduction associated with different respirators, the EPA's human health risk assessments assume National Institute for Occupational Safety and Health (NIOSH) protection factors (*i.e.*, respirators are used according to OSHA's standards). If the respirator does not fit properly, use of chlorpyrifos may cause unreasonable adverse effects on the pesticide handler.

Engineering Requirement for Handlers

EPA is considering requiring that a closed pesticide delivery system be used for mixing and loading chlorpyrifos for applications to several uses as described above. Professional applicators likely have closed pesticide delivery systems because they handle multiple chemicals, some of which likely already require closed pesticide delivery systems. Thus, the impacts of this restriction would likely be small for situations where hired applicators are used. Individual or independent growers are much less likely to have closed pesticide delivery systems than commercial firms, so these restrictions could impede their ability to use chlorpyrifos. Users who do not already have the appropriate equipment would have to hire a commercial firm to make chlorpyrifos applications, probably at an increase in cost, or use an alternative insecticide, which (as described above) could be more expensive and (in some cases) less efficacious. Users could also invest in a closed pesticide delivery system. The cost of a closed pesticide delivery system varies and depends on the complexity of the system. Based on available information, the cost of the equipment may have been around $300.[47] It seems unlikely, however, that a grower would incur such an expense if chlorpyrifos is the only chemical applied to the field that requires a closed pesticide delivery system.

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[45] Economic Analysis of the Agricultural Worker Protection Standard Revisions. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 2015. p. 205. Available at www.regulations.gov, docket number EPA-HQ-OPP-2011-0184-2522.

[46] 29 CFR § 1910.134

[47] Giles K., & Billing, R. 2013. Designs and Improvements in Closed Systems. Report to: Ken Everett, Pesticide Enforcement Branch, California Department of Pesticide Regulation.

EPA is also considering the requirement of an enclosed cab for airblast applications of chlorpyrifos. Users that do not currently own a tractor with an enclosed cab could hire commercial applicators to apply chlorpyrifos, at an increased cost, or switch to alternative insecticides. As described above, users face increased costs using the available alternatives for some uses, and for some crops (i.e., California oranges, apples, and Southeastern peaches) effective alternatives are not available and yield and quality losses are possible. The characteristics of some orchards do not lend themselves well to enclosed cabs. In these situations, this requirement will most likely result in growers using alternatives insecticides.

3. Use Prohibitions, Application Method Restrictions, and Rate Reductions

For the following application methods, potential risk estimates of concern could not be resolved with additional PPE or engineering controls. For that reason, the EPA is considering additional options for mitigating these risks, including application method prohibitions, restricting use of particular application methods to select use sites, and/or application rate reductions.

The subset of uses that are ultimately retained to address potential dietary risk (discussed in section IV.A.1) will impact the mitigation approach taken to address potential occupational risk. At this time, the EPA is presenting use prohibitions and application restrictions for risk estimates that were below the LOC. Once the EPA considers the SAP's conclusions, the EPA may further revise the human health risk assessment and proposed/considered mitigation. This includes consideration of additional refinements to the occupational risk estimates where possible. The EPA will also consider the benefits of the crops that are ultimately retained, as well as public comments, prior to finalizing any use prohibitions and/or application restrictions.

The impacts of the prohibitions and restrictions on uses will depend on the use site. As described in Section III.C, there are alternatives available to chlorpyrifos for most use sites, at an increased cost to users in many cases. There are exceptions, and some chlorpyrifos users could see reductions in pest control using the alternatives, resulting in reduced yield or quality of some crops.

a. Use Prohibitions and Application Restrictions – with the 10X UF_{DB}

Aerial and chemigation applications

Even with engineering controls, risks of concern were identified for most uses from mixing and loading for aerial and chemigation applications. Most MOEs for mixers and loaders with engineering controls ranged from 9.6 to 71. Exceptions include mixing and loading for ornamental and/or shade trees, herbaceous plants (WP in WSP), ornamental non-flowering plants (microencapsulated formula) and mosquito/vector control (L/SC/EC). Therefore, EPA is considering limiting application to select uses or prohibit aerial and chemigation application of chlorpyrifos to all uses except chemigation application of microencapsulated formula on ornamental non-flowering plants and mosquito/vector control. See Appendix A for a complete list of considered prohibited uses.

Although the use of global positioning systems (GPS) has vastly replaced the use of flaggers to guide aerial applications, the agency continues to assess exposure as use of flaggers is not explicitly prohibited on pesticide products containing chlorpyrifos. All liquid applications of chlorpyrifos products results in potential risks of concern for flaggers with the maximum amount of PPE (double layer (coveralls), gloves, and an elastomeric half mask respirator). Potential risks of concern were identified for flaggers with granule application for treatment of peanuts regardless of PPE. Use of chlorpyrifos granule products also resulted in risks of concern without use of a respirator for application on sweet potato, corn (pre-plant), sunflower, and tobacco. No risks of concern were identified for flaggers with granule application to sod farms (turf). Therefore, the agency is considering prohibiting use of flagger for all applications except granule application to sod farms (turf).

Groundboom application

Risk estimates with engineering controls were still below EPA's LOC of 100 for mixing and loading the following formulations and respective uses (MOEs = 39 – 98):

- Liquid/Soluble Concentrate: Corn (pre-plant and post-emergence), cotton (except MS), tree nut orchard floors (pecans, almonds, walnuts), ornamental lawns and turf, and sod farms
- Wettable powder in WSP: Ornamental lawns and turf, sod farms (turf), ornamental woody shrubs and vines (pre-transplant)
- Dry flowable (DF) /water-soluble granule (WSG) in WSP: Tree nut orchard floors (pecans, almonds, walnuts), corn, sorghum grain, soybean, rutabaga, and turnip

Consequently, EPA is considering prohibiting chlorpyrifos application to the above uses and formulations by groundboom application. This would also address risks of concern to groundboom applicators for corn (pre-plant), cotton (except Mississippi).

WSP formulations are assessed having the protection factor of engineering controls. The DF/WSG in WSP formulations do not fully meet the LOC of 100 for sweet potato (pre-plant, soil broadcast), cole crops (excludes Brussels sprout and cauliflower), mint (peppermint and spearmint), peanut, sunflower, and tobacco with MOEs ranging from 92 to 98. Chlorpyrifos is regarded as a high benefit for these uses.

Airblast application

Risk estimates for mixing and loading with engineering controls for citrus (CA and AZ at a rate of 6.0 lbs a.i./Acre) resulted in MOEs of 96 (L/SC/EC) and 67 (wettable powder in WSP and DF/WDG in WSP). The MOE for airblast application to citrus at the highest rate was 64 with engineering controls. Given recent chlorpyrifos restrictions in the state of California, use in California is expected to be negligible after 2020. EPA is considering reducing the application rate applied to citrus in Arizona to 4.0 lbs a.i./acre. MOEs for this reduced rate are 98 and still below the EPA's LOC of 100. However, citrus is recognized as a high-benefit use for chlorpyrifos. Reducing this rate will also address potential post-application risks of concern for citrus (assuming retention the 10X UF_{DB}).

Tractor-drawn spreader

Use of double layer (coveralls), gloves, and a half face respirator results in the highest MOEs for mixing, loading, or applying chlorpyrifos by tractor-drawn spreader. MOEs for mixing and loading soybean and corn were 74 and 79, respectively. Engineering controls, excluding applications by SmartBox®, results in slightly lower risk estimates. Consequently, EPA is considering prohibiting tractor drawn spreader application on these uses.

Handheld application methods

Regardless of PPE, risk estimates for application with mechanically pressurized handgun were below EPA's level of concern for all uses except ornamental woody shrubs and vines and seed orchard trees (MOEs = 440 to 8300); MOEs of concern ranged from 2.1 to 83 for all other uses. As a result, EPA is considering limiting mechanically-pressurized handgun application only to ornamental woody shrubs and vines and seed orchard trees.

The agency is considering prohibiting manually pressurized handwand application to indoor commercial/institutional/industrial premises and food processing plant premises. The risk estimate for these uses is 16 with maximum PPE.

To address risks of concern to occupational handlers using backpack sprayers, the agency is considering prohibiting all uses with the retention of the 10X UF_{DB} except for the formulations, uses, and conditions listed in Section IV.A.2.

The highest MOEs with maximum PPE (double-layer (coveralls), gloves, and an elastomeric half mask respirator) for application of chlorpyrifos by belly grinder or brush roller are 43 and 45, respectively. Given the limited uses for this application method, none of which are food uses, the agency is considering prohibiting application of chlorpyrifos by these handheld methods.

EPA is also considering prohibiting application of granular formulation by hand dispersal to commercial/institutional/industrial premises and utilities (pad) and by belly grinder to ornamental wood shrubs and vine. Prohibiting application to sewer manholes by brush roller may also be considered. MOEs for these applications with double layer (coveralls), gloves, and an elastomeric half mask respirator ranged from 1.4 to 7.1.

Microencapsulated formulations on ornamentals in nurseries and in greenhouses (post-application)

Occupational post-application risks of concern from microencapsulated formulations extend up to >35 days for ornamentals in nurseries and greenhouses. Extending REIs beyond a week, even on the basis on select activities, is not considered practical. Other uses which have risk estimates below the agency's LOC of 100 at the FQPA safety factor of 10X include grape and cole crops. For these uses, EPA is in the process of determining the most appropriate DFR study to

characterize risks for mitigation. Given the alternative formulations of chlorpyrifos available with significantly shorter REIs, EPA is considering prohibiting microencapsulated formulations for use on ornamentals in nurseries and greenhouses.

Seed Treatment

Occupational handlers applying chlorpyrifos for seed treatment may potentially conduct multiple tasks, such as sewing, bagging, loading, and applying. Additional activities increase the amount of potential exposure to these workers. These activities were assessed with the maximum amount of PPE available:

Table 19: Seed Treatment Activities and PPE

Activity	Maximum PPE assessed
Sewing seeds after seed treatment	Single layer (long sleeved shirt and long pants), no gloves and no respirator
Bagging seeds after seed treatment	
Loading/Applying liquid for seed treatment	Double layer (coveralls), gloves and PF10 respirator
Multiple activities for seed-treatment	

As a result, the agency is considering prohibiting use of chlorpyrifos as a seed treatment for the following formulations and crops based on risks to multiple activities workers or occupational handlers that conduct multiple activities for seed treatment (e.g., applying and bagging):

- Liquid formulation on beans, corn, cotton
- Microencapsulated formulation on beans
- Wettable powder in WSP on beans and corn

b. Use Prohibitions and Application Restrictions – without the 10X UF_{DB}

MOEs for aerial application of granular formulations of chlorpyrifos on peanuts is 5 with engineering controls. MOEs for other aerial granular applications range are 9.4 (sweet potato) and 9.5 (sunflower, tobacco) also with engineering controls. Therefore, EPA is considering prohibiting this application method on peanuts. Although the risk estimates are still below a LOC of 10 for sweet potato, sunflower, and tobacco, these uses are proposed to be retained given the benefits associated with the use of chlorpyrifos on these crops.

The agency is also considering prohibiting backpack sprayer application to ornamental and/shade trees, herbaceous plants, ornamental woody shrubs and vines. MOEs for application to these non-food sites are 3.8 with maximum PPE (double layer (coveralls), gloves, and an elastomeric half mask respirator) and therefore are of concern.

For handheld applications, EPA is considering prohibiting brush roller application for sewer manholes and hand dispersal to commercial/institutional/industrial premises and utilities (pad). With double layer (coveralls), gloves, and an elastomeric half mask respirator, the MOE is 1.4

for broadcast hand dispersal application to commercial/institutional/industrial premises and utilities (pad) and, therefore, is below the LOC. The agency is also considering prohibiting application with belly grinders on ornamental woody shrubs and vines. With maximum PPE, the MOE is 7.1 and below the LOC of 10 for these uses.

4. Re-Entry Interval

With retention of the 10X UF_{DB}, risk estimates exceed the LOC of 100 for over 30 activities/uses. These include: berries, field and row crops, tree fruit (deciduous, evergreen), forestry, tree nuts (almonds), ornamental nurseries (non-bearing fruit trees), fruiting vegetables, brassica vegetables, leafy vegetables, and grapes. As multiple DFR studies were submitted for many uses, the MOEs for chlorpyrifos on these crops may vary depending on activity and study location. EPA is in the process of determining the most appropriate DFR study to characterize risks for mitigation. Proposed REIs for uses with identified risks of concern may extend over one week. At the 1X UF_{DB}, the MOEs exceed the LOC for approximately 10 crop groups with proposed REIs extending from 2 to 5 days. See Appendix D2 for the mitigation being considered to address occupational post-application risks of concern. Mitigation measures for other risks of concern may impact the selection of uses that are maintained and, thus, how EPA addresses these post-application risks of concern.

5. Pesticide Resistance Management

Pesticide resistance occurs when genetic or behavioral changes enable a portion of a pest population to tolerate or survive what would otherwise be lethal doses of a given pesticide. The development of such resistance is influenced by a number of factors. One important factor is the repeated use of pesticides with the same mode (or mechanism) of action. This practice kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers. These individuals will eventually be unaffected by the repeated pesticide applications and may become a substantial portion of the pest population. An alternative approach, recommended by resistance management experts as part of integrated pest management (IPM) programs, is to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population. This approach may delay and/or prevent the development of resistance to a particular mode (or mechanism) of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

The EPA is proposing to include resistance-management labeling for insecticides/acaricides from PRN 2017-1, for products containing chlorpyrifos, in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides.[48] Resistance management label language for insecticides may be found at: https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

[48] https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year

Additional information on the EPA's guidance for resistance management can be found at the following website: https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management.

6. Spray Drift Management

EPA is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all chlorpyrifos products. Reducing spray drift is expected to reduce the extent of environmental exposure and risk to non-target plants and animals, including listed species whose range and/or critical habitat co-occur with the use of chlorpyrifos. These spray drift reduction measures, once finalized in the Interim Decision, will be considered in forthcoming consultation with the Services, as appropriate.

EPA is proposing the following spray drift mitigation language to be included on all chlorpyrifos product labels for products applied by liquid spray application. The proposed spray drift language includes mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. EPA is also providing recommendations that allow chlorpyrifos registrants to standardize all advisory language on chlorpyrifos product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once effective.

- Applicators must not spray during temperature inversions.

- For aerial applications,
  - Do not apply when wind speeds exceed 10 mph at the application site.
  - The boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Applicators must use ½ swath displacement upwind at the downwind edge of the field.
  - The release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.

- For groundboom applications,
  - Do not apply when wind speeds exceed 10 mph at the application site.
  - Apply with a release height no more than 3 feet above the ground or crop canopy.

- Airblast applications:
  - Sprays must be directed into the canopy.
  - Do not apply when wind speeds exceed 10 miles per hour at the application site.
  - User must turn off outward pointing nozzles at row ends and when spraying outer row.

Buffers were required to mitigate potential spray drift risk to bystanders in the July 2012 *Spray Drift Mitigation Decision for Chlorpyrifos.* Buffer distances implemented as a result of that decision are not superseded by this PID, and are included below for reference:

Table 20: Buffer Distances				
Application rate (lb ai/A)	Nozzle Droplet Type	Required Setback (Buffer Zones) (feet)		
		Aerial	Airblast	Ground
>0.5 - 1	coarse or very coarse	10	10	10
>0.5 - 1	medium	25	10	10
>1 - 2	coarse or very coarse	50	10	10
>1 - 2	medium	80	10	10
>2 - 3	coarse or very coarse	80[1]	10	10
>2 - 3	medium	100[1]	10	10
>3 - 4	medium or coarse	NA[2]	25	10
>4	medium or coarse	NA	50	10

[1]Aerial application of greater than 2 lb ai/A is only permitted for Asian Citrus Psyllid control, up to 2.3 lb ai/A.
[2]NA is not allowed.

Spray drift mitigation for chlorpyrifos has the potential to decrease an applicator's flexibility to make timely applications for both ground and aerial applications (e.g., windspeed and temperature inversions). Applicators may see a decrease in flexibility of application timing and an increase in managerial effort for scheduling production activities, ultimately increasing costs for the user if chlorpyrifos applications are not made in a timely manner. Some users may be forced to use alternative insecticides, which may be more costly and/or less effective than chlorpyrifos. Fixed-wing aircraft will have reduction in usable boom length, which may necessitate more passes to complete an application, potentially increasing application costs. EPA has determined the changes in release height and swath displacement will have minimal impact on aerial applications. The agency anticipates little impact with residential buffers and considers that this size buffer corresponds to good application practices when applying near residential areas.

7. Updated Water-Soluble Packaging Language for Chlorpyrifos

EPA is proposing updated directions for use language be added to chlorpyrifos labels that are packaged in WSP, consistent with the language being proposed across WSP products in registration review. The improved clarity is expected to ensure proper use of these products and to minimize exposure to occupational handlers.

B. Tolerance Actions

The chlorpyrifos tolerance expressions established 40 CFR § 180.342 will be updated to incorporate newly revised crop group definitions, OECD rounding class practice, commodity definition revisions, crop group conversions/revisions, and harmonization with Codex. The agency will consider the input and recommendations from the September 2020 FIFRA Scientific Advisory Panel (SAP) on new approach methodologies for neurodevelopmental toxicity once the

SAP report is released. After receiving the SAP's conclusions which are anticipated in December 2020, EPA will examine the need for further tolerance actions. The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances. Refer to Section III.A.4 for details.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR § 155.56 and § 155.58, the agency is issuing this PID. The agency has made the following PID: (1) no additional data from registrants are required at this time and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A and Appendix A.

The agency has concluded that there is no evidence demonstrating that chlorpyrifos potentially interacts with estrogen, androgen, or thyroid pathways. Therefore, EDSP Tier 2 testing is not recommended. For more information, see the *EDSP Weight of Evidence Conclusions on the Tier 1 Screen Assays for the List 1 Chemicals*[49] and Appendix C. The proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of chlorpyrifos.

D. Data Requirements

The agency does not anticipate calling-in additional data for registration review of chlorpyrifos at this time. The EPA will consider requiring submission of pollinator and residue chemistry data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for chlorpyrifos and will allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the agency to change its PID, the EPA may issue an interim registration review decision for chlorpyrifos. However, a final decision for chlorpyrifos may be issued without the agency having previously issued an interim decision. A final decision on the chlorpyrifos registration review case will occur after: (1) an endangered species determination under the ESA and any needed § 7 consultation with the Services, and (2) the agency completes a revised cumulative risk assessment for OPs.

B. Implementation of Mitigation Measures

[49] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0849

Once the Interim Registration Review Decision is issued, the chlorpyrifos registrants must submit amended labels that include the label changes described in Appendix A. The agency will issue a label table after considering the input and recommendations from the September 2020 FIFRA Scientific Advisory Panel (SAP) on new approach methodologies for neurodevelopmental toxicity. The revised labels and requests for amendment of registrations must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Appendix A: Summary of Proposed and Considered Actions for Chlorpyrifos

NOTE: The proposed and considered actions below reflect the suite of mitigation measures being considered for each of the currently labeled chlorpyrifos uses. If the agency moves forward with the use restrictions being proposed to reduce dietary exposure from drinking water, select occupational and post-application actions proposed below may not be needed. The agency will reexamine the proposed and considered mitigation after considering public input during the comment period and conclusions from the 2020 SAP.

Registration Review Case#: 0100 PC Code: 059101 Chemical Type: Insecticide Chemical Family: Organophosphate Mode of Action: Acetylcholinesterase inhibition						
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Proposed Actions with 10X FQPA SF**	**Proposed Actions with the 1X FQPA SF**
Infants and children	Dietary (drinking water)	Ingestion	Acute Steady state	Neurotoxicity	To reduce potential dietary exposure to chlorpyrifos, the agency is considering label amendments to limit use of chlorpyrifos to the 11 high-benefit and/or critical uses (alfalfa, apple, cherries (tart), asparagus, citrus, cotton, peach, soybean, strawberry, sugar beet, wheat (spring), and wheat (winter)) in select regions, as well as public health uses, as identified in Section IV.A.1. of this PID.	To reduce potential dietary exposure to chlorpyrifos, the agency is considering label amendments to prohibit the following uses: Peppers, trash storage bins, and wood treatment; and restrict the following uses to certain regions: corn, cherries (tart), citrus, pecans and peach; and reduce the application rate for cherries (tart) by region, as identified in Section IV.A.1. of this PID.
Females 13-49 years of age	Dietary (drinking water)	Ingestion	Acute Steady state	Neurotoxicity		
Considered mitigation for Occupational Risks of Concern						
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Mitigation Actions Considered with 10X UF_{DB}**	**Mitigation Actions Considered with the 1X UF_{DB}**
Occupational handler risks from mixing and loading most aerial and chemigation applications: Liquid/Soluble Concentrate/Emulsifiable	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting aerial and chemigation application of chlorpyrifos to all uses except for aerial use on ornamental non-flowering	Consider prohibiting application of granules on peanuts. Consider use of double layer (coveralls), gloves, and an

Concentrate (L/SC/EC) and granule					plants and as a wide area mosquito adulticide (L/SC/EC). Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for mixing and loading aerial mosquito adulticide applications.	elastomeric half mask respirator, for: Citrus, non-bearing fruit and nut trees (nursery), radish (pre-plant), turfgrass (sod or seed), cherries, hybrid cottonwood/poplar plantations, mint (peppermint and spearmint), peanut, rutabaga, strawberries (pre-plant), sunflower (pre-plant), sweet potato, tobacco, tree fruits (apple, nectarine, peach, pear, plum/prune), tree nuts (almonds, filberts, hazelnuts, pecans, walnuts), turfgrass (ornamental and sod farms), clover (grown for seed), cranberry, sunflower (post-emergence/foliar). Consider single layer (long-sleeved shirt and long pants), gloves and a particulate filtering facepiece for: Asparagus, Brussels sprouts, cauliflower, cole crops, strawberries, sugar beets, and radish.
Occupational handler risks from mixing and loading aerial application only: L/SC/EC and granule	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting all aerial application of chlorpyrifos on ornamental non-flowering plants and as a wide area mosquito adulticide (L/SC/EC). Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for mixing and loading aerial mosquito adulticide applications.	L/SC/EC: • Consider requiring engineering controls for mixing and loading corn (post-emergence). • Consider requiring single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece for: Alfalfa, cotton (except Mississippi),

						sorghum, wheat, Christmas tree plantations, and carrots. Granule: • Consider double layer (coveralls), gloves, and either a particulate filtering facepiece or an elastomeric half mask respirator for corn (pre-plant). • Consider requiring single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece for peanut and sweet potato.
Occupational handler risks from mixing and loading chemigation only applications: L/SC/EC	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting all chemigation application of chlorpyrifos.	Consider requiring engineering controls for mixing and loading for use on: Tree nuts, orchard floors (pecans, almonds, walnuts), corn (pre-plant). Consider single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece for mixing a loading for: Alfalfa, cotton (except Mississippi), sorghum, soybean, and wheat.
Occupational handler risks from mixing and loading most aerial and chemigation applications: Dry flowable/water-dispersable granules (DF/WDG) in WSP	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting all aerial and chemigation application of chlorpyrifos DF/WDG in WSP formulations.	N/A

Occupational handler risks from mixing and loading most aerial and chemigation applications: Wettable Powder (WP), and Spray (all starting formulations	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application of WP to all uses except ornamental and/or shade trees, herbaceous plants. Consider prohibiting application of spray (all starting formulations) to the following uses: Citrus, carrots, corn (post-emergence), alfalfa, corn (pre-plant), Christmas tree plantations, cole crops, cotton (except Mississippi), sorghum, soybean, wheat, asparagus, Brussels sprouts, cauliflower, cole crops, strawberries, sugar beets, radish, clover (grown for seed; foliar), corn (post-emergence), cranberry, hybrid cottonwood/ poplar plantations grown for pulp, sunflower (post-emergence/ foliar), non-bearing fruit and nut trees (nursery), radish (pre-plant), sweet potato (pre-plant), cherries, mint (peppermint and spearmint), peanut, rutabaga, strawberries (pre-plant), sunflower (pre-plant), tobacco, tree fruits (apple, fig (CA only), nectarine, peach, pear, plum/prune), ornamental and/or shade trees, herbaceous plants, tree	N/A

					nuts (almonds, filberts/hazelnuts, pecans, walnuts), and turfgrass (ornamental and sod farms).	
Occupational handler risks from mixing and loading groundboom applications for: L/SC/EC	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application of L/SC/EC formulations by groundboom to: Corn (pre-plant, post-emergence), cotton (except Mississippi), tree nut orchard floors (pecans, almonds, walnuts), ornamentals lawns and turf, sod farms. Consider requiring engineering controls for mixing and loading L/SC/EC formulations for: Radish (pre-plant), alfalfa, cotton, sorghum grain, soybean, wheat, rutabaga, Brussels sprouts (at plant, post-plant), grapes (foliar, dormant, delayed dormant), sweet potato (pre-plant, soil broadcast), nursery stock (preplant), cole crops, cauliflower, mint (peppermint, spearmint), peanut, pineapple, strawberries (pre-plant), sunflower (pre-plant), tobacco (pre-plant), beets (table, sugar, at plant), clover (grown for seed; foliar), hybrid cottonwood/poplar plantations, and cranberry.	Consider requiring single layer (long-sleeved shirt, long pants), gloves, and a particulate filtering facepiece for: Corn (pre-plant and post-emergence), radish (pre-plant), rutabaga, Brussels sprouts (at-plant, post-plant), grapes (foliar, dormant, delayed dormant), sweet potato (pre-plant, soil broadcast), cotton (except Mississippi), cole crops, cauliflower, mint (peppermint, spearmint), peanut, pineapple, strawberries (pre-plant), sunflower (pre-plant), tobacco (pre-plant), cranberry, alfalfa, cotton, sorghum grain, soybean, wheat, beets (table, sugar; at plant), clover (grown for seed; foliar), hybrid cottonwood/poplar plantations, tree nut orchard floors (pecans, almonds, walnuts), nursery stock (pre-plant), ornamental lawns and turf, and sod farms.

					Consider requiring double layer (coveralls), gloves and particulate filtering facepiece for carrots. Consider requiring double layer (coveralls) and gloves for: Asparagus. beets (tables, sugar, at plant), citrus orchard floors, forest plantings (reforestation, plantation, tree farm), grass (forage/fodder/hay), legume, vegetables, nonagricultural outdoor buildings and structures, and onions. Consider requiring single layer (long-sleeved shirt and long pants) and gloves for: Conifers and deciduous trees, seed orchard trees, ornamental and/or shade trees, herbaceous plants, ornamental woody shrubs and vines, and golf course (fairways, tees, greens).	
Occupational handler risks from mixing and loading groundboom applications for: DF/WDG in WSP	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application of DF/WDG in WSP to: Tree nut orchard floors (pecans, walnuts, almonds), corn, sorghum grain, soybean, rutabaga, and turnip.	N/A
Occupational handler risks from mixing and loading	Air Residues	Dermal absorption	Acute Steady state	Neurotoxicity	Consider prohibiting application of WP (in WSP) to	N/A

groundboom applications for: WP (in WSP)		Inhalation			ornamental lawns and turf, sod farms (turf), and ornamental woody shrubs and vines (pre-transplant).	
Occupational handler risks from applying groundboom applications for: Spray (all starting formulations) considered for prohibition or engineering controls	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application of spray (in all starting formulations) to corn (pre-plant). Consider engineering controls for application on: Alfalfa, cotton, sorghum grain, wheat, radish, turnip, ornamental lawns and turf and sod farms (turf).	N/A
Occupational handler risks from applying groundboom applications for: Spray (all starting formulations) considered for additional PPE	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider double layer (coveralls), gloves, and an elastomeric half mask respirator for: Alfalfa, sorghum grain, soybean, and wheat. Consider double layer (coveralls), gloves, and particulate filtering facepiece for: Brussels sprouts (at plant, post-plant, and post-emergence), cauliflower, cole crops, , grapes (foliar, dormant, delayed dormant), mint (peppermint, spearmint), peanut, pineapple, rutabaga, strawberries (pre-plant), sunflower (pre-plant) sweet potato (pre-plant and soil broadcast), tobacco (pre-plant), nursery stock (pre-	Consider requiring single layer (long-sleeved shirt, long pants) and gloves for application to corn (pre-plant), tree nut orchard floors (pecans, almonds, walnuts), and cotton (except Mississippi).

					plant), rutabaga, clover (grown for seed, foliar), hybrid cottonwood and poplar plantations and potentially alfalfa, sorghum grain, soybean, and wheat. Consider single layer (long-sleeved shirt and long pants), gloves, and an elastomeric half mask respirator for: sweet potato (pre-plant and soil broadcast). Consider single layer, gloves, and particulate filtering facepiece for: Cranberry, beets (table, sugar; at plant), clover (grown for seed), and hybrid cottonwood and poplar plantations. Consider single layer and gloves for the following: Carrots, asparagus, beets (table, sugar, at plant), citrus orchard floors, cole crops (excludes Brussels sprouts and cauliflower), cotton, forest plantings (reforestation, plantation, tree farm), grapes (dormant, delayed dormant), grass (forage/fodder/hay), legume vegetables, nonagricultural outdoor buildings and structures, onions, peppers,	

					strawberries, ornamentals and/or shade trees, herbaceous plants, ornamental woody shrubs and vines, conifers and deciduous trees, seed orchard trees, forest trees (softwoods and conifers), and golf course (fairways, tees, and greens).	
Occupational handler risks from airblast applications: Mixing and loading L/SC/EC	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider requiring engineering controls for: Citrus, non-bearing fruit and nut trees (nursery), and tree fruits (nectarine, peach - dormant, delayed dormant). Consider requiring double-layer (coveralls), gloves, and an elastomeric half mask respirator (PF10) for: Cherries, tree fruits (pear, plum/prune (dormant, delayed dormant), and tree nuts (almond, filberts, hazelnuts, pecans, walnuts). Consider requiring single layer (long pants and long-sleeved shirt) and glove for: Ornamental and/or shade trees, ornamental woody shrubs and vines, herbaceous plants, Christmas tree plantations, and grapes.	Consider requiring single layer (long-sleeved shirt and long pants) and gloves for: Citrus, non-bearing fruit and nut trees (nursery), tree fruits (nectarine, peach - dormant, delayed dormant).
Occupational handler risks from airblast applications:	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider reducing application rate from 6.0 lbs a.i./Acre to 4.0 lbs a.i./Acre in Arizona.	N/A

Mixing and loading DF/WDG in WSP and WP (in WSP)						
Occupational handler risks from airblast applications: Applying spray (all starting formulations)	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider reducing application rate from 6.0 lbs a.i./Acre to 4.0 lbs a.i./Acre in Arizona. Consider requiring engineering controls for all uses.	N/A
Occupational handler: Seed treatment for liquid, microencapsulated, and wettable powder via WSP to multiple activities workers when applied on beans, corn, and cotton.	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting seed-treatment for the following uses and formulations: • Liquid formulation on beans, corn, cotton • Microencapsulated formulation on beans • Wettable powder in WSP on beans and corn	N/A
Occupational handler: Mixing and loading, and applying by tractor-drawn spreader	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application on corn, soybean. Consider single layer (long-sleeved shirt and long pants) and an elastomeric half mask respirator for alfalfa. Consider single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece for: Rutabaga and sweet potato.	N/A

					Consider single layer (long-sleeved shirt and long pants), and a particulate filtering facepiece for: Asparagus, cole crops, (excludes Brussels sprouts and cauliflower), ginseng, sugar beets, sunflower, citrus orchard floors, onions, tobacco, ornamental lawns and turf, sod farms (turf), and nursery stock.	
Occupational handler: Application by tractor-drawn spreader					Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for: Peanut and sorghum grain. Consider requiring double layer (coveralls) and gloves for: Citrus orchard floors, onions, ornamental lawns and turf, and sod farms (turfs). Consider requiring single layer (long-sleeved shirt and long pants), gloves, and a particulate facepiece for: Radish, rutabaga, and alfalfa. Consider requiring single layer (long-sleeved shirt and long pants) and a particulate facepiece for: Cauliflower (post-plant), turnip, Brussels sprouts (post-plant), sweet potato, cole crops (except	

					cauliflower) ginseng, sugar beets, sunflower, and tobacco.	
Occupational handler: Wide area mosquito adulticide applications from mixing, loading, and applying ground (airblast surrogate) and aerial applications.	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for mixers and loaders. Consider requiring engineering controls for applicators.	Consider requiring gloves and chemical resistant headgear for ground (airblast surrogate) applicators Consider requiring engineering controls for aerial applicators.
Occupational handler: Mechanically-pressurized handgun applications	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application by mechanically-pressurized handgun for all uses except on ornamental woody shrubs and vines and seed orchard trees.	Consider requiring double layer (coveralls), gloves, and a particulate filtering facepiece respirator
Occupational handler: Manually-pressurized handwand	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application to Indoor commercial, institutional, industrial premises, food processing plant premises. Consider requiring double layer PPE (coveralls), gloves, and an elastomeric half mask respirator (PF10) for wood treatment and nursery (pine seedlings). Consider requiring single layer (long-sleeved shirt and long pants), gloves, and a particulate filtering facepiece for wide area/general outdoor treatment.	Consider single layer (long-sleeved shirt and long pants) and gloves for Wood protection treatment, nursery (pine seedlings), wide area/ general outdoor treatment, Christmas tree plantations, conifers and deciduous trees; plantation nurseries, grapes, seed orchard trees, forest trees (softwoods, conifers), golf course turf, mounds/nests, non-agricultural outdoor buildings and structures, indoor commercial/institutional/industrial premises (see master label description), food processing plant premises, ornamental woody shrubs and vines, ornamental non-flowering plants, tree fruits

					Consider single layer (long-sleeved shirt and long pants) and gloves for: Christmas tree plantations, conifers and deciduous trees; plantation nurseries, grapes, seed orchard trees, forest trees (softwoods, conifers), golf course turf, mounds/nests, non-agricultural outdoor buildings and structures, ornamental woody shrubs and vines, ornamental non-flowering plants, outdoor commercial/institutional/industrial premises (see master label description), agricultural farm premises, poultry litter, tree fruits (cherries, nectarines, peaches, plum/prunes), tree nuts (almonds) - pre-plant, tree nuts (apple) - pre-plant, and fruits and nuts (non-bearing, see master label description).	(cherries, nectarines, peaches, plum/prunes), tree nuts (almonds) - pre-plant, and tree nuts (apple) - pre-plant.
Occupational handler: application by • Belly grinder • Brush roller • Rotary spreader • Hand dispersal	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application by brush roller and belly grinder. Consider prohibiting application to ornamental woody shrubs and vines by rotary spreader. Consider requiring single layer (long-sleeved shirt and long	Consider prohibiting brush roller application for sewer manholes. Consider requiring single layer (long-sleeved shirt and long pants) and gloves for brush roller application to wood protection treatment and structural (e.g., warehouses, food handling establishments, home bathrooms)

					pants) and gloves for rotary spreader application to nursery stock, golf course turf, ornamental and/or shade trees, herbaceous plants, ornamental lawns and turf, sod farms (turf). Consider prohibiting hand dispersal to commercial/ institutional/industrial/premis es, utilities (pad). Consider requiring single layer (long-sleeved shirt and long pants) and gloves for hand dispersal (spo.t treatment) to golf course (turf), sod farm (turf).	Consider prohibiting belly grinder application for ornamental woody shrubs and vines Consider prohibiting hand dispersal to commercial/institutional/industrial premises and utilities (Pad)
Occupational handler risks from backpack sprayer applications: L/SC/EC	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting application by broadcast (soil and foliar) and drench/soil-/ground-directed to: ornamental and/or shade trees, herbaceous plants, outdoor commercial/institutional/indu strial premises, non-agricultural outdoor buildings and structures, wide area/ general outdoor treatment, wood protection treatment, Christmas tree plantations, tree fruit (cherries), seed orchard trees, grapes, and forest trees (softwoods, conifers)	Consider prohibiting broadcast (foliar) application with backpack sprayer of L/SC/EC on ornamental and/or shade trees, herbaceous plants. Consider double layer (coveralls) and glove for outdoor commercial/institutional/industrial premises, non-agricultural outdoor buildings and structures, and wide area/ general outdoor treatment.

					Consider limiting broadcast (foliar) application to golf course turf with double layer (coveralls), gloves, and an elastomeric half mask respirator. Consider limiting use on the following for only spot treatment with baseline PPE: ornamental and/or shade trees, herbaceous plants, ornamental lawns and turf, sod farms (turf), outdoor commercial/institutional/industrial premises, non-agricultural outdoor buildings and structures, and golf course turf.	
Occupational handler risks from backpack sprayer applications: DF/WDG in WSP	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting broadcast (foliar) or drench/soil/ground-directed application to: ornamental woody shrubs and vines, Christmas tree plantations, tree fruits (cherries), tree nuts (almond), tree fruit (nectarine, peach, plum/prune), fruit and nut (non-bearing, nursery), tree fruits (apple). Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for broadcast	Consider prohibiting backpack sprayer of dry flowable/water-dispersible granules in WSP for broadcast (foliar) on ornamental woody shrubs and vines.

					(foliar) application to grapes (pre-bloom), trunk spray/drench to tree fruits (apple) and drench/soil-ground directed grapes (pre-bloom).	
Occupational handler risks from backpack sprayer applications: WSP	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting broadcast use on ornamental and/or shade trees, herbaceous plants.	Consider prohibiting backpack sprayer broadcast application of WSP on ornamental and/or shade trees, herbaceous plants
Occupational handler risks from backpack sprayer applications: ME					Consider requiring double layer (coveralls), gloves, and an elastomeric half mask respirator for ornamental non-flowering plants and ornamental woody shrubs and vines.	N/A
Occupational handler: Flagging	Air Residues	Dermal absorption Inhalation	Acute Steady state	Neurotoxicity	Consider prohibiting flagging and require use of GPS or mechanical flagging systems with the exception of granule application to sod farms (turf).	N/A
Occupational post-application risks of concern	Residues	Dermal absorption	Acute Steady state	Neurotoxicity	Consider prohibiting use of microencapsulated formulations on ornamentals in nurseries and greenhouses. Considering extending REIs for select uses and activities. See Appendix D2 for potential REI extensions.	Considering extending REIs for select uses and activities. See Appendix D2 for potential REI extensions.
Proposed Ecological Mitigation						
Avian	Residues on treated site	Ingestion	Acute Chronic	Developmental Reproductive	Application method restrictions are expected to reduce risks to non-target organisms.	
Mammals	Residues on treated site	Ingestion	Acute Chronic	Developmental Reproductive		

Terrestrial Invertebrates	Residues on treated site	Dermal absorption Ingestion	Acute Chronic	Acute toxicity	Proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all chlorpyrifos products.
Fish	Water	Dermal absorption Ingestion	Acute Chronic	Acute toxicity	
Aquatic Invertebrates	Water	Dermal absorption Ingestion	Acute Chronic	Acute toxicity	

Appendix B: Endangered Species Assessment

This Appendix provides general background about the agency's assessment of risks from pesticides to endangered and threatened (listed) species under the Endangered Species Act (ESA). Additional background specific to chlorpyrifos appears at the conclusion of this Appendix.

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* (i.e., Revised Method) in March 2020.[50] During the same timeframe, EPA also released draft BEs for carbaryl and methomyl, which were the first to be conducted using the Revised Method.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role in this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Chlorpyrifos was one of the first three pilot chemicals that EPA conducted a nationwide ESA consultation. EPA completed a biological evaluation and initiated consultation with the FWS and NMFS in January 2017. [51] Pursuant to a consent decree, at the end of December 2017, NMFS issued its Biological Opinion (BiOp) on chlorpyrifos, diazinon, and malathion. [52] In July 2019,

[50] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional
[51] https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment
[52] https://www.fisheries noaa.gov/resource/document/biological-opinion-pesticides-chlorpyrifos-diazinon-and-malathion

EPA re-initiated formal consultation with NMFS on the December 2017 BiOp.[53] EPA re-initiated consultation because new information on how the pesticides were actually being used may show that the extent of the effects of the actions may be different than what was previously considered. As part of this re-initiation, EPA provided additional usage data it believes may be relevant to the consultation. In its transmittal of this information to NMFS, EPA also referenced usage data and information that had been recently submitted by the registrants of pesticide products containing chlorpyrifos, malathion, and diazinon. After reviewing information EPA provided to NMFS on the 2017 BiOp, NMFS determined that it was appropriate to revise the chlorpyrifos, malathion, and diazinon BiOp. NMFS plans to issue a revised final BiOp for chlorpyrifos, diazinon, and malathion by June 2022. FWS has not yet issued a BiOp on chlorpyrifos. EPA plans to address risks to listed species and critical habitats from use of chlorpyrifos as part of the final registration review decision, pending completion of the nationwide consultation process.

[53] https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0141-0136

Appendix C: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic 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, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for chlorpyrifos, the 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 § 408(p), chlorpyrifos is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The 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 the 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 § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. Chlorpyrifos is on List 1 and the review conclusions are available in the chlorpyrifos public docket EPA-HQ-OPP-2008-0850.[54] A second list of chemicals identified for EDSP screening was published on June 14, 2013,[55] 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. 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 the EPA website.[56]

[54] EDSP Weight of Evidence Conclusions on the Tier 1 Screening for the List 1 Chemicals https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0849
[55] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[56] https://www.epa.gov/endocrine-disruption

In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of chlorpyrifos. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

Appendix D1: Occupational Post-Application Risks of Concern[1]

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
Berry: Low	Strawberry LC, WP Hand Harvesting	1.0	40	AZ	40 at Day 0	48 at Day 1 78 at Day 2 88 at Day 3 120 at Day 4
	Cranberry LC, WDG Hand Harvesting, Scouting	1.5	26	AZ	26 at Day 0	32 at Day 1 52 at Day 2 58 at Day 3 83 at Day 4 100 at Day 5
Mint	Peppermint/ Spearmint LC, WDG Irrigation	2.0	10	CA	10 at Day 0	86 at Day 1 120 at Day 2
			11	OR	11 at Day 0	110 at Day 1
			3.5	MN	110 at Day 1	110 at Day 1
Grapes	Grapes, LC Hand weeding, scouting	2.0	92	CA	92 at Day 0	390 at Day 1
	Grapes, LC Hand weeding, scouting		11	CA	11 at Day 0	46 at Day 1 100 at Day 2
	Grapes, LC Hand harvesting, leaf pulling, tying/training (wine grape)		6	CA	25 at Day 1	55 at Day 2 63 at Day 3 73 at Day 4 85 at Day 5 98 at Day 6 110 at Day 7
	Grape, LC Turning (table grape only)		3	CA	13 at Day 1	29 at Day 2 33 at Day 3 38 at Day 4 44 at Day 5 51 at Day 6 59 at Day 7 69 at Day 8 79 at Day 9 92 at Day 10 110 at Day 11

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
Field and Row Crops: Tall	Corn: Sweet; Corn: Field, Including Grown for Seed WDG Detassling, hand harvesting)	1.5	0.8	IL	26 at Day 1	68 at Day 2 180 at Day 3
			1.0	MN	30 at Day 1	66 at Day 2 140 at Day 3
			1.4	OR	54 at Day 1	200 at Day 3
	Corn: Sweet; Corn: Field, Including Grown for Seed WDG Detassling, hand harvesting	1.0	1.2	IL	40 at Day 1	100 at Day 3
			1.5	MN	46 at Day 1	99 at Day 3 220 at Day 4
			2.1	OR	81 at Day 1	310 at Day 3
Tree Fruit: Deciduous	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant) LC for all, WDG for all, and WP for apples only Scouting, pruning, training	2.0	30	CA	480 at Day 1	480 at Day 1
			15	WA	63 at Day 2	180 at Day 3
			21	NY	50 at Day 2	110 at Day 3
	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant) LC for all, WDG for all, and WP for apples only	2.0	13	CA	200 at Day 1	200 at Day 1
			6	WA	26 at Day 2	76 at Day 3 130 at Day 4
			9	NY	21 at Day 2	45 at Day 3 96 at Day 4 180 at Day 5

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	Hand harvesting					
	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant) LC for all, WDG for all, and WP for apples only Thinning fruit	2.0	5	CA	78 at Day 1	110 at Day 2
			2	WA	10 at Day 1	30 at Day 2 50 at Day 3 83 at Day 4 140 at Day 5
			3	NY	8 at Day 1 18 at Day 2	37 at Day 3 69 at Day 4 130 at Day 5
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Transplanting	3.0	51	CA	51 at Day 0	810 at Day 1
			25	WA	110 at Day 1	110 at Day 1
			35	NY	35 at Day 1	84 at Day 1 180 at Day 2
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Scouting, pruning, training	3.0	20	CA	20 at Day 0	320 at Day 2
			10	WA	10 at Day 0	42 at Day 1 120 at Day 2
			14	NY	14 at Day 1	33 at Day 2 73 at Day 3 160 at Day 4
	Nectarine (WDG and emulsifiable concentrate	3.0	8.4	CA	130 at Day 1	130 at Day 1
			4	WA	17 at Day 1	51 at Day 2 85 at Day 3 140 at Day 4

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	(EC)) & Peaches (EC) (Dormant and Delayed Dormant) Hand harvesting		6	NY	14 at Day 1	33 at Day 2 73 at Day 3 160 at Day 4
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Thinning fruit	3.0	3.3	CA	52 at Day 1	71 at Day 3 97 at Day 4 130 at Day 5
			2	WA	7 at Day 1 20 at Day 2	33 at Day 3 56 at Day 4 93 at Day 5 160 at Day 6
			2	NY	5 at Day 1 12 at Day 2	25 at Day 3 46 at Day 4 85 at Day 5 160 at Day 6
	Cherries (Sour) Transplanting	4.0	38	CA	38 at Day 0	610 at Day 1
			19	WA	19 at Day 0	80 at Day 1 230 at Day 2
			26	NY	26 at Day 0	140 at Day 2
	Cherries (Sour) Scouting, pruning, training		15	CA	15 at Day 0	240 at Day1
			7.5	WA	32 at Day 1	92 at Day 3 150 at Day 4
			10	NY	10 at Day 0	25 at Day 2 55 at Day 3 120 at Day 4
	Cherries (Sour) Hand harvesting		6.3	CA	100 at Day 1	100 at Day 1
			3.1	WA	13 at Day 1	38 at Day 2 64 at Day 3 110 at Day 5
			4.3	NY	10 at Day 1	23 at Day 2 48 at Day 3 89 at Day 4 160 at Day 5
	Cherries (Sour) Thinning fruit		2.4	CA	39 at Day 1	53 at Day 2 73 at Day 3 99 at Day 4 140 at Day 5
			1.2	WA	5.1 at Day 1 15 at Day 2	25 at Day 3 42 at Day 4 70 at Day 5 120 at Day 6

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
			1.7	NY	4 at Day 1 8.8 at Day 2 19 at Day 3	35 at Day 4 64 at Day 5 120 at Day 6
Tree Fruit: Evergreen	Citrus LC, WDG Hand harvesting	4.0	21;	CA	21 at Day 0	89 at Day 1 200 at Day 2
	Citrus LC, WDG Transplanting	6.0 (CA and AZ)	86	CA	86 at Day 0	360 at Day 1
	Citrus LC, WDG Scouting, Hand pruning		34	CA	34 at Day 0	140 at Day 1
	Citrus LC, WDG Hand harvesting		14	CA	14 at Day 0	60 at Day 1 130 at Day 2
Forestry	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant) LC Scouting	2.0	180	CA	180 at Day 0	180 at Day 1
			87	WA	87 at Day 0	370 at Day 1
			21	NY	21 at Day 0	50 at Day 1 110 at Day 2
	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant) LC Irrigation	2.0	30	CA	30 at Day 0	480 at Day 1
			15	WA	15 at Day 0	63 at Day 1 180 at Day 2
			6.3	NY	15 at Day 1	33 at Day 2 71 at Day 3 130 at Day 4

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant) LC Irrigation	2.0	9	CA	150 at Day 1	150 at Day 1
			4.6	WA	19 at Day 1	56 at Day 2 94 at Day 3 160 at Day 4
Tree Nuts[2]	Almonds (Dormant and Delayed Dormant) Harvesting Mechanical (Shaking)	4.0	37	CA	37 at Day 0	76 at Day 1 210 at Day2
			45	CA	45 at Day 0	730 at Day 1
			1700	TX	1700 at Day 0	1700 at Day 0
			280	LA	280 at Day 0	280 at Day 0
			160	GA	160 at Day 0	160 at Day 0
	Almonds (Dormant and Delayed Dormant) Transplanting	4.0	31	CA	31 at Day 0	63 at Day 1 180 at Day 2
			38	CA	38 at Day 0	27,000 at Day 1
			1400	TX	1400 at Day 0	1400 at Day 0
			230	LA	230 at Day 0	230 at Day 0
			130	GA	130 at Day 0	130 at Day 0
	Almonds (Dormant and Delayed Dormant) Scouting	4.0	12	CA	12 at Day 0	25 at Day 1 70 at Day 2 120 at Day 3
			15	CA	15 at Day 0	240 at Day 1
			560	TX	560 at Day 0	560 at Day 0
			92	LA	92 at Day 0	92 at Day 0 1300 at Day 1
			53	GA	53 at Day 0	480 at Day 1
Ornamentals/ Nurseries (Outdoor Only)	Non-bearing Fruit Trees (Peach, Nectarine) Container moving, hand pruning, tying/training	3.0	51	CA	51 at Day 0	810 at Day 1
			25	WA	25 at Day 0	110 at Day 1
			35	NY	35 at Day 0	84 at Day 1 180 at Day 2
Field and Row Crops	Alfalfa (LC, WDG), Soybean (LC, WDG) Scouting	1.0	26	CA	26 at Day 0	82 at Day 1 280 at Day 2
			12	TX	12 at Day 0	340 at Day 1
			10	MS	10 at Day 0	1500 at Day 1
			29	CA	29 at Day 0	380 at Day 1
			12	TX	12 at Day 0	340 at Day 1

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
			38	AZ	38 at Day 0	210 at Day 1
	Alfalfa LC, WDG Irrigation		15	CA	15 at Day 0	47 at Day 1 160 at Day 2
			6.9	TX	6.9 at Day 0	200 at Day 1
			6	MS	6 at Day 0	890 at Day 1
			17	CA	17 at Day 0	220 at Day 1
			7	TX	370 at Day 1	370 at Day 1
			22	AZ	22 at Day 0	120 at Day 1
Vegetable: Fruiting	Pepper WDG Hand harvesting, tying	1.0	26	CA	26 at Day 0	82 at Day 1 280 at Day 2
			12	TX	12 at Day 0	340 at Day 1
			10	MS	10 at Day 0	1500 at Day 1
			29	CA	29 at Day 0	380 at Day 1
			12	TX	12 at Day 0	640 at Day 1
			38	AZ	38 at Day 0	210 at Day1
	Pepper WDG Irrigation		15	CA	15 at Day 0	47 at Day 1 160 at Day 2
			6.9	TX	200 at Day 1	200 at Day 1
			5.6	MS	890 at Day 1	890 at Day 1
			17	CA	17 at Day 1	220 at Day 1
			7	TX	370 at Day 1	370 at Day 1
Vegetable: Head and Stem Brassica	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG), cauliflower (WP, WDG) Hand Weeding	1.0	40	AZ	40 at Day 0	48 at Day 1 78 at Day 2 88 at Day 3 120 at Day 4
	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG), cauliflower (WP, WDG) Irrigation		23	AZ	23 at Day 0	28 at Day 1 45 at Day 2 51 at Day 3 72 at Day 4 89 at Day 5 110 at Day 6
	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG),		10	AZ	10 at Day 0	13 at Day 1 20 at Day 2 23 at Day 3 33 at Day 4 40 at Day 5 49 at Day 6 61 at Day 7

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	cauliflower (WP, WDG) Scouting, hand harvesting					75 at Day 8 92 at Day 9 110 at Day 10
Vegetable: Leafy	Collards (WP, WDG), Bok Choy (WP), Kale (WP, WDG), Kohlrabi (WP, WDG) Hand harvesting	1.0	40	AZ	40 at Day 0	48 at Day 1 78 at Da y2 88 at Day 3 120 at Day 4
	Collards (WP, WDG), Bok Choy (WP), Kale (WP, WDG), Kohlrabi (WP, WDG) Irrigation		23	AZ	23 at Day 0	28 at Day 1 45 at Day 2 51 at Day 3 72 at Day 4 89 at Day 5 110 at Day 6
Vegetable, leafy	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Hand weeding	2.0	16	AZ	16 at Day 0	48 at Day 1 78 at Day 2 88 at Day 3 120 at Day 4
	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Irrigation		11	AZ	11 at Day 0	28 at Day 1 45 at Day 2 51 at Day 3 72 at Day 4 89 at Day 5 110 at Day 6
	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Hand weeding, topping		5	AZ	13 at Day 1	20 at Day 2 23 at Day 3 33 at Day 4 40 at Day 5 49 at Day 6 61 at Day 7 75 at Day 8 92 at Day 9 110 at Day 10
Cotton	Cotton	1.0	31	CA	31 at Day 0	100 at Day 1

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	LC, WDG Module builder operator		15	TX	15 at Day 0	420 at Day 1
			12	MS	12 at Day 0	1900 at Day 1
			36	CA	36 at Day 0	470 at Day 1
			14	TX	14 at Day 0	780 at Day 1
			47	AZ	47 at Day 0	260 at Day 1
	Cotton LC, WDG Picker operator, raker		12	CA	12 at Day 0	38 at Day 1 130 at Day 2
			6	TX	160 at Day 1	160 at Day 1
			4	MS	710 at Day 1	710 at Day 1
			14	CA	14 at Day 0	180 at Day 1
			5	TX	290 at Day 1	290 at Day 1
			18	AZ	18 at Day 0	98 at Day 1 420 at Day 2
	Cotton LC, WDG Tramper		6	CA	18 at Day 1	61 at Day 2 91 at Day 3 140 at Day 4
			3	TX	75 at Day 1	190 at Day 2
			2	MS	340 at Day 1	340 at Day 1
			6	CA	84 at Day 1	130 at Day 2
			3	TX	140 at Day 1	140 at Day 1
			8	AZ	46 at Day 1	200 at Day 2
Turfgrass	Turf grown for sod or seed LC, WP Maintenance, harvesting slab, transplanting/planting	3.76	40	CA (Very high exposure activities)	40 at Day 0	130 at Day 1
			56	IN (Very high exposure activities)	56 at Day 0	300 at Day 1
			34	MS (High exposure activities)	34 at Day 0	560 at Day 1
			21	CA (High exposure activities)	21 at Day 0	130 at Day 1
			8	IN (High exposure activities)	30 at Day 1	100 at Day 2
			14	MS (High exposure activities)	14 at Day 1	130 at Day 1
Microencapsulated Formulation Application						
Nursery (Microencap.	Ornamentals – Nurseries and Greenhouses	1.4	74	Ornamentals-smooth	74 at Day 0	120 at Day 0.33 40 at Day 1 29 at Day 2 260 at Day 3

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
Formulations)	Container moving, hand pruning, pinching, tying/training		50	Ornamentals- hairy	50 at Day 0	140 at Day 1
	Ornamentals – Nurseries and Greenhouses Irrigation		9.0	Ornamentals- smooth	5 at Day 1 4 at Day 2 32 at Day 3	Over 35 days; MOE = 30 or less at Day 35
			6	Ornamentals- hairy	17 at Day 1	
	Ornamentals – Nurseries and Greenhouses Hand harvest, cut flower		3.6	Ornamentals- smooth	2 at Day 1 1 at Day 2 12 at Day 3	Over 35 days; MOE = 12 or less at Day 35
			2	Ornamentals- hairy	7 at Day 1 7 at Day 2 8at Day 3 13 at Day 4	
Greenhouse						
Greenhouse (Total Release Fogger and. Liquid Concentrate Formulations)	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers* Irrigation handset	2	10	CA	10 at Day 0	86 at Day 1 120 at Day 2
			11	OR	11 at Day 0	110 at Day 1
			3.5	MN	110 at Day 1	110 at Day 1
	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging		3.7	CA	34 at Day 1	48 at Day 2 69 at Day 3 98 at Day 4 140 at Day 5
			4.3	OR	42 at Day 1	350 at Day 2
			1.4	MN	44 at Day 1	68 at Day 2 100 at Day 3

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
	Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers* Hand harvesting flowers					
	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs Total release aerosol foggers Hand harvest cut flowers	0.29	18	Ornamentals- hairy	18 at Day 0	44 at Day 1 140 at Day 2
Greenhouse - Oxon						
Greenhouse nursery	Greenhouse nursery Irrigation handset	2.0	5.0	CA	45 at Day 1	64 at Day 2 91 at Day3 130 at Day 4
			5.7	OR	56 at Day 1	460 at Day 2
			1.9	MN	59 at Day 1	90 at Day 2 140 at Day 3
	Greenhouse nursery Hand harvest		2.0	CA	18 at Day 1	25 at Day 2 36 at Day 3 51 at Day 4 73 at Day 5 100 at Day 6
			2.2	OR	22 at Day 1	180 at Day 2
			0.7	MN	23 at Day 1	36 at Day 2 55 at Day 3 84 at Day 4

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0[3]	DFR Study Location	MOE; Estimated REI Range (days)[4] for LOC >10	MOE; Estimated REI Range (days)[5] for LOC > 100
						130 at Day 5

[1]Range of MOEs is dependent on study used. See Appendix 11 for full range of occupational post-application risk estimates.[57]
[2] Formulations: EC = emulsifiable concentrate, LC = liquid concentrate, WDG = water dispersed granular, WP = wettable powder
[3] Dermal LOC = 10
[4] Dermal LOC = 100

[57] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0958

Appendix D2: Considered Mitigation for Occupational Post-Application Risks of Concern[1]

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10[3]	Considered REI (days) for LOC of 100[3]
Berry: Low	Strawberry, LC, WP Hand Harvesting	1.0	40	AZ	N/A	Day 3: 88 Day 4: 120
	Cranberry LC, WDG Hand Harvesting (raking), scouting	1.5	26		N/A	Day 4: 83 Day 5: 100
Mint	Peppermint/Spearmint LC, WDG Irrigation	2.0	10	CA	N/A	Day 1: 86 Day 2: 120
			11	OR	N/A	N/A
			3.5	MN	N/A	N/A
Grapes	Grapes, LC Hand weeding, scouting	2.0	11	CA	N/A	Day 2: 100
	Grapes, LC Hand harvesting, leaf pulling, tying/training (wine grape)		6	CA	N/A	Day 4: 73 Day 5: 85 Day 6: 98 Day 7: 110
	Grape, LC Turning (table grape only)		3	CA	N/A	Day 9: 79 Day 10: 92 Day 11: 110
Field and Row Crops: Tall	Corn: Sweet; Corn: Field, Including Grown for Seed Sweet and Field Corn (including grown for seed) (LC), Sunflower, sorghum (LC, WDG)	1.5	0.8	IL	N/A	Day 3: 180
			1.0	MN	N/A	Day 3: 140
			1.4	OR	N/A	Day 2: 200

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	Detassling, hand harvesting (corn only)					
	Corn: Sweet; Corn: Field, Including Grown for Seed Sweet and Field Corn (including grown for seed) (LC), Sunflower, sorghum (LC, WDG) Detassling, hand harvesting (corn only)	1.0	1.2	IL	N/A	Day 2: 100
			1.5	MN	N/A	Day 2: 99 Day 3: 220
			2.1	OR	N/A	Day 1: 81 Day 2: 310
Tree Fruit: Deciduous	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant) LC for all, WDG for all, and WP for apples only Scouting, pruning, training	2.0	30	CA	N/A	N/A
			15	WA	N/A	Day 1: 63 Day 2: 180
			21	NY	N/A	Day 2: 110
	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant) LC for all, WDG for all, and WP for apples only Hand harvesting	2.0	13	CA	N/A	N/A
			6	WA	N/A	Day 2: 76 Day 3: 130
			9	NY	N/A	Day 3: 96 Day 4: 180
	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines (Dormant and Delayed Dormant)	2.0	5	CA	N/A	Day 2: 110

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	LC for all, WDG for all, and WP for apples only Thinning fruit		2	WA	N/A	Day 4: 83 Day 5: 140
			3	NY	Day 1: 8 Day 2: 18	Day 5: 130
	Nectarine (WDG and EC) & Peach (EC) (Dormant and Delayed Dormant) Transplanting	3.0	51	CA	N/A	N/A
			25	WA	N/A	N/A
			35	NY	N/A	Day 1: 84 Day 2: 180
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Scouting, pruning, training	3.0	20	CA	N/A	Day 1: 320
			10	WA	N/A	Day 2: 120
			14	NY	N/A	Day 2: 73 Day 3: 160
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Hand harvesting	3.0	8.4	CA	N/A	N/A
			4	WA	N/A	Day 3: 85 Day 4: 140
			6	NY	N/A	Day 3: 64 Day 4: 120
	Nectarine (WDG and emulsifiable concentrate (EC)) & Peaches (EC) (Dormant and Delayed Dormant) Thinning fruit	3.0	3.3	CA	N/A	Day 3: 97 Day 4: 130
			2	WA	Day 1: 7 Day 2: 20	Day 5: 93 Day 6: 160
			2	NY	Day 2: 12	Day 5: 85 Day 6: 160
	Cherries (Sour) Transplanting	4.0	38	CA	N/A	N/A
			19	WA	N/A	Day 1: 80 Day 2: 230
			26	NY	N/A	Day 2: 140
	Cherries (Sour)		15	CA	N/A	N/A

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	Scouting, pruning, training		7.5	WA	N/A	Day 2: 92 Day 3: 150
			10	NY	N/A	Day 3: 120
	Cherries (Sour) Hand harvesting		6.3	CA	N/A	N/A
			3.1	WA	N/A	Day 4: 110
			4.3	NY	N/A	Day 4: 89 Day 5: 160
	Cherries (Sour) Thinning fruit		2.4	CA	N/A	Day 3: 73 Day 4: 99 Day 5: 140
			1.2	WA	5.1 at Day 1 15 at Day 2	Day 5: 70 Day 6: 120
			1.7	NY	4 at Day 1 8.8 at Day 2 19 at Day 3	Day 6: 120
Tree Fruit: Evergreen	Citrus LC, WDG – not CA or AZ Hand harvesting	4.0	21	CA	N/A	Day 1: 89 Day 2: 200
	Citrus AZ and CA = LC, WDG; all states = WP Hand harvesting	6.0 (CA and AZ)	14	CA	N/A	Day 2: 130
Forestry	Hybrid Cottonwood (grown for pulp)/ Poplar Plantations (Dormant and Delayed Dormant) LC Hand weeding	2.0	180	CA	N/A	N/A
			87	WA	N/A	N/A
	Hybrid Cottonwood (grown for pulp)/ Poplar Plantations (Dormant and Delayed Dormant) LC Scouting	2.0	30	CA	N/A	N/A
			15	WA	N/A	Day 2: 180
			21	NY	N/A	Day 2: 110

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant)	2.0	6.3	NY	N/A	Day 3: 71 Day 4: 130
	LC		9	CA	N/A	N/A
	Irrigation		4.6	WA	N/A	Day 3: 94 Day 4: 160
Tree Nuts	Almonds (Dormant and Delayed Dormant)	4.0	37	CA	N/A	Day 1: 76 Day 2: 210
			45	CA	N/A	N/A
	Harvesting Mechanical (Shaking)		1700	TX	N/A	N/A
			280	LA	N/A	N/A
			160	GA	N/A	N/A
	Almonds (Dormant and Delayed Dormant)	4.0	31	CA	N/A	Day 2: 180
			38	CA	N/A	N/A
	Transplanting		1400	TX	N/A	N/A
			230	LA	N/A	N/A
			130	GA	N/A	N/A
	Almonds (Dormant and Delayed Dormant)	4.0	12	CA	N/A	Day 2: 70 Day 3: 120
			15	CA	N/A	N/A
	Scouting		560	TX	N/A	N/A
			92	LA	N/A	N/A
			53	GA	N/A	N/A
Ornamentals/ Nurseries (Outdoor Only)	Non-bearing Fruit Trees (Peach, Nectarine)	3.0	51	CA	N/A	N/A
			25	WA	N/A	N/A
	Container moving, hand pruning, tying/training, transplanting		35	NY	N/A	Day 1: 84 Day 2: 180
Field and Row Crops	Alfalfa (LC, WDG), Soybean (LC, WDG)	1.0	26	CA	N/A	Day 1: 82 Day 2: 280
			12	TX	N/A	N/A
	Scouting		10	MS	N/A	N/A
			29	CA	N/A	N/A
			12	TX	N/A	N/A
			38	AZ	N/A	N/A
	Alfalfa		15	CA	N/A	Day 2: 160
			6.9	TX	N/A	N/A
	LC, WDG		6	MS	N/A	N/A
			17	CA	N/A	N/A
	Irrigation		7	TX	N/A	N/A

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
			22	AZ	N/A	N/A
Field and Row Crops: Low to Medium (Outdoor Only)	Pepper WDG Hand harvesting, tying	1.0	26	CA	N/A	Day 1: 82 Day 2: 280
			12	TX	N/A	N/A
			10	MS	N/A	N/A
			29	CA	N/A	N/A
			12	TX	N/A	N/A
			38	AZ	N/A	N/A
	Pepper WDG Irrigation		15	CA	N/A	Day 2: 160
			6.9	TX	N/A	N/A
			5.6	MS	N/A	N/A
			17	CA	N/A	N/A
			7	TX	N/A	N/A
Vegetable: Fruiting	Pepper WDG Hand harvesting, tying	1.0	26	CA	N/A	Day 1: 82 Day 2: 280
			12	TX	N/A	N/A
			10	MS	N/A	N/A
			29	CA	N/A	N/A
			12	TX	N/A	N/A
			38	AZ	N/A	N/A
	Pepper WDG Irrigation		15	CA	N/A	Day 2: 160
			6.9	TX	N/A	N/A
			5.6	MS	N/A	N/A
			17	CA	N/A	N/A
			7	TX	N/A	N/A
Vegetable: Head and Stem Brassica	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG), cauliflower (WP, WDG) Hand Weeding	1.0	40	AZ	N/A	Day 2: 78 Day 3: 88 Day 4: 120
	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG), cauliflower (WP, WDG) Irrigation		23	AZ	N/A	Day 4: 72 Day 5: 89 Day 6: 110
	Broccoli (WP, WDG), Brussels sprouts (LC, WP, WDG), cabbage (WP, WDG),		10	AZ	N/A	Day 8: 75 Day 9: 92 Day 10: 110

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100[3]
	cauliflower (WP, WDG) Scouting, hand harvesting					
Vegetable: Leafy	Collards (WP, WDG), Bok Choy (WP), Kale (WP, WDG), Kohlrabi (WP, WDG) Hand harvesting	1.0	40	AZ	N/A	Day 2: 78 Day 3: 88 Day 4: 120
	Collards (WP, WDG), Bok Choy (WP), Kale (WP, WDG), Kohlrabi (WP, WDG) Irrigation		23	AZ	N/A	Day 4: 72 Day 5: 89 Day 6: 110
Vegetable, leafy	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Hand Weeding	2.0	16	AZ	N/A	Day 2: 78 Day 3: 88 Day 4: 120
	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Irrigation		11	AZ	N/A	Day 4: 72 Day 5: 89 Day 6: 110
	Cole Crops: Including Brussels sprouts (LC) and cauliflower (EC) Hand harvesting, topping		5	AZ	N/A	Day 8: 75 Day 9: 92 Day 10: 110
Cotton	Cotton LC, WDG Mechanical harvesting- Module builder operator	1.0	31	CA	N/A	N/A
			15	TX	N/A	N/A
			12	MS	N/A	N/A
			36	CA	N/A	N/A
			14	TX	N/A	N/A
			47	AZ	N/A	N/A
	Cotton LC, WDG		12	CA	N/A	Day 2: 130
			6	TX	N/A	N/A
			4	MS	N/A	N/A
			14	CA	N/A	N/A
			5	TX	N/A	N/A

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100[3]
	Picker operator, raker		18	AZ	N/A	Day 1: 98 Day 2: 420
	Cotton LC, WDG Tramper		6	CA	N/A	Day 3: 91 Day 4: 140
			3	TX	N/A	Day 1: 75 Day 2: 190
			2	MS	N/A	N/A
			6	CA	N/A	Day 1: 84 Day 2: 130
			3	TX	N/A	N/A
			8	AZ	N/A	Day 2: 200
Microencapsulated Formulation Application						
Nursery (Microencap. Formulations)	Ornamentals – Nurseries and Greenhouses Container moving, hand pruning, pinching, tying/training	1.4	74	Ornamentals- smooth	N/A	Day 0.33: 120 Day 1: 40 Day 2: 29 Day 3: 260
			50	Ornamentals- hairy	N/A	N/A
	Ornamentals – Nurseries and Greenhouses Irrigation		9.0	Ornamentals- smooth	Day 1: 5 Day 2: 4 Day 3: 32	Proposed cancelling use of microencapsulated formulations in nurseries MOE = 30 or less at Day 35
			6	Ornamentals- hairy	Day 1: 17	
	Ornamentals – Nurseries and Greenhouses Hand harvest, cut flower		3.6	Ornamentals- smooth	Day 1: 2 Day 2: 1 Day 3: 12	Proposed cancelling use of microencapsulated formulations in nurseries MOE = 12 or less at Day 35
			2	Ornamentals- hairy	Day 1: 7 Day 2: 7 Day 3: 8 Day 5: 13	
Greenhouse						
Greenhouse (Total Release Fogger and. Liquid Concentrate Formulations)	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging	2	10	CA	N/A	Day 1: 86 Day 2: 120
			11	OR	N/A	N/A
			3.5	MN	N/A	N/A

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers* Irrigation handset					
	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers* Hand harvesting flowers		3.7	CA	N/A	Day 4: 98 Day 5: 140
			4.3	OR	N/A	Day 2: 350
			1.4	MN	N/A	Day 3: 100
	Ornamentals – *Liquid Concentrates* Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs Total release aerosol foggers Hand harvesting (flowers)	0.29	18	Ornamentals- hairy	N/A	Day 2: 140
Greenhouse - Oxon						
Greenhouse nursery	Greenhouse nursery	2.0	5.0	CA	N/A	Day 3: 91 Day 4: 130

Crop Group	Crop, Formulation, Activity[2]	App. Rate (lbs ai/A)	MOEs at Day 0	DFR Study Location	Considered REI (days) for LOC of 10^3	Considered REI (days) for LOC of 100^3
	Irrigation handset		5.7	OR	N/A	Day 2: 460
			1.9	MN	N/A	Day 2: 90 Day 3: 140
	Greenhouse nursery Hand harvest		2.0	CA	N/A	Day 5: 73 Day 6: 100
			2.2	OR	N/A	Day 2: 180
			0.7	MN	N/A	Day 4: 84 Day 5: 130

[1]Risk estimates may be found: https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0958
[2] Formulations: EC = emulsifiable concentrate, LC = liquid concentrate, WDG = water dispersed granular, WP = wettable powder
[3]N/A = REI of 24 hours is protective of risks of concern.

EXHIBIT B

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

Declaration of Dr. Mary Elissa Reaves

I, Dr. Mary Elissa Reaves, state as follows:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based upon my personal knowledge and/or my review of information contained in the records of the United States Environmental Protection Agency ("EPA" or the "Agency") or supplied by current employees.

2. I am currently the Director of the Pesticide Re-evaluation Division ("PRD") in EPA's Office of Pesticide Programs ("OPP"). I have worked for EPA for over 18 years. Since coming to the Agency in August 2003, I have served in various positions within OPP, including as Acting Branch Chief of the Risk

Management and Implementation Branch IV ("RMIB4") of PRD from January 2011 to May 2011 and as Branch Chief of the Risk Assessment Branch IV of the Health Effects Division ("HED") from October 2011 to March 2015. I was the Acting Associate Director of the Antimicrobials Division ("AD") from March 2015 until September 2015 and was the Associate Director of HED from December 2016 until June 2019. I was the Acting Director of PRD from June 2019 until December 2020, and have been the Director of PRD since December 2020.

3. I am making this Declaration in support of EPA's opposition to Petitioners' Motion for a Partial Stay Pending Review filed in the above captioned case.

4. PRD is the division assigned with the responsibility to develop EPA's regulatory position regarding the re-evaluation of conventional pesticides that are currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA"). Part of PRD's responsibility includes overseeing the periodic "registration review" of conventional pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

5. FIFRA requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 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.* The pesticide 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. *See*, *e.g.,* Chlorpyrifos; Cancellation Order, 65 Fed. Reg. 76,233 (Dec. 6, 2000); Chlorpyrifos; End-Use Products Cancellation Order, 66 Fed. Reg. 47,481 (Sept. 12, 2001). There are

currently 25 chlorpyrifos registrants and 76 total chlorpyrifos registrations, and a total of 41 registered or conditionally registered supplemental distributor products.

6. On March 18, 2009, EPA opened a public docket to initiate registration review of chlorpyrifos. *See*, *e.g.*, Chlorpyrifos Summary Document Registration Review: Initial Docket, March 2009 (Mar. 18, 2009), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0002.

7. The registration review of chlorpyrifos has raised numerous novel and complex scientific issues. 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 Science Advisory Panel at least six times.

8. In December 2020, EPA released the Proposed Interim Decision for the Registration Review of Chlorpyrifos ("2020 PID") for a 60-day public comment period. Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (Dec. 7, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0964. The 2020

PID concluded that "[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern." *Id*. at 19. However, the 2020 PID also noted that if one considered only the uses that result in estimated drinking water concentrations ("EDWCs") below the drinking water level of comparison ("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, which were the uses for which the EDWCs were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos.

9. In connection with the release of the 2020 PID, EPA also invited comments on the following assessments: Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review (Sept. 15, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944 ("2020 HHRA"); Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review (Sept. 15, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0940; and Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (Sept. 22, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941 ("2020 DWA"); Chlorpyrifos Usage and Benefits Assessment for Non-crop Uses (Nov. 9,

2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0966; and Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (Nov. 18, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969. EPA subsequently extended the 60-day comment period by 30 days, which then closed on March 7, 2021. Comment Period Extension for Chlorpyrifos (Feb. 4, 2021), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-1014. The Agency received 144 public comments on the 2020 PID and supporting assessments, which the Agency has yet to fully consider. EPA intends to issue a final interim decision on or before the October 1, 2022 registration review deadline.

10. On April 29, 2021, following the release of the 2020 PID in which EPA indicated that it had found aggregate exposures of chlorpyrifos associated with registered uses to be unsafe but provided a possible path forward for mitigating risks from chlorpyrifos, the Ninth Circuit Court of Appeals issued a decision in a case concerning the longstanding challenge from a petition on the chlorpyrifos tolerances. *See League of United Latin Am. Citizens (LULAC) v. Regan,* 996 F.3d. 673 (9th Cir. 2021). In September 2007, Pesticide Action Network North America ("PANNA") and Natural Resources Defense Council ("NRDC") had submitted to EPA a petition (the "2007 Petition") seeking

revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA due to alleged safety concerns.

11. Ultimately, EPA denied the 2007 Petition in full on March 29, 2017, and then denied objections to the March 2017 denial order. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Petition To Revoke Tolerances, 82 Fed. Reg. 16,581 (April 5, 2017) (the "2017 Order Denying Petition"); Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555 (July 24, 2019). Neither the 2017 Petition Denial nor the 2019 Order denying objections contained a determination concerning the safety of chlorpyrifos to support leaving the tolerances in place.

12. Finding that EPA could not leave tolerances in place without making the requisite safety finding under the FFDCA, the Court concluded that EPA's actions on chlorpyrifos violated the FFDCA and 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 under FFDCA section 408(d)(4)(A)(i), provided that such modification is supported by a safety finding (the "Final Rule"); and (3) modify or cancel related FIFRA registrations for food use in a timely fashion. 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.

13. Despite the Court's conclusion that EPA's actions, based on the record before the court, were a "total abdication of EPA's statutory duty", the Court recognized that EPA might have additional information that would allow EPA to make a safety finding for modified tolerances. *See*, *e.g.*, the 2020 PID. Given the limited window for issuing the Final Rule and the Court's directive not to engage in additional fact-finding or further delay, the Agency focused on whether the 2020 PID and completed 2020 HHRA and 2020 DWA were adequate to support a safety finding for the chlorpyrifos tolerances.

14. As stated above, EPA had concluded that aggregate exposures to chlorpyrifos from registered uses were unsafe. 2020 PID at 19. However, 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. *Id*. EPA had conducted additional analyses of particular uses as reflected in the 2020 PID considered to have high benefits to chlorpyrifos users to determine whether those uses might be safe if certain restrictions were in place and other uses were cancelled. In particular, EPA examined whether the concentrations of chlorpyrifos and its oxon metabolite in

drinking water would exceed safe levels if the only registered uses were the 11 considered and in the geographic areas evaluated. 2020 DWA. In order to retain these 11 uses, all other uses would need to be cancelled.

15. In order to determine if modification of tolerances was a viable option in accordance with the terms of the 2020 PID, EPA initiated discussions with Gharda Chemicals International, Inc. ("Gharda"), Corteva, Adama, and Drexel, each of which held technical registrations of chlorpyrifos, in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be sufficiently resolved in a 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 the Final Rule. The meetings with Gharda occurred on May 27, June 3, June 17, June 24, July 14, and August 16, 2021.

16. In addition to meeting with EPA, Gharda submitted two letters to EPA proposing terms for Gharda's voluntary cancellation of certain chlorpyrifos uses. Gharda's first letter, dated May 12, 2021 ("First Gharda Letter"), stated that Gharda 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." The First Gharda

Letter further stated that Gharda was "willing to negotiate and execute an agreement with EPA containing at least" nine separate terms, including further discussion of the geographic restrictions proposed in the 2020 PID as to the 11 high-benefit crops identified therein, allowing use on several crops in addition to the 11 uses in the 2020 PID, phase-out schedules that would allow some uses to continue until 2026, additional existing stocks orders that would allow additional time for phase-out, and retention of all import tolerances for chlorpyrifos. EPA could not accept Gharda's proposed terms for several reasons. Specifically, EPA could not accept the request to retain uses beyond the 11 identified in the PID since EPA specified it could only make a safety determination if all other uses were cancelled. Moreover, EPA had concerns about the extended phase-out and existing stocks requests and retention of all tolerances to cover residues in imported commodities, due to underlying safety concerns with the pesticide.

17. Following further discussions between EPA and Gharda, as discussed in Paragraph 15[1] of this Declaration, Gharda submitted its second letter, dated June 7, 2021 (the "Second Gharda Letter"). The Second Gharda Letter stated 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 identified in the [2020 PID]…subject to [nine] conditions.

[1] Note all internal cross-references in this doc should auto-update when right-clicking and selecting "Update Field".

These conditions included allowing use of chlorpyrifos on cotton in Texas in addition to the 11 uses identified in the 2020 PID, a proposal that EPA and Gharda "reach mutually agreeable provisions" allowing for the sale of all finished Gharda technical product in the United States and overseas to be processed and sold for all registered uses, retention of all import tolerances for chlorpyrifos, and agreement that all products lawfully treated with chlorpyrifos be permitted to clear the channels of trade, pursuant to 21 U.S.C. 346a(l)(5). EPA also could not accept the terms proposed in the Second Gharda Letter, given the continued concern about lengthy existing stocks provisions, retention of import tolerances, and lack of a safety determination beyond what was proposed in the 2020 PID. Although discussions continued with Gharda throughout July 2021, ultimately, there was not agreement on the terms Gharda was proposing.

18. Section 6(f) of FIFRA provides that "[a] registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses." 7 U.S.C. 136(d)(1)(A). To implement a voluntary product cancellation or use termination, the registrant would submit a letter to EPA (specifically, to the product manager or chemical review manager) requesting voluntary cancellation of the product or use(s). To cancel one or more uses, while retaining other use(s), the registrant also needs to submit a revised label with the changes highlighted.

19. After receipt of the letter, EPA will publish a notice in the Federal Register with a comment period of at least 30 days. 7 U.S.C. 136(d)(1)(B). FIFRA provides for a 180-day comment period for certain actions. 7 U.S.C. 136(d)(1)(C)(ii). However, the registrant may request that the Agency waive the longer comment period in favor of a 30-day comment period, which speeds up the approval process. *Id.* At the conclusion of the comment period, unless there are substantive comments or the registrant rescinds the cancellation request, EPA typically will publish the final cancellation order and, for products with retained uses, approve the revised label. If EPA has received substantive comments, EPA may modify or reconsider the cancellation as appropriate. The voluntary cancellation process is described in detail on EPA's website. *See* U.S. EPA, Voluntary Cancellation of a Pesticide Product or Use, *available at* https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use. Chapter 21 of EPA's Pesticide Registration Manual, also publicly available on EPA's website, specifies the correct distribution code registrants should use when requesting a voluntary cancellation of a product or use(s). *See* U.S. EPA, Pesticide Registration Manual: Chapter 21 - Directions for Submitting Applications and Contacting EPA, *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications.

20. Typically, as part of registration review, when EPA identifies risks that need to be mitigated, PRD would receive label amendment applications and voluntary cancellation requests from pesticide registrants consistent with the terms of the Agency's regulatory determination. In general, most of these voluntary cancellation request submissions do not require discussions between the registrant and EPA. But in some instances, a registrant may want to negotiate different terms for label amendments or existing stocks for use or product cancellations. Submissions that include additional terms or conditions that have not been agreed to by the Agency cannot be accepted as voluntary cancellation requests by EPA. Requests including such terms or conditions are instead considered by EPA to be proposals to be used to facilitate further discussion between the Agency and the requestor regarding the scope and terms of a voluntary cancellation. This is because, under section 6(a)(1) of FIFRA, EPA may allow the sale and use of existing stocks only to the extent consistent with FIFRA. 7 U.S.C. 136d(a)(1). If a voluntary cancellation request is conditioned upon continued sale and distribution of existing stocks that would be inconsistent with FIFRA, *e.g.*, an extended period during which an unsafe dietary risk would continue, the Agency could not issue a cancellation order including those existing stocks terms.

21. Because the First Gharda Letter and Second Gharda Letter included a number of terms and conditions beyond the scope of the 2020 PID (*see* Paragraphs

16 and 17 of this Declaration), EPA considered these letters to be proposals to be used for further negotiation between the Agency and Gharda, rather than voluntary cancellation requests.

22. Moreover, since the First Gharda Letter and Second Gharda Letter are requests to delete certain uses, not requests for full product cancellations, Gharda was required to submit revised labels with the changes highlighted for EPA's review and approval. *See* Paragraph 18 of this Declaration. Neither the First Gharda Letter nor the Second Gharda Letter were accompanied by any such application to revise labels; as a result, EPA was unable to accept these letters as official requests for amendments to the terms and conditions of Gharda's registration.

23. Since EPA considered these letters to be proposals for voluntary cancellation rather than voluntary cancellation requests, EPA was unable to accept these letters as official requests for amendments to the terms and conditions of Gharda's registration. As such, the First Gharda Letter and Second Gharda Letter did 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. Moreover, since no other registrant submitted an acceptable request for voluntary cancellation of the uses (and applications to amend labels for products) beyond the 11 geographically limited uses identified in the 2020 PID,

there was no basis for EPA to conclude that aggregate exposures would be limited consistent with the proposal in the 2020 PID. After all, the proposed mitigation in the PID was just a proposal on which several entities submitted comments. For example, multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses in the 2020 PID. Some, including cranberry and banana growers, argued that their uses should be included among the 11 considered uses; others, including advocacy and environmental groups, argued that EPA's safety determination supporting even those limited 11 uses was not supported by the available science. *See, e.g.*, Comment submitted by Cranberry Institute et al. (Mar. 12, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1075; the Colombian Banana Association – Augura (Feb. 8, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1021; and Comment submitted by Earthjustice et al. (Mar. 12, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1107.

24. Consequently, without acceptable voluntary cancellation requests providing a basis to conclude that modified tolerances would be safe (consistent with the 2020 PID proposal), EPA concluded that, based on the information before the Agency and taking into consideration the registered uses for chlorpyrifos at the time, it was unable to determine within the timeframe specified by the Ninth Circuit that the chlorpyrifos tolerances were safe, since aggregate exposures to

chlorpyrifos exceeded safe levels. 86 FR 48315 (Aug. 30, 2021). Therefore, EPA issued the Final Rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. *Id.*

25. In response to that Final Rule, EPA received several objections and requests for hearing, as well as requests to stay the rule. The Agency is in the process of finalizing its response to those objections and requests and intends to issue its response on or before February 28. Following the issuance of its Order responding to objections and hearing and stay requests, EPA intends to contact the registrants and ask them to submit requests to voluntarily cancel food uses of their registered chlorpyrifos products. If such voluntary cancellation requests are not forthcoming, EPA intends to initiate cancellation proceedings under section 6(b) of FIFRA. 7 U.S.C. 136d(b). Any such cancellation proceedings – which may take up to two years – would address existing stocks consistent with FIFRA.

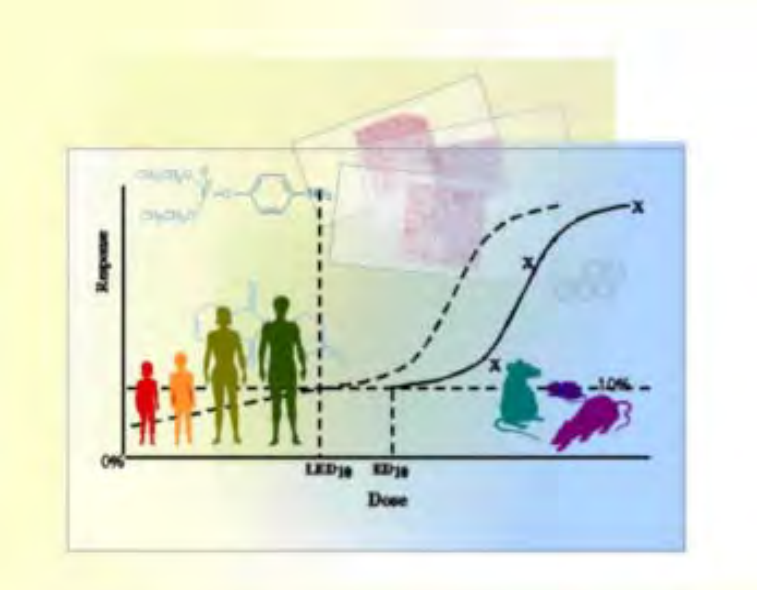
In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this _17__ day of February 2022.

Dr. Mary Elissa Reaves

EXHIBIT C

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).

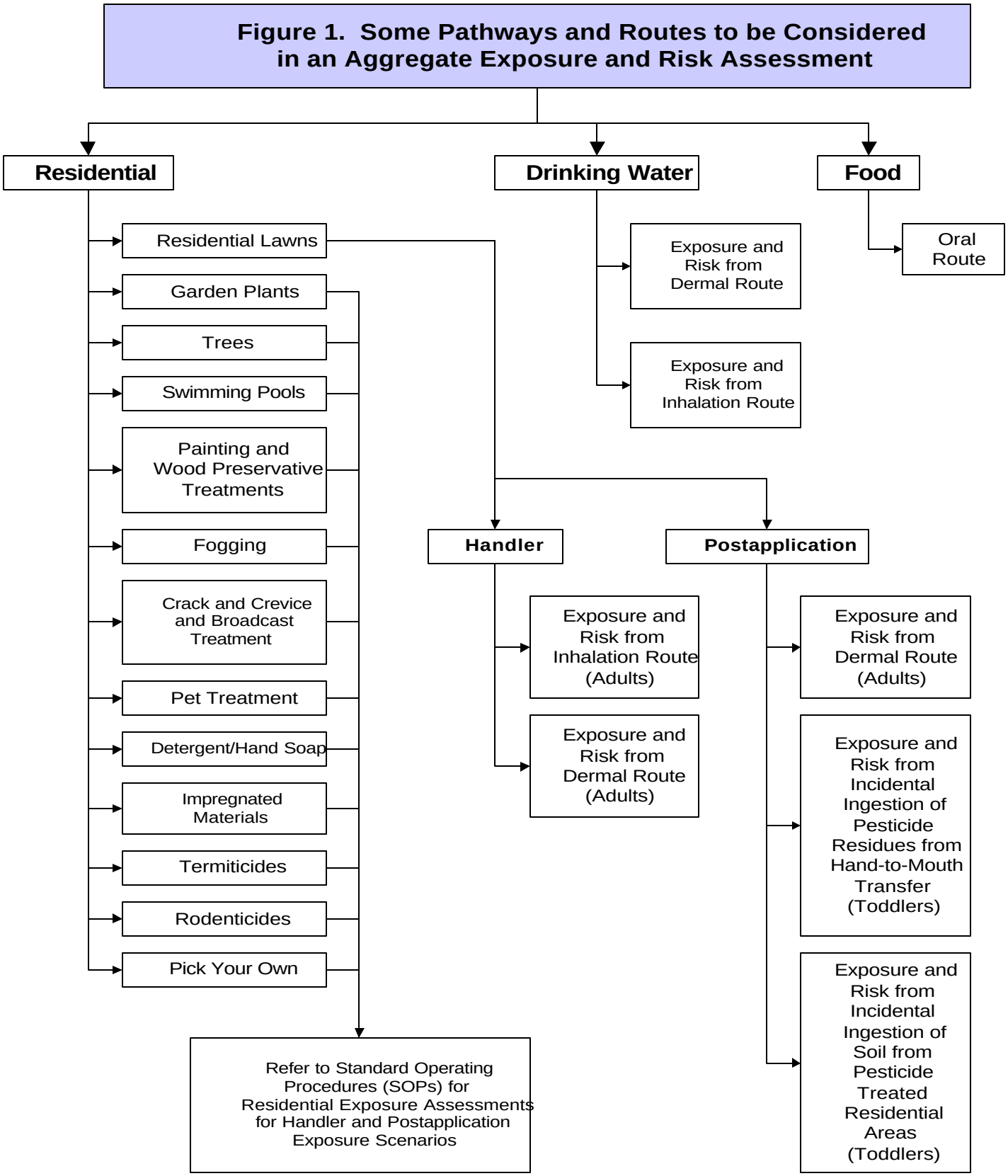
Additional details on the residential analytical methods, assumptions, and default values are described in the Draft Residential SOP's (1997a). Note that the SOP's are undergoing revision and will be released in an updated form.

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.

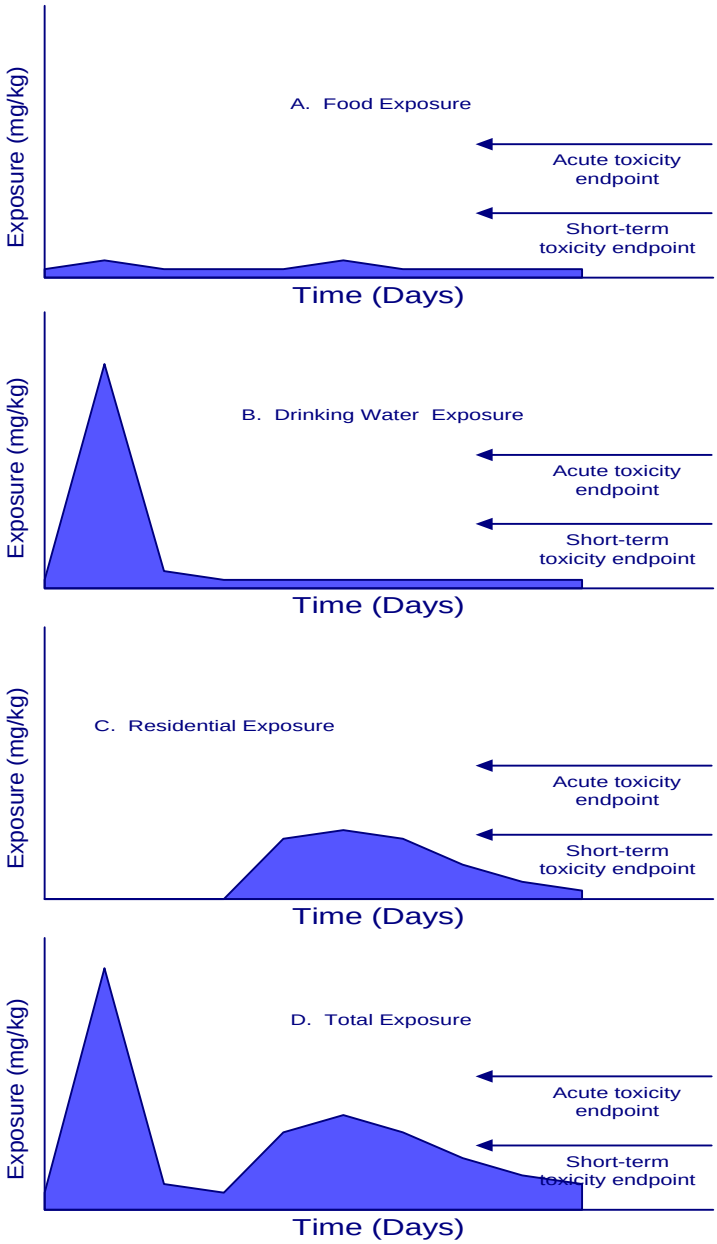
The use of a rolling time-frame approach will allow for more detailed use of toxicological data than today's methods and better incorporates the time-frame associated with the dosing which produces a toxic effect. OPP currently selects multiple toxicological endpoints for pesticides to reflect a variety 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.

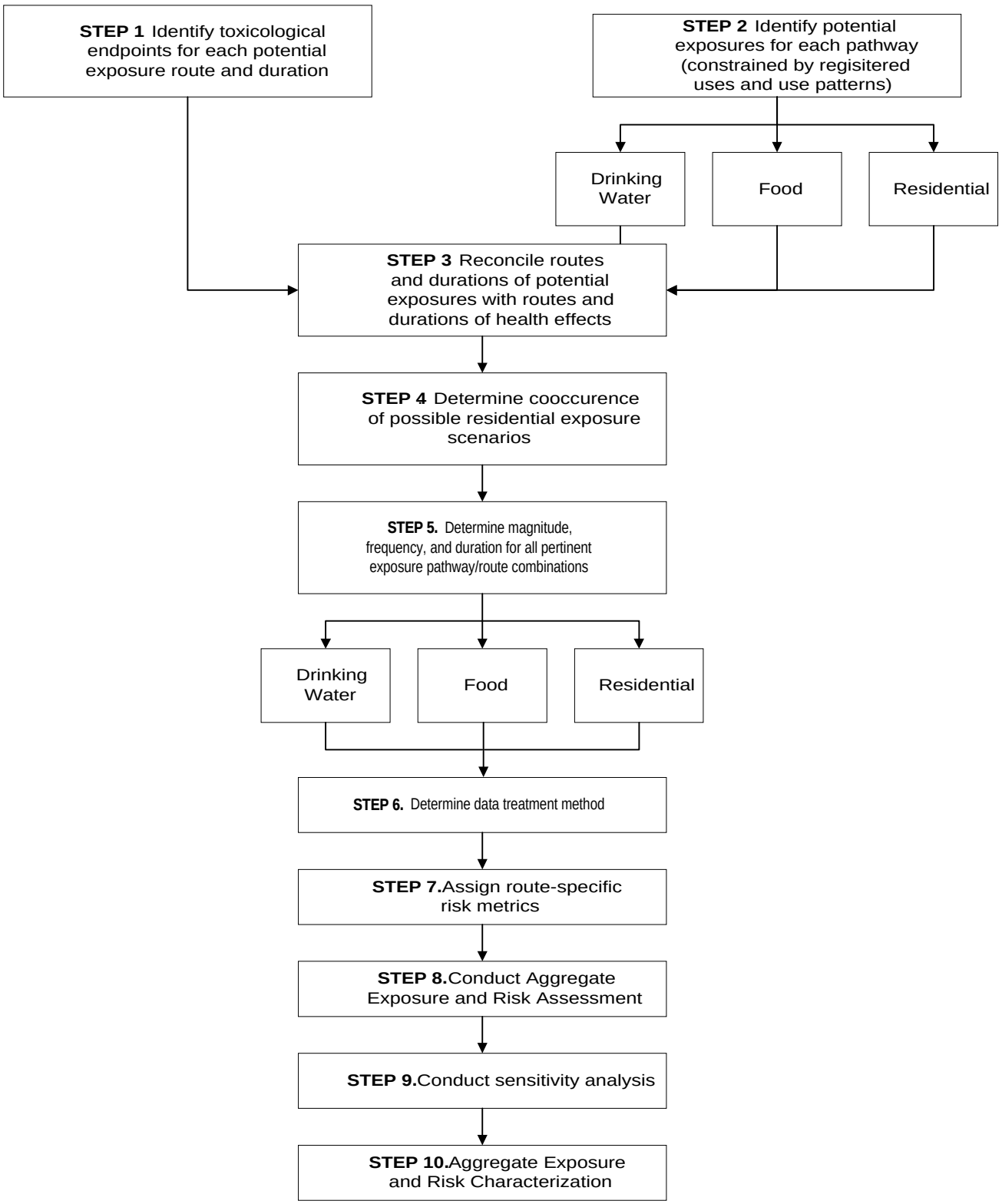
Section IV describes OPP's practices and proposed principles which it intends to use in conducting aggregate exposure and risk assessments under FFDCA. These practices expand upon the Interim Aggregate Exposure and Risk Assessment Guidance. These principles and practices are illustrated in the form of "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
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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 D

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

Declaration of Neil Anderson

I, Neil Anderson, state as follows:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based upon my personal knowledge and/or my review of information contained in the records of the United States Environmental Protection Agency ("EPA" or the "Agency") or supplied by current employees.

2. I am currently the Deputy Director of the Biological and Economic Analysis Division ("BEAD") in the EPA's Office of Pesticide Programs ("OPP"). I have held this position since April 2019. I have worked in the OPP for over 30 years and have served in various positions. Prior to holding the position of Deputy Director, I served as the acting Deputy Director of the Antimicrobials Division in

OPP from September 2018 to March 2019 and as a Branch Chief in the Pesticide Re-evaluation Division ("PRD") in OPP from 2010 to 2018.

3. I am making this Declaration in support of EPA's opposition to Petitioners' Motion for a Partial Stay Pending Review filed in the above captioned case.

4. FIFRA requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 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.* FIFRA defines "unreasonable adverse effects on the environment," in part, as "(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." 7 U.S.C. § 136(bb).

5. BEAD provides pesticide use-related information and economic analyses in support of pesticide regulatory activities. Information about how much and the manner in which pesticides are actually used helps EPA evaluate potential exposures, the need for various pesticides, and the potential economic impacts of regulatory options.

6. The pesticide 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. *See*, *e.g.,* Chlorpyrifos; Cancellation Order, 65 Fed. Reg. 76,233 (Dec. 6, 2000); Chlorpyrifos; End-Use Products Cancellation Order, 66 Fed. Reg. 47,481 (Sept. 12, 2001).

7. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), EPA is required to re-evaluate existing registered pesticides at least 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 152.50.

8. On March 18, 2009, EPA opened a public docket to initiate registration review of chlorpyrifos. *See*, *e.g.*, Chlorpyrifos Summary Document Registration Review: Initial Docket, March 2009 (Mar. 18, 2009), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0002.

9. In December 2020, EPA released the Proposed Interim Decision for the Registration Review of Chlorpyrifos ("2020 PID") for a 60-day public comment period. Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (Dec. 7, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0964. The 2020 PID concluded that "[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern." *Id.* at 19. However, the 2020 PID also noted that if one considered only the uses that result in estimated drinking water concentrations ("EDWCs") below the drinking

water level of comparison ("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 and only in certain regions of the United States due to benefits considerations, and concluded that those uses resulted in EDWCs that were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos.

10. The 11 uses and the geographic restrictions assessed in the 2020 PID were identified by BEAD as presenting high benefits to growers or by Corteva as a critical registered use. BEAD completed an assessment of the usage, role and pest management benefits of chlorpyrifos in agricultural settings ("2020 Benefits Assessment"). Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (Nov. 18, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969. This document was released for public comment following the release of the 2020 PID in December. The Agency received 144 public comments on the 2020 PID and supporting assessments and intends to respond to those comments during registration review.

11. In addition, pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 et seq., BEAD conducted a small business analysis to assess the

economic impact of the Final Rule on small entities ("2021 SBA Analysis"). Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021) (attached to this declaration). That analysis was prepared consistent with other analyses that are prepared for rules subject to notice and comment pursuant to the RFA. The RFA 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 revoking tolerances 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.

12. On February 10, 2022, Gharda Chemicals International, Inc. ("Gharda") and several growers and grower groups (collectively, "Petitioners") filed in the Eighth Circuit Court of Appeals a Motion for a Partial Stay Pending Review (the "Motion for Partial Stay"). *RRVSG Assoc., et al., v. Regan, et al.*, No. 22-1294 (8th Cir. 2022). Petitioners state that they will suffer irreparable economic harm absent a stay of the Final Rule and specifically identify alleged impacts relating to sugarbeets (*id.* at 22), peaches (*id.* at 23), cherries (*id.*), and soybeans (*id.* at 24).

13. As noted in EPA's 2020 Revised Benefits of Agricultural Uses of Chlorpyrifos memorandum, chlorpyrifos is widely used on agricultural crops in the

United States, with an average of 8.8 million acres being treated annually between 2014-2018. 2020 Benefits Memo at 2. On average, however, only around 3% of the total acres harvested of those crops are actually treated with chlorpyrifos. 2020 Benefits Memo at 9-10.

14. For the 11 uses that were assessed in the 2020 PID (alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and spring and winter wheat), the Agency estimates that 6.7 million acres were treated with chlorpyrifos, based on data from 2010-2014 and 2014-2018. Compared to the total of acres harvested for those commodities in the United States, that means that approximately 4.4% of the total acres harvested was treated with chlorpyrifos. 2020 Benefits Memo at 9-10.

15. EPA's estimate of impacts on growers (combination of yield losses and/or increases in pest control cost) across the subset of these 11 uses can be calculated from Table 2.1-1 of EPA's 2020 Benefits Memo. Adding up the range of impacts from that table for the 11 identified uses yields a range of impacts between $9.2 and $96.6 million per year, with likely losses around $53 million.

16. The fact that 4.4% of the 11 crops are treated with chlorpyrifos also means that the impact on total farm revenues due to the loss of chlorpyrifos is likely to be relatively small. Overall, EPA estimates the total annual revenue for the 11 high-benefit crops to be $82 billion, based on EPA's estimates of gross

revenue in its 2021 SBA Analysis. Comparing the impacts of substituting alternatives for chlorpyrifos and/or absorbing yield losses to the total annual revenue for those high benefit crops indicates that anticipated losses would account for under 0.1% of growers' expected revenue.

17. Moreover, based on the 2021 SBA Analysis, 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. 2021 SBA Analysis at 2.

18. EPA's analysis of possible small business impacts compares per-acre losses to average gross revenue per acre to determine the impact of losing chlorpyrifos. EPA has found that gross revenue per acre varies considerably across crops with field crops such as sorghum and sunflower generating average revenues of around $300 per acre while many fruit and vegetable crops generate revenues of $5,000 to $10,000 per acre, on average. The per-acre comparison to gross revenue

is likely an over-estimate of the impacts as a proportion of gross revenue for a farm. The per-acre impacts would only equal farm impacts under certain very stringent conditions: (1) The grower would have to produce only the crop in question; (2) All acres in production would have to be treated with chlorpyrifos, and (3) Chlorpyrifos would have to be applied every year. 2021 SBA Analysis at 6-7.

19. As a general matter, overall farm-level impacts will be lower than the per-acre impacts because farms tend to produce a diverse selection of crops, including crops that do not rely on chlorpyrifos. Even small farms typically diversify production across multiple crops for a number of reasons, and many farms also raise livestock. Crop and livestock production are often complementary, with crops providing feed for livestock and livestock often providing manure to improve soil fertility. Differences in field characteristics, such as soil type, draining, and slope, can influence which crops are grown. Rotation of multiple crops across seasons or years (on the same field) is a common agricultural practice utilized for many agronomic purposes, including pest management. Moreover, because different crops have different planting and maturation dates, diversification allows the grower to spread the demand for resources across time and avoid shortages, especially of labor, at peak times. Diversification reduces the risk of yield and/or price variability within a single commodity. *Id*. at 7.

20. The Petitioners in the Red River Valley case claim that the loss of chlorpyrifos will result in an economic loss of $82 million on sugarbeets. *Id.* at 23, citing Att. 2, Ex. G (Hastings Decl.) at ¶¶20-21; Att. 2, Ex. F (Geselius Decl.) at ¶22; Att. 2, Ex. I (Metzger Decl.) at ¶18). This number greatly exceeds EPA's estimate of likely impacts of loss of chlorpyrifos of $2.6 to $32.2 million, with likely costs being closer to $6.8 million when taking into consideration the limited extent of severe sugarbeet root maggot problems (*i.e.*, EPA estimates that only 20% of chlorpyrifos-treated sugarbeet acres in Minnesota and only 10% of chlorpyrifos-treated sugarbeet acres in North Dakota are subject to severe sugarbeet root maggot pressure) that would result in yield losses without chlorpyrifos. *See* 2020 Benefits Memo at 49. The declarants (Geselius and Metzger) state in their declarations that they multiply the Agency's $500 loss per acre value with the average number of sugarbeet acres treated with chlorpyrifos (regardless of target pest) by their cooperative members to calculate losses of $30 million and $17.5 million per year, respectively. Ex. F at ¶22; Ex. I at ¶18. EPA's $500 loss per acre estimate is only relevant to the losses expected from acres in counties that are subject to severe sugarbeet root maggot pressure; that amount of loss is not expected on every acre to which chlorpyrifos is applied. *See* 2020 Benefits Memo at 49. Some of those acres would not be expected to have severe

infestations of root maggot or even any root maggot pressures at all; for some acres, chlorpyrifos may be applied to target other pests.

21. Moreover, EPA estimates that, on average, only 61,200 acres total (targeting all pests) are treated with chlorpyrifos in these states but recognizes that the extent of acres infested with pests can vary from year to year. 2020 Benefits Memo at 8. EPA acknowledges that chlorpyrifos use seems to have increased substantially in 2020, based on Kynetec survey data from 2022, although there is insufficient information to know if that is long-term increase. Based on EPA's analysis, the expected impact in Minnesota and North Dakota is likely to be a cost closer to $5.1 million when considering the limited extent of severe sugarbeet root maggot that would be uncontrolled without chlorpyrifos. 2020 Benefits Memo at 49. Due to the different pest pressures in other sugarbeet states, EPA calculates a cost of around $1.8 million per year in those other states. Together, that is a cost of $6.8 million per year, or about 2.8% of the total revenue for sugarbeet-acres treated with chlorpyrifos. 2020 Benefits Memo at 48-49.

22. For most crops treated with chlorpyrifos, EPA has determined that there are alternatives for controlling the pests targeted by chlorpyrifos. 2020 Benefits Memo at 5. For example, EPA has concluded that there are several alternatives for controlling the primary soybean pests (soybean aphid, bean leaf beetle, and spider mite). Thiamethoxam and imidacloprid are among the effective

alternatives for controlling major soybean pests. The costs of these alternatives are slightly higher than the cost of chlorpyrifos but still only impact about 0.2-0.8% of gross revenue. Essentially, the estimated range of impacts on total soybean revenue ($3.1-12.2 million) is a function of the acres treated – 3.1 million, on average, out of 71 million acres harvested recently. 2020 Benefits Memo at 46. EPA has also registered flupyradifurone for use on soybeans, which is also an effective pesticide against soybean pests, although since it was registered in 2017, it was not included in the 2020 Benefits Memo. (https://www3.epa.gov/pesticides/chem_search/ppls/000264-01198-20190905.pdf).

23. For most crops on which chlorpyrifos is registered, EPA has concluded that there are adequate alternatives to provide control of the pests typically targeted by chlorpyrifos. 2020 Benefits Memo at 5. While some alternatives may not be as efficacious or may be more expensive, they are available for most crops. Memo at 5. Moreover, pesticides represent only one method of pest control for farmers. Growers may use other methods of pest control to reduce susceptibility to pests, e.g., removing damaged tree limbs and pruning carefully to decrease opportunities for wood-boring insects, integrated pest management, biological control with natural insect enemies, etc.

24. In addition, as pesticide markets open through the loss of a control option or new pests emerge, existing chemicals are registered on additional crops or new products are developed. Although EPA concludes that most growers who use chlorpyrifos will replace it with other insecticides, some growers may find non-chemical management tactics such as biological control with insect natural enemies to be cost effective over time as understanding of their optimal deployment improves. As a result of the introduction of new effective insecticides and improvements in deploying non-chemical pest management strategies, estimated impacts to growers may decrease over time. 2020 Benefits Memo at 13.

25. EPA recognizes that there may be some crops in certain locations for which the alternatives are not adequate. Yield losses may occur, but the severity and the timing of those losses can be uncertain. For example, orchard crops may still be able to produce fruit, until the infestations become so bad that trees are lost, but those effects can take a number of years to be fully realized. For example, a peach tree or cherry tree can still continue to produce fruit, even if infested with trunk borers, although the life of the tree may be shortened as a result of the infestation. 2020 Benefits Memo at 22-23. By EPA's estimation (as described in the 2020 Benefits Memo at 22-23), in heavily infested orchards, only about 20% of trees are affected by borers and about half of those trees continue to bear fruit. In

contrast, EPA has been unable to find reliable quantitative estimates for yield losses and shortened tree lifetime for tart cherries. *Id.*

26. EPA recognizes that emerging pests and the potential for resistance present some uncertainties in evaluating potential economic costs for growers. However, unless there is evidence of a particular pest imminently becoming a large problem or resistance becoming widespread, these factors are simply uncertainties. For example, although the Cherry Marketing Institute expressed concern that chlorpyrifos is the only effective chemistry for the treatment of trunk borers and that loss of the pesticide would open the industry to substantial loss of trees (Ex. T, ¶ 10), EPA's data indicates that the trunk borer is a minor pest, in terms of chlorpyrifos use on tart cherry trees. While there is a possibility of increased pest pressure in the future, at this time it is premature to conclude that loss of chlorpyrifos will have a major impact on cherry farmers since the trunk borer is not a widespread pest for cherry trees at this time. It is unclear whether growers will have economic injury from these factors because the very nature of these factors is speculative. EPA does not typically include costs associated with these factors due to their very speculative nature. *See* 2020 Benefits Memo at 13.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18th day of February 2022.

Neil Anderson

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Chlorpyrifos Revocation Small Business and Employment Analysis

FROM: Brett Gelso, Ph.D., Team Lead Economist
Derek Berwald, Ph.D., Senior Economist
Economic Analysis Branch

THRU: T J Wyatt, Acting Chief
Economic Analysis Branch

TO: Alexandra Feitel, Chemical Review Manager
Dana Friedman, Branch Chief
Risk Management and Implementation Branch I
Pesticide Reevaluation Division (7508P)

Summary

EPA regulates pesticides that are used on crops grown for food by setting tolerances, which are limits on the amount of pesticide residues that remain in or on food or animal feed that is sold in the U.S. Under the Federal Food, Drug, and Cosmetics Act (FFDCA), if a pesticide does not have a food tolerance, pesticide residues left on food or animal feeds will render the commodity "adulterated" and it cannot be sold. EPA is pursuing a rulemaking that will revoke all food tolerances for chlorpyrifos, which means that growers will no longer be able to apply chlorpyrifos to food crops. This memo presents information on the potential impact to small farms of the tolerance revocation as well as possible job losses for the industry. Based on the analysis in this memo, EPA finds that there is not a significant impact on a substantial number of small entities and that there are unlikely to be significant job losses as a result of this rule.

EPA performed an earlier small business analysis (EPA, 2015a); this memo updates that analysis with recent information on the impacts of cancelling chlorpyrifos tolerances on the farm industry. A small business analysis, based on guidelines in the RFA, allows EPA to determine whether a rule has the potential to cause a significant economic impact on a substantial number of small entities (SISNOSE), in this case, small farms. In both the 2015 analysis and this one, EPA determined that there is not a SISNOSE from revocation of chlorpyrifos tolerances on all food crops.

There are approximately 2 million farms currently in the U.S.; out of those farms there are about 1.5 million small farms that produce crops (Census of the Ag, 2017), of which an estimated 43,430 are farms 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. Estimated impacts per-acre of a specific crop will likely overestimate the impacts as a proportion of total farm income. Based on the criteria set forth in this analysis, EPA certifies that the revocation of the tolerances for chlorpyrifos will not have a significant impact on a substantial number of small entities. However, EPA acknowledges that some small farms, especially those without alternatives to chlorpyrifos, could face large per-acre impacts.

Background

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., calls for agencies to consider the economic impacts rules will have on small entities. The purpose of the RFA is to ensure that, in developing rules, agencies identify and consider ways of tailoring regulations to the size of the regulated entities because small entities may face disproportionately large impacts, particularly from recordkeeping and reporting requirements. The RFA does not require an agency to minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The Regulatory Flexibility Act (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. 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), is not subject to notice and comment and does not require a regulatory flexibility analysis. However, EPA is conducting the analysis in this memo to understand the impacts of chlorpyrifos on the small business community and inform EPA decisionmakers.

The RFA does not analytically define the terms "significant" or "substantial" with regard to extent of economic impact and number of small entities affected, and there is general agreement that there can be no one-size-fits-all methodology for making the SISNOSE determination. Therefore, the EPA established general guidelines (EPA 2006) for determining whether an action may be certified as having no significant economic impact on a substantial number of small

entities (no SISNOSE). In general, the determination depends on the magnitude of the potential economic impacts on the directly regulated small entities.

Following general EPA guidelines (EPA 2006), OPP considers losses of more than 3% of gross revenue at the farm level to be a significant impact on the small entities identified; losses of less than one percent of gross revenue are not considered significant and losses between one and three percent of gross revenue at the farm level are possibly significant.

If the estimated impact is greater than 1% of per-farm gross revenue, OPP determines whether a substantial number of small entities may be affected, where a substantial number depends on both the absolute number and share of small entities directly affected.

OPP continues the use of thresholds at which the number of small entities impacted would not be considered "substantial" used in past analyses (Wyatt, 2008; EPA 2015b; EPA, 2016). If the estimated impact is between 1% and 3% of average per-farm gross revenue, OPP set the following thresholds at which the number of small entities that may be impacted would not be considered "substantial:"

- Less than 100 small farms may be so impacted, provided the number represents less than 30% of all affected small farms;
- Between 100 and 1,000 small farms may be so impacted, provided the number represents less than 20% of all affected small farms; or
- More than 1000 small farms may be so impacted, but the number represents less than 10% of all affected small farms.

If the estimated impacts exceed 3%, or if impacts cannot be quantified, the thresholds at which OPP concludes a substantial number of small farms would not be affected are as follows:

- Less than 100 small farms may be so impacted, provided the number represents less than 20% of all affected small farms;
- Between 100 and 1,000 may be so impacted, but account for less than 10% of all affected small farms; or
- More than 1000 small farms may be so impacted, but the number represents less than 5% of all affected small farms.

The revocation of tolerances for chlorpyrifos could potentially affect any small farm producing crops, since chlorpyrifos is currently registered for use on most crops.

Methodology

Identifying Small Entities

Under the RFA, "small entity" includes small businesses, small governments, and small organizations. The RFA references the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration (SBA) to define "small

business" by regulation. SBA has established such definitions for each of the business categories listed in the North American Industrial Classification System (NAICS) in 13 CFR 121.201. A small business is defined by either the number of employees employed by the business or by the annual dollar amount of sales/revenues of the business.

For the purposes of assessing the potential adverse economic impacts on small entities directly regulated by this action, EPA has focused its analysis on producers of crops (*i.e.*, small farms) who may currently use chlorpyrifos for control of insect pests and may have adverse economic impacted as a result of the action revoking the tolerances for chlorpyrifos. EPA did not assess the impacts to livestock producers, although tolerances will be revoked for meat, eggs, and milk. The only direct use of chlorpyrifos in livestock production affected by the revocation is for a cattle ear tag to repel insects for which there are multiple alternative insecticides available. Otherwise, tolerances account for residues that may be present in livestock products via feed, such as corn, that may be produced with chlorpyrifos; as minimal impacts are expected in these commodities as a result of the tolerance revocation, livestock producers will not incur any indirect impacts such as increases in feed prices. OPP has also determined that small governments and small organizations will not be affected by the revocation of the tolerances addressed in this action since these entities would not be using chlorpyrifos to produce food commodities.

As noted earlier, the level at which an entity is considered small is determined for each sector by the SBA, identified by NAICS code. Farms that produce crops are classified under NAICS code 111, Crop Production, or NAICS code 112, Animal Production. For these sectors, the SBA defines small entities as farms with total annual sales of $1,000,000 or less[1]. Over 95 percent[2] of U.S. farms are considered small under the SBA definition, according to data from the 2017 Census of Agriculture (USDA NASS 2019), the most recent data available.

Table 1 presents several statistics from the U.S. Department of Agriculture on large and small farms. The Small Business Administration defines a small farm to be one with annual revenue of less than $1,000,000. According to data from the 2017 Census of Agriculture (USDA NASS, 2019), the average farm with revenues less than $1,000,000 per year has about 120 acres in crop production and annual revenue of about $65,187, including revenue from the production of all agricultural products, including livestock.

[1] Two subsectors within NAICS 112 are defined differently, feedlots (112112) are defined to be small if revenues are less than $7.5 million per year and chicken egg production facilities (112310) are defined to be small if revenues are less than $15 million per year. These entities are unlikely to have significant crop production relative to their primary activity.

[2] In order to calculate the number of small farms producing crops under the $1 million dollar threshold, farms with revenues of less than $1 million was divided by total farms \

Table 1. Farms that Produce Crops, Average Crop Acreages and Average Crop Revenue, 2017

	All Farms	Large Farms	Small Farms	Small Farms Using Insecticides
Number of Farms[1]	1,475,627	68,322	1,407,305	264,175
Average Crop Acreage	207 acres	2009 acres	120 acres	206 acres
Average Revenue	$194,625	$3,504,201	$65,187	$65,187
Average Revenue per Acre	$937	$1,745	$542	$542

Source: 2017 Census of Agriculture

[1] Number of farms include farms that produce crops for NAICS 111 (Crop Production) and NAICS 112 (Animal Production). Total farms producing crops for NAICS 111 and 112 are given on Table 75 in the 2017 Census of the Agriculture. Farm revenue for farms that produce crops were derived from Table 72. Small farms producing crops was the difference between total farms producing crops and large farms producing crops.

Pesticide use is somewhat more common among large farms than small farms. Data from the 2017 Census indicate that about 86% of farms using insecticides such as chlorpyrifos are small under the SBA definition[3]. The percentage of small farms using insecticides was estimated by dividing small farms using insecticides by all farms using insecticide. Small crop-producing farms that use pesticides tend to be larger, on average, than all small crop-producing farms and have higher revenues.

Estimating Impacts Resulting from Tolerance Revocation

EPA regulates pesticides that are used on crops grown for food by setting tolerances, which are limits on the amount of pesticide residues that remain in or on food or animal feed that is sold in the U.S. Under FFDCA, if a pesticide does not have a food tolerance, pesticide residues left on food or animal feed will render the commodity "adulterated" and it cannot be sold. Thus, as a consequence of revoking the food tolerances, growers who would normally rely on chlorpyrifos will need to use an alternative means of pest control. If the alternative is less effective, or if alternatives are not available, growers may suffer yield or quality losses that could result in reductions in revenue. More expensive alternatives could result in higher production costs. In the case of chlorpyrifos, effective alternatives are available for most crops, although often at higher cost. In some cases, alternatives may be less effective (*e.g.*, asparagus, peanuts, grapefruit,

[3] The percentage of small farms using insecticides was estimated as the number of small farms using insecticides divided by all farms using insecticides

lemons, oranges) or unavailable (*e.g.*, cutworms in Michigan asparagus and borers in Southeast peaches).

The purpose of this analysis is to estimate the farm-level impacts of revoking tolerances as a proportion of gross revenue. In November 2020, EPA published *Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)* (EPA 2020) which estimated the per-acre benefits of chlorpyrifos in a variety of crops, including those most reliant on chlorpyrifos use. These estimates of benefits are sufficient to provide estimates of the costs of revoking chlorpyrifos tolerances, as the per-acre benefits to growers are equivalent to the costs or impacts imposed on them by making chlorpyrifos unavailable for use. These per-acre impacts are part of an overall farm enterprise that typically produces multiple crops. Because the impacts do not affect all of the acreage on a farm, the farm-level impact, as a percentage of gross revenue, will be lower than that of the per-acre impacts of specific crops.

To assess the value of chlorpyrifos on a crop, in the benefits memo EPA identified the primary pests targeted by chlorpyrifos through a review of the label and private pesticide market research data consisting of the results of marketing surveys of growers. University extension recommendations along with the market research data were used to identify the likely alternatives to chlorpyrifos and the costs of the alternatives to chlorpyrifos. Differences in insecticide costs were estimated on a per-acre basis. In situations where crops have no alternatives or less efficacious alternatives to chlorpyrifos, yield and/or quality losses were also considered. Only currently registered alternatives were considered. However, for the crops for which alternatives are limited or not available, new control methods may be registered or be developed over time. Past experience has shown that as new pests occur or markets for existing pests open up, new chemicals are developed or existing chemicals use patterns are expanded to fill the gaps in pest control, although EPA did not consider that possibility when developing the benefit estimates that are the basis for the analysis here.

Farm-Level Impacts Resulting from Tolerance Revocation

For this analysis, per-acre losses are compared to average gross revenue per acre to determine the impact of losing chlorpyrifos. Average gross revenues are calculated from USDA statistics on acreage, production, and value of crops (see Appendix). As shown in the Appendix, gross revenue per acre varies considerably across crops with field crops such as sorghum and sunflower generating average revenues of around $300 per acre while many fruit and vegetable crops generate revenues of $5,000 to $10,000 per acre, on average. The average revenue for a small farm is $542 per acre (Table 1), indicating a mix of crops that is likely skewed toward field crops. This per-acre comparison to gross revenue is likely an over-estimate of the impacts as a proportion of gross revenue for a farm. The per-acre impacts would only equal farm impacts under certain very stringent conditions:

- The grower would have to produce only the crop in question,
- All acres in production would have to be treated with chlorpyrifos, and

- Chlorpyrifos would have to be applied every year.

Overall farm-level impacts will be lower than the per-acre impacts because farms tend to produce a diverse selection of crops, including crops that do not rely on chlorpyrifos. Even small farms typically diversify production across multiple crops for a number of reasons, and many farms also raise livestock. Crop and livestock production are often complementary, with crops providing feed for livestock and livestock often providing manure to improve soil fertility. Differences in field characteristics, such as soil type, draining, and slope, can influence which crops are grown. Rotation of multiple crops across seasons or years (on the same field) is a common agricultural practice utilized for many agronomic purposes, including pest management. Moreover, because different crops have different planting and maturation dates, diversification allows the grower to spread the demand for resources across time and avoid shortages, especially of labor, at peak times. Diversification reduces the risk of yield and/or price variability within a single commodity. In addition, several states, such as California, Oregon and New York, have taken action to eliminate chlorpyrifos use, and those changes have not been considered in the estimates here. Growers in those states will lose access to chlorpyrifos even without EPA action, and those cost impacts should rightly be considered a result of state action, not the revocation of tolerances being considered here.

Further, as indicated by the low percent crop treated with chlorpyrifos for many crops, the pests targeted by chlorpyrifos may be sporadic in nature. Thus, it would be rare that all acres in production on a farm would require treatment with chlorpyrifos, much less every year.

Number of Farms Impacted

Private agricultural market data (Kynetec USA, 2020) are used to estimate the number of farms applying pesticides by active ingredient. Data are collected through a stratified survey using a statistically valid sample by state, not including Alaska and Hawaii. For this analysis, EPA summed the number of entities estimated to use chlorpyrifos for each crop. This could overestimate the number of entities using chlorpyrifos because the same entity might use chlorpyrifos on multiple crops.

The market survey data do not distinguish farms by size according to the SBA definition. According to data from the 2017 Census of Agriculture (USDA NASS 2019), about 86% of the farms using insecticides are considered small. EPA uses these percentages to estimate the number of small farms using chlorpyrifos that may be impacted at levels exceeding one percent of average per-farm gross revenue.

Estimated Impacts and Conclusion

Table 2 summarizes the results of the crop-specific assessments. The table presents the range of cost per acre for each crop, based on the 2020 chlorpyrifos benefits memo (EPA 2020). Also

shown is the impact per acre of the high-end impact estimate, shown as a percentage of gross revenue per acre. The use of high-end impact estimates may tend to overestimate the impact. Gross revenue per acre is presented in the Appendix to the 2020 chlorpyrifos benefits memo and also reproduced as an appendix to the memo. For most of the crops listed, EPA concluded that there are adequate alternatives to provide control of pests typically targeted by chlorpyrifos. However, use of alternatives may entail additional control costs to the grower. In some cases, alternatives may not be as efficacious as chlorpyrifos and yield or quality losses may occur. Table 2 also presents the estimated number of farms using chlorpyrifos for each crop, based on proprietary market survey data (Kynetec, 2010 – 2014 and 2014 - 2018).

Table 2. Summary of Impacts of Revoking Chlorpyrifos Tolerances.

Crop	Impact / Acre [1]	Percent of Per-Acre Gross Revenue (High Impact)	Farms Impacted [2] (Large and Small)
Crops with impacts greater than 3% of Gross Revenue per Acre			
MI Asparagus[4]	$0 - $450	25%	80
Lemons [3]	$10 - $290	4%	210
Oranges (CA) [3]	$8 - $201	5%	900
Other Citrus, (CA)	$8 - $201	5%	270
GA and SC Peaches[3,4]	$12 - $430	10%	100
Fresh Peas	$10 - $370	48%	10
Sorghum	$3 - $4	3%	370
OR Strawberries[3,4]	$6 - $7,813	100%	40
MN and ND Sugarbeets[3,4]	$13 - $498	45%	160
Subtotal			**2,140**

Crop	Impact / Acre [1]	Percent of Per-Acre Gross Revenue (High Impact)	Farms Impacted [2] (Large and Small)
Crops with Impacts between 1% and 3% of Gross Revenue per Acre			
Beans, Succulent	$29	2%	40
Broccoli	$8 - $68	1%	10
Cabbage	$14 - $78	1%	10
Cauliflower	$11 - $90	1%	10
Cherries (sweet)	$3 - $65	4%	810
Cherries (tart)	$17 - $170	2%	130
Corn	$6 - $8	1%	6480
Cotton, foliar treatment	$0 - $14	2%	200
Cotton, seed treatment	$0 - $9	1%	1750
Grapefruit [3]	$9 - $44	1%	100
Grapes (Table)	$7 - $130	1%	80
Grapes (Wine)	$4 - $91	2%	80
Onions	$11 - $66	1%	240
Oranges, Florida	$2 - $33	1%	370
Other Citrus (FL)	$8 - $201	1%	90
Peanuts [3]	$10 - $10	1%	350
Pecans	$1 - $11	1%	1140
Sugar Beets, other than MN and ND	$0 - 12	1%	1570
Subtotal			**12,170**
Crops with Impacts less than 1% of Gross Revenue per Acre			
Alfalfa	$0 - $1	0%	9530
Almonds[3]	$7 - $35	1%	580
Apples	$12 - $51	1%	2470
Apricots	$7 - $33	1%	10
Asparagus	$6 - $20	1%	110
Canola	$2 - $3	1%	20
Celery	$0 - $0	0%	10
Cranberry	$14 - $35	<1%	300
Cucumbers	$0 - $0	0%	10
Dry Beans/Peas	$0 - $19	0%	40
Garlic	$0 - $0	0%	10
Hazelnuts	$0 - $3	<1%	40
Mint	$19	1%	290
Peaches	$8 - $27	0%	400
Pears	$5 - $37	0%	190
Peppers	$5 - $10	0%	10
Pistachios	$0 - $0	0%	10
Plums/Prunes	$7 - $33	1%	70
Sorghum (Milo)	$2	1%	270

Crop	Impact / Acre [1]	Percent of Per-Acre Gross Revenue (High Impact)	Farms Impacted [2] (Large and Small)
Soybeans	$1 - $4	1%	9610
Strawberries	$0 - $0	0%	210
Sunflowers	$0 - $1	0%	560
Sweet Corn [5]	$1 - $3	0%	300
Tobacco	$4 - $4	0%	800
Tomatoes	$7 - $7	0%	10
Walnuts	$2 - $36	0%	1160
Wheat, Spring	$0 - $1	0%	1300
Wheat, Winter	$0 - $1	0%	1090
Subtotal			**29,120**
Crops with Little Chlorpyrifos Use [6]			
Cantaloupe[7]	not estimated	-	not estimated
Potato	not estimated	-	not estimated
Pumpkins[7]	not estimated	-	not estimated
Squash[7]	not estimated	-	not estimated
Watermelons[7]	not estimated	-	not estimated
Subtotal			**-**
TOTAL			**43,430**

1 Source: EPA estimates.

2 Source: Kynetec USA (2020) for sugarbeets, sorghum and brassica crops. When there are less than 10 affected farms, the number is rounded up to 10.

3 In addition to chemical cost increases, these crops may also have some losses due to a reduction in yield or quality.

4 These crops have important regional conditions that require analysis at a regional level.

5 The number of sweet corn farms account for foliar chlorpyrifos applications only and does not account for farms that use chlorpyrifos-treated sweet corn seed, for which usage data are not available.

6 The impacts were not calculated for these crops because the percent of the crop treated (PCT) is low which indicates that there are cost-effective alternatives available and/or that the target pests are sporadic in nature or not particularly damaging.

7 The impacts were not calculated because usage data for chlorpyrifos as a seed treatment is unavailable for these crops.

The total number of farms estimated to use chlorpyrifos is 43,430 (Kynetec USA, 2020, Table 2). While there may be a few more farms using chlorpyrifos on crops for which data are not available, this figure could also be an overestimate because farms that produce multiple crops may be counted multiple times for each of the crop surveyed.

According to data from the 2017 Census of Agriculture (USDA NASS, 2019), about 86% of farms using insecticides are "small" under the SBA definition. Using that percentage as a proxy for farms that apply chlorpyrifos and applying that percentage to the number of farms using chlorpyrifos in Table 2, EPA estimates that about 37,468 small farms could be affected by the revocation of tolerances for chlorpyrifos. This is an overestimate, because farms that use insecticides may not use chlorpyrifos, and because farms that produce multiple crops can be counted more than once in the pesticide use surveys.

Table 3 presents EPA's conclusions on the SISNOSE analysis. Of the 43,430 farms using chlorpyrifos, about 29,120 farms are estimated to be using it on crops where the impacts of the tolerance revocation are expected to be less than one percent of gross revenue (Table 2). Assuming that about 86% of farms that use chlorpyrifos are small, about 25,122 small farms are estimated to incur impacts of less than one percent of the farm's total gross revenue (Table 3). Impacts of less than 1% of gross revenue are not considered 'significant' under the criteria established above.

Impacts of between 1 – 3% of gross revenues may be significant. About 10,499 small farms are estimated to incur impacts between 1% and 3% of gross revenue per acre if upper-bound loss estimates are realized; this is about 0.75% of all small farms that produce crops (Table 3). Because the estimated number of small farms affected is less than 10% of all small farms, EPA finds that a substantial number of small entities will not face impacts between 1 and 3% of gross revenue.

The estimated number of farms with impacts between 1% and 3% is clearly an overestimate if farms grow multiple crops or also produce livestock, for example. If cost estimates as a percentage of gross revenue are overestimated, then the number of farms facing that impact is an overestimate. For example, the impact from revoking tolerances is about 1% of gross revenue per acre for onions, and there are about 240 onion producers using chlorpyrifos (see Table 2). If a farm producing onions using chlorpyrifos receives half of its gross revenue from other crops not treated with chlorpyrifos, then the cost as a share of total gross revenue for the farm is only about 0.5%. If half of the onion farms had revenue from other crops sufficient to bring cost as a share of gross revenue below 1%, then 120 onion farms would actually be in the lower impact category. The same is true for other crops, and for the farms with impacts above 3%. All of the estimates of impacts are based on high-end assumptions, so estimates of the number of farms affected are also biased upward.

About 1,846 small farms may see impacts greater than 3% of per-acre gross revenue at the upper range of losses (Table 3). This represents about 0.13% of all small farms growing crops. The previous section defined the thresholds for a substantial number of small farms; when more than 1,000 small farms face impacts above 3% of gross revenues, EPA does not consider there to be a substantial number of small farms affected if the total is less than 5% of all small farms. That is the case here, as only about 0.13% of small farms potentially have impacts above 3% (Table 3).

Table 3. Estimated Impacts of Chlorpyrifos Tolerance Revocation on Small Farms

Impact as Percentage of Gross Revenue per Acre	Number of All Farms Using Chlorpyrifos[1]	Small Farms Using Chlorpyrifos[2]	Percentage of All Small Farms[3]
< 1%	29,120	25,122	1.79%
1 - 3%	12,170	10,499	0.75%
>3%	2,140	1,846	0.13%
Total	43,430	37,468	2.66%

[1] See Table 2

[2] Based 86% of farms using insecticides are small

[3]Estimated number of small farms using chlorpyrifos divided by the total number of small farms producing crops (1,407,305).

Based on the criteria set forth in the previous section, EPA certifies that the revocation of the tolerances for chlorpyrifos will not have a significant impact on a substantial number of small entities. However, EPA acknowledges that some small farms, especially those without alternatives to chlorpyrifos, could face large per-acre impacts, as shown in Table 2.

Impact on Jobs

The revocation of food tolerances for chlorpyrifos will have a negligible impact on jobs. The jobs potentially affected are those of people who apply chlorpyrifos, those who work on farms where chlorpyrifos is used, and those who are in the industry manufacturing chlorpyrifos or selling the chemical.

In the first category are people who apply pesticides, such as professional pesticide applicators. For most crops there are alternative pesticides available to substitute for chlorpyrifos, and one or more applications of alternatives will be needed to replace those of chlorpyrifos. The application of alternative pesticides will be performed by the same people who apply chlorpyrifos today. In the few cases where there are not replacements, the impact on employment is still likely to be small, because even for pesticide applicators, applying chlorpyrifos is only a small part of their overall job applying pesticides. Because farms are not expected to cease farming because of the tolerance revocation, there will be no reduction in jobs for farmers, farmworkers, or pesticide handlers. As discussed above, chlorpyrifos is typically only applied to a subset of the crops grown on a farm, and even then, not necessarily on the full acreage of those crops. In extreme cases, growers may choose to change cropping patterns, but unless they cease farming altogether and do not sell the farm to someone else, there will be farm work and pesticide applications will continue.

For registrants and people who work manufacturing, transporting and selling pesticides, other pesticides will be substituted for chlorpyrifos, and these will also need to be manufactured, transported and sold to agriculture. Without chlorpyrifos, the need for other pesticides will increase, offsetting any potential jobs losses from ceasing manufacturing of chlorpyrifos. At most, there may be a shift in employment within the pesticide industry as employment manufacturing chlorpyrifos is offset by increases in jobs making other pesticides, possibly even within the same firm.

This means the most likely effect would be a shift in employment within the pesticide industry (possibly even within the same company). Other insecticides may be more or less labor intensive than chlorpyrifos in their production, but it seems unlikely that there will be a significant change in employment given that no single chemical will replace all chlorpyrifos usage.

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Appendix: Grower Revenue

EPA used data on area cultivated and value of production from the National Agricultural Statistics Service (NASS) of USDA to calculate average gross revenue per acre. A five-year (2010 – 2014) average is used unless recent price increases indicate substantially higher revenues currently.

Crop	Acres Harvested (Avg. Annual)	Gross Revenue (Avg. Annual)	Gross Revenue (Avg. Annual $ per acre)
ALFALFA	18,375,000	$10,038,403,600	$546
ALMONDS	822,000	$5,100,158,000	$6,205
APPLES	326,730	$2,892,088,600	$8,852
APRICOTS	11,404	$45,578,800	$3,997
ASPARAGUS	25,680	$86,513,000	$3,369
BEANS/PEAS (Dry)	1,533,180	989,730,200	$646
BEANS (Snap, Bush, Pole, String)	157,464	$249,372,100	$1,584
BROCCOLI[1]	124,920	$878,913,800	$7,036
CABBAGE[1]	57,434	$401,307,200	$6,987
CANOLA	1,400,560	$469,069,600	$335
CAULIFLOWER[1]	40,976	$396,934,600	$9,687
CELERY	28,580	$376,764,000	$13,183
CHERRIES (sweet)	87,378	$786,386,200	$9,000
CHERRIES (tart)	37,070	$74,307,600	$2,005
CORN (grain)	84,655,400	$66,043,095,400	$780
COTTON	9,274,520	$6,192,680,600	$668
CRANBERRIES	39,980	$314,384,800	$7,864
CUCUMBERS (fresh market)	39,980	$191,819,200	$4,877
CUCUMBERS (processing)	39,328	$174,862,000	$2,074
GARLIC	84,324	$255,807,200	$10,514
GRAPEFRUIT	24,330	$270,440,800	$3,731
GRAPES (raisin)	72,480	$792,405,000	$3,942
GRAPES (table)	201,000	$1,200,629,600	$11,435
GRAPES (wine)	105,000	$2,887,594,600	$4,876
HAZELNUTS	592,200	$94,470,000	$3,224
LEMONS	29,300	$454,421,000	$8,268
MINT	54,960	$191,789,600	$2,080
ONIONS	92,160	$919,155,000	$6,322
ORANGES (FL)	434,460	$1,456,223,400	$3,352
ORANGES (CA)	177,444	$759,065,600	$4,278
PEACHES	83,656	$493,190,600	$5,495
PEANUTS	1,261,020	$1,269,374,000	$1,007
PEARS	51,720	$416,869,800	$8,060

Crop	Acres Harvested (Avg. Annual)	Gross Revenue (Avg. Annual)	Gross Revenue (Avg. Annual $ per acre)
PEAS (Fresh/Green/Sweet)	179,700	$138,392,200	$770
PECANS (in shell)	4,938,401	$556,737,800	$1,127
PEPPERS (bell)	45,940	$589,605,400	$12,834
PEPPERS (chile)	20,920	$163,307,000	$7,806
PISTACHIOS	179,200	$1,389,330,000	$7,753
PLUMS / PRUNES	74,800	$272,710,000	$3,646
POTATOES	1,065,580	$3,990,486,000	$3,745
PUMPKINS	49,060	$133,716,800	$2,726
SORGHUM[1]	6,104,000	$1,497,555,800	$245
SOYBEANS	77,074,800	$40,578,872,000	$526
SQUASH	41,306	$218,161,600	$5,282
STRAWBERRIES	58,551	$2,507,214,000	$42,821
SUGARBEETS[1] (Except MN and ND)	498,260	718,550,000	$1,442
SUGARBEETS[1] (MN and ND)	627,400	693,810,400	$1,106
SUNFLOWER	1,629,260	$572,820,200	$352
SWEET CORN (fresh market)	223,326	$734,824,200	$3,290
SWEET CORN (processing)	330,912	$312,695,800	$945
SWEET CORN (combined)	554,238	$1,047,520,000	$1,890
TOBACCO	346,564	$1,471,710,200	$4,247
TOMATOES (fresh market)	100,302	$1,125,381,200	$11,220
TOMATOES (processing)	283,220	$1,093,076,600	$3,859
WALNUTS	272,000	$1,520,686,000	$5,591
WATERMELON	120,988	$488,717,800	$4,039
Wheat (Spring)	13,978,000	$4,377,700,800	$313
Wheat (Winter)	32,631,000	$9,772,478,200	$299

Sources: USDA NASS, 2010 – 2014
[1] USDA NASS, 2014 – 2018

EXHIBIT E

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 18, 2020

MEMORANDUM

SUBJECT: Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)

FROM: Nikhil Mallampalli, Biologist
Rebeccah Waterworth, Biologist
Biological Analysis Branch

Derek Berwald, Economist
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Monisha Kaul, Chief
Biological Analysis Branch

Timothy Kiely, Chief
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Patricia Biggio, Chemical Review Manager
Dana Friedman, Chief
Risk Management and Implementation Branch II
Pesticide Re-evaluation Division (7508P)

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Summary

The United States Environmental Protection Agency (EPA) is currently in the process of re-evaluating the risks posed to human health from the use of chlorpyrifos. 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. 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, containerized ant and roach bait products for residential usage. On average, 8.8 million acres of agricultural crops were treated with chlorpyrifos annually from 2014 – 2018 (Kynetec, 2019).

The timing of the agency's recent regulatory work has been substantially dictated by court-ordered deadlines regarding this insecticide. In 2015, EPA issued risk assessments covering risks to human health posed by dietary exposure to chlorpyrifos. The Agency has revised these risk assessments (US EPA 2020a, 2020b) and is also evaluating the pest management benefits of chlorpyrifos in selected agricultural and non-agricultural use settings. This memorandum provides risk managers within the Agency a high-level assessment of the usage, role and pest management benefits of chlorpyrifos in agricultural settings. The benefits of chlorpyrifos in non-agricultural settings are available in another document (US EPA, 2020c).

Benefits of Chlorpyrifos to Agriculture

The total annual economic benefit of chlorpyrifos to crop production is estimated to be $19 - $130 million. These estimates are based on the additional costs of alternative pest control strategies likely to be used in the absence of chlorpyrifos or reduced revenue for some crops that do not have effective alternatives to chlorpyrifos for some pests. In some cases, effective alternatives could not be found; for those crops, the benefit of chlorpyrifos was estimated by yield or quality losses if chlorpyrifos were no longer available for use.

The high benefits estimate reflects the wide use of chlorpyrifos on many different crops. However, despite the wide use of chlorpyrifos, the majority of the benefits are concentrated on specific crops and regions that rely on chlorpyrifos without available alternatives to control pests. In particular, there are potentially high total costs for some Minnesota and North Dakota sugarbeets, soybeans (nationwide), California oranges, Southeast peaches, and apples (nationwide); the high-end total cost for each of these crops is estimated to be in excess of $7 million per year. High total costs are driven by high per-acre costs in the case of sugarbeets, orange, apple and peach, and by the extent of acres treated in the case of large field crops like soybean despite relatively low costs per acre.

When considering the benefits of chlorpyrifos, some recent developments are important to keep in mind. California is ending almost all agricultural uses of chlorpyrifos by the end of 2020 (CDPR 2019), so high benefits in crops grown in California, reflect past use, rather than benefits that will remain if these uses are still registered nationally in the future. Since 2019, several states, including California, Hawaii, New York, Maryland, and Oregon, have initiated state-level actions to phase out all or most uses of chlorpyrifos.

Chapter 1. Background

The Federal Insecticide Fungicide and Rodenticide Act (FIFRA), Section 3(g), mandates that EPA periodically review the registrations of all pesticides to ensure that they do not pose unreasonable adverse effects to human health and the environment. This periodic review is necessary in order to consider scientific advancements, changes in policy, and changes in use patterns that may alter the conditions underpinning previous registration decisions. In determining whether effects of pesticide use are unreasonable, FIFRA requires that the Agency consider the risks and benefits of any use of the pesticide.

Safety to Human Health

There are inherent risks associated with the use of pesticides, which are substances that are toxic by design. Therefore, EPA imposes requirements on the use of pesticides with the intent to avert unreasonable adverse effects to human health and the environment. However, EPA uses a more stringent standard for dietary risks, which is that food and drinking water exposure will have a reasonable certainty of no harm. The Federal Food, Drug, and Cosmetic Act (FFDCA) 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 drinking water and all non-occupational exposures (e.g., in residential settings) but does not include occupational exposures to workers.

Under the FFDCA, risks to infants and children are given special consideration. Young children and infants may face greater household exposures because of their behaviors (via combined mouthing and intense play activities) and due to age specific diets. 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)).

There are risks to human health from chlorpyrifos exposure. Chlorpyrifos residues can appear in food from crops that were treated with the pesticide, and in drinking water from spray drift or runoff from treated fields. Bystanders and farmworkers can be exposed through application to crops.

Organophosphate insecticides inhibit acetylcholinesterase (AChE), which is an enzyme essential for nervous system function. AChE helps break down the neurotransmitter acetylcholine, and it is essential to the function of the nervous system. When acetylcholinesterase is inhibited, acetylcholine builds up at nerve endings leading to overstimulation of the nervous system. The symptoms of mild acetylcholinesterase inhibition include headache, nausea, dizziness, sweating, and salivation. More severe reactions include muscle twitching and tremors, lack of coordination, vomiting, abdominal cramps, and blurred vision. Very high exposure, such as from an accident, can lead to respiratory paralysis and death (Roberts and Reigart 2016). AChE

inhibition has been the health endpoint that EPA has used in risk assessments for chlorpyrifos and setting tolerances for chlorpyrifos (US EPA, 2016).

There is also epidemiological data that reports an association between chlorpyrifos exposure and potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos (Raugh *et al.* 2006, Rauh *et al.* 2011) or organophosphate pesticide metabolites (Engel et al. 2007, Engel et al. 2011, Young et al. 2005, Eskenazi et al. 2007).

Chlorpyrifos is a widely used pesticide in agricultural settings, with an average of about five million pounds applied annually on about 8.8 million acres (Kynetec, 2019, years 2014 – 2018). There are potential exposures from residues of chlorpyrifos that remain on food when it is eaten. Runoff from agricultural applications can lead to exposure to chlorpyrifos or its metabolites from drinking water. These issues are more fully described in the risk assessment memoranda supporting the Preliminary Interim Decision (PID).

This document replaces an earlier version with incorrect per acre benefit estimates for some crops in Table 2.1-1.

Chapter 2. Estimated Benefits of Chlorpyrifos Agricultural Uses

Section 2.1 Introduction and Summary

This chapter presents the estimates of the total and per-acre benefits of chlorpyrifos in agriculture, based on the costs of alternative pest control strategies likely to be used in the absence of chlorpyrifos. In some cases, effective alternatives could not be found; for those crops the benefits were modeled with yield or quality losses if chlorpyrifos were no longer available for use. The total benefit of chlorpyrifos is estimated to be between $19 and $130 million annually. The high benefit reflects the wide use of chlorpyrifos on many different crops. However, despite the wide use of chlorpyrifos, the majority of the total benefits are concentrated on specific crops and regions that rely on chlorpyrifos without available alternatives to control pests. In particular, there are potentially high benefits for some Minnesota and North Dakota sugarbeets, soybeans nationally, California oranges, Southeast peaches, and apples nationally. The total cost for each of these crops is estimated to be above $7 million per year. High total benefits are driven by high per-acre cost of alternatives in apple and orange, a lack of alternatives leading to potential yield loss in Southeastern peach and Minnesota and North Dakota sugarbeet, and by the extent of acres treated in the case of large field crops like soybean despite relatively low benefits per acre. The large range in cost estimates is due to the differences between the high- and low-cost estimates, mostly for the aforementioned crops.

Section 2 of this chapter describes the methodology used for estimating the benefits of chlorpyrifos. The methodology follows that of previous EPA estimates of the impacts on small businesses (EPA, 2015a). Cost estimates are updated using more recent pesticide usage data, information from the USDA Office of Pest Management Policy, and information obtained through public comments on EPA's small business impact estimates (EPA, 2015a). This analysis was originally performed in 2016, using pesticide usage data from 2010-2014. More recent usage data are now available, and EPA used 2014 – 2018 data to evaluate chlorpyrifos usage in agricultural crops to see if there were significant changes that warranted further analysis. There appeared to be large changes in usage for *Brassica* and sugarbeet; both crops had significant costs in the earlier analysis, so these are revaluated in this document using more recent information. Sorghum was also re-evaluated because of chlorpyrifos use against an emerging invasive pest. Section 3.3 highlights some uncertainties and data limitations in the cost estimates for individual crops. The analysis in this chapter is based on a number of conservative assumptions which are likely to overestimate the actual impacts. For example, the analysis assumes the same pest pressure on every chlorpyrifos treated acre, and the least expensive alternatives are not always chosen as replacements. The analysis also does not account for any changes in cropping patterns and the development of new pesticides or new uses for existing pesticides to fill gaps in pest control without chlorpyrifos.

Table 2.1-1 summarizes the results of the crop-specific assessments for those crops. For most of the crops listed, EPA concludes that there are adequate alternatives to chlorpyrifos to provide control of the pests typically targeted by chlorpyrifos. However, use of alternatives may entail additional control costs to the grower. In some cases, alternatives may not be as efficacious as chlorpyrifos and yield or quality losses may occur. In addition, there do not appear to be adequate alternatives in some crops or regions (e.g., cutworms in Michigan asparagus, borers in

Michigan cherries and Southeast peaches, wireworm in Northern sugarbeets, and symphylans in Oregon strawberries), so for these uses yield losses are estimated.

Table 2.1-1. Benefits of Chlorpyrifos Tolerances, Per-acre and Total Annual Benefits.

Crop	Impact/Acre	Acres Affected	Total Annual Benefit
Alfalfa	$0 - $1	1,029,000	$0 - $1,029,000
Almond [0]	$7 - $35	144,000	$1,009,000 - $5,040,000
Apple [0]	$12 - $51	196,000	$2,346,000 - $9,971,000
Apricot [1]	$7 - $33	100	$1,000 - $4,000
Asparagus, Michigan	$0 - $450	6,000	$0 - $2,569,000
Asparagus, other states [2]	$6 - $20	8,000	$89,000 - $178,000
Beans, succulent [3]	$29	5,000	$137,000
Beans, dry	$0 - $19	6,000	$118,000
Brassica crops[7]			
Broccoli	$8 - $68	6,000	$44,000 - $374,000
Cabbage	$14 – $78	3,000	$42,000 - $234,000
Cauliflower	$11 - $90	200	$2,000 - $18,000
Celery	negligible	100	negligible
Cherry, Sweet	$3 - $65	28,000	$84,000 - $1,811,000
Cherry, Tart	$18 - $201	12,000	$292,000 - $482,000
Corn	$6 - $8	677,000	$4,060,000 - $5,414,000
Cotton, seed treatments	$0 - $9	482,000	$0 - $4,338,000
Cotton, foliar treatments	$0 - $14	126,000	$0 - $1,768,000
Cranberry	$14 - $35	12,000	$174,000 - $434,000
Fig	negligible	negligible	negligible
Garlic	negligible	200	negligible
Grapefruit	$9 - $44	22,000	$202,000 - $987,000
Grape, Raisin	$4 - $30	11,000	$331,000
Grape, Table	$7 - $130	42,000	$293,000 - $5,439,000
Grape, Wine	$4 - $91	23,000	$90,000 - $2,058,000
Hazelnut	$0 - $3	3,000	$0 - $10,000
Lemon	$10 - $290	16,000	$156,000 - $4,526,000
Mint [4]	$19	92,000	$876,000 - $2,582,000
Onion	$11 - $66	58,000	$636,000 - $3,815,000
Orange, California	$8 - $201	39,000	$310,000 - $7,795,000
Orange, Florida	$2 - $33	95,000	$190,000 - $3,134,000
Peach, Georgia and South Carolina	$12 - $430	18,000	$215,000 - $7,703,000
Peach, other states	$8 - $29	11,000	$88,000 – $297,000
Peanut [0,4]	$10	114,000	$1,143,000
Pear	$5 - $37	6,000	$30,000 - $223,000
Peas, succulent	$10 - $370	400	$4,000 - $166,000
Pecan	$1 - $11	115,000	$115,000 - $1,262,000
Pepper	$5 - $10	500	$5,000 - $14,000
Pistachio	negligible	negligible	negligible
Plum/Prune	$7 - $33	3,000	$20,000 - $96,000
Potato	negligible	400	negligible

Crop	Impact/Acre	Acres Affected	Total Annual Benefit
Sorghum[6]	$3 - $4	108,000	$324, 000 - $756,000
Soybean	$1 - $4	3,080,000	$3,080,000 - $12,321,000
Strawberry, Oregon	$6 - $7,813	600	$3,600 - $4,258,000
Strawberry, other states	$10 - $65	11,000	$105,000 - $686,000
Sugarbeet, Minnesota and North Dakota[6]	$13 - $498	60,000	$774,000 - $29,639,000
Sugarbeet, other states[6]	$10 - $13	140,000	$1,403,000 - $1,823,000
Sunflower	$0 - $1	123,000	$0 - $123,000
Sweet Corn[5]	$1 - $3	54,000	$54,000 - $163,000
Tobacco[3]	$4	37,000	$149,000
Tomato[3]	$7	2,000	$11,000
Walnut	$2 - $36	124,000	$248,000 - $4,457,000
Wheat, Spring	$0 - $1	783,000	$0 - $783,000
Wheat, Winter	$0 - $1	549,000	$0 - $549,000
Total		**8,484,000**[7]	**$19,134,000 - $129,675,000**

Sources: EPA estimates of per-acre impacts (Chapter 3.3); average acres treated at least once with chlorpyrifos based on Kynetec, 2016 and 2019 (years: 2010-2014 and 2014-2018, respectively). Figures subject to rounding.

Footnotes:

[0] Cost estimates do not account for possible yield losses.

[1] Assumes same per-acre cost as for plums/prunes.

[2] Range is from $6-10/acre, with some acres treated twice, average of 1.4 applications per affected acre (2010-2014).

[3] No range estimated. Limited data suggest only single alternative.

[4] No range estimated for per-acre cost. Limited data suggest only a single alternative. No information available on acres treated with chlorpyrifos; range is from 50-100% of the crop.

[5] Seed treatment usage data were not available for sweet corn, so the percent of the crop treated is underestimated and thus the per acre cost of revoking the chlorpyrifos tolerance may also be underestimated.

[6] Estimates of per-acre impacts are based on Kynetec (2019) usage data from 2014-2018.

[7] Estimated total acreage treated from 2014-2018 is 8.8 million acres annually. This estimate in the table is lower because it excludes some crops, is based on usage from 2010-2014 for most of the crops, and because acreage for this table is based on estimates of percent crop treated and harvested acreage (see Section 2.2).

The estimated total cost has a wide range, between $19 and $130 million per year. The midpoint of this range is $74 million. The extremes will have a low probability of occurrence, since all affected acres would have to incur either the lowest or the highest impact. To better characterize the likely benefits for chlorpyrifos, EPA considers three factors.

First, we consider the range of costs for those sites that contribute the most to the total national cost. The average cost for crops with the greatest affected area, such as soybean (3.1 million acres treated with chlorpyrifos), alfalfa (1.0 million acres treated with chlorpyrifos), and cotton (608,000 acres treated with chlorpyrifos), may tend to be at the lower end of the range, since these sites have numerous alternatives from which a grower could choose to replace chlorpyrifos. The estimated range of costs for these crops is relatively small. In contrast, the average cost for crops such as vegetables and fruit in specific areas with important pest problems, is likely to be closer to the upper end of the estimated ranges. For several crops, a range of estimates was not created because of limited alternatives to chlorpyrifos. Some of the highest per-acre crop costs are for *Brassica* crops, which are based on yield loss estimates and information from the original analysis in 2016. This information indicated that there were no feasible registered alternatives,

but more recent data suggests growers have largely stopped using chlorpyrifos, indicating the presence of feasible alternatives, as discussed below.

Second, there are several sites for which alternatives may not provide the same level of pest control as chlorpyrifos, but for which estimates of yield loss are not available. Almonds and peanuts are examples, in that estimates of damage caused by borers are not available. Per-acre costs may exceed the upper bound estimate shown in Table 2.1-1, at least on some acres. This factor suggests that total costs would tend toward the upper end of the range.

Finally, another source of variation in the estimated total benefits of chlorpyrifos tolerances is the variability in the number of affected acres. Pest pressure varies from year to year which leads to variation in the number of acres that are treated. Further, as with any input to production, usage may vary according to the cost of the input and the value of the output. Variation in acres treated within individual crops could have substantial impacts on variability in total cost. If, in a given year, there is particularly high pest pressure in a crop with high per-acre impacts, total cost is likely to be relatively high. The converse would lead to a relatively lower total cost. This factor suggests that the range in cost may be wider than shown in Table 2.1-1 in some years, but does not suggest where, over a period of years, costs may fall within the range.

Overall, consideration of these three factors leads EPA to conclude that the total benefits of chlorpyrifos is likely to fall near the midpoint of the range.

Section 2.2 Methodology

To estimate the benefits of chlorpyrifos, EPA has to determine the difference in per acre cost of pest control with and without chlorpyrifos for each crop, multiply that by the acres affected if chlorpyrifos were not available, and sum across crops to find a total. In the equation below, TB is the total benefit of chlorpyrifos, b_i is the estimated per-acre benefit of chlorpyrifos for crop i, and A_i is the average acres in crop i treated with chlorpyrifos:

$$TB = \sum_i b_i \cdot A_i$$

The variable b_i, which we estimate in this chapter for crops treated with chlorpyrifos, should be interpreted as the average per acre benefit of chlorpyrifos for crop i. Multiplying b_i by the average acreage treated with chlorpyrifos in crop i yields the expected benefit for crop i.

The benefits of chlorpyrifos are the difference in per acre cost of production using the identified alternative, plus yield losses if any. To estimate the benefits for each use site (b_i,), we compare the baseline situation using the per acre cost of production using chlorpyrifos, to a situation where the producer of the crop uses the next best available control strategy, which may mean there are additional pesticide costs or possible yield losses.

There are several steps to estimate of the components of the total benefit equation. First, we identify the acreage treated with chlorpyrifos for each crop to estimate A_i. The second major piece is to estimate b_i. That involves several steps. First, identify the pests targeted with chlorpyrifos in those crops, and then identify reasonable alternative control strategies using

registered alternatives to chlorpyrifos, if they exist. After the target pests and alternative control strategies are determined, we estimate the per acre cost of pest control with and without chlorpyrifos; the difference is the per acre benefit of chlorpyrifos, b_i. In most cases, a range of cost estimates are used. The last step is to multiply the per acre incremental benefit for each crop by the acres treated with chlorpyrifos to estimate a total incremental benefit per crop, which are then summed for a total incremental benefit. These estimates represent annual benefits.

Estimating Acreage Treated with Chlorpyrifos

Chlorpyrifos is registered on many crops, but its importance, and therefore the magnitude of impacts, will vary according to the pests that might damage the crop and the registered alternatives available for their control. The percent of a crop that is treated (PCT) can often be an indicator of the importance of a chemical like chlorpyrifos because it is applied at the discretion of the farmer who often is able to scout for the presence of pests before deciding whether to make an application. In particular, low PCT of a chemical often indicates that cost-effective alternatives are available or that pests controlled by the chemical are sporadic or not very damaging and, therefore, the costs in the absence of chlorpyrifos will be negligible.

Market research data from Kynetec (2016, 2019) used for estimating acreage and cost are collected and sold by a private market research firm for the years 1998-2018. Data are collected on pesticide use for about 60 crops by annual surveys of agricultural pesticide users in the continental United States. The survey methodology provides statistically valid results at the state level. To develop the market research data, growers are surveyed about pesticide use on the crops they grow, and they can identify up to three pests they are targeting with a pesticide treatment. To estimate the acres affected by a change to chlorpyrifos registration, we used Market Research Data average number of acres treated from 2010 – 2014 or 2014 - 2018 in the states surveyed divided by the acres grown in those states to estimate the PCT. This PCT is used to extrapolate total treated acreage in the whole country, by multiplying the PCT by national acres harvested reported by the USDA National Agricultural Statistics Survey (Table 2.2-1). This analysis was originally performed using market research data (Kynetec, 2016) for the years 2010 – 2014, but was updated for three crop crops (*Brassica*, sugarbeets, and sorghum) using data (Kynetec, 2019) years from 2014 – 2018 when that data became available. These crops appeared to have significant differences in chlorpyrifos use patterns, and *Brassica* and sugarbeets were also significant contributors to the original high benefit estimates for chlorpyrifos.

Table 2.2-1. Percent Crop Treated with Chlorpyrifos and Acres Harvested.

Crop	Acres Harvested	Percent Treated with Chlorpyrifos	Acres Treated with Chlorpyrifos
Alfalfa	18,375,000	6%	1,029,000
Almond	822,000	18%	144,000
Apple	327,000	60%	196,000
Apricot	11,000	<1%	100
Asparagus, Michigan	10,000	60%	6,000
Asparagus, other states	16,000	50%	8,000
Beans, succulent	269,000	2%	5,000

Crop	Acres Harvested	Percent Treated with Chlorpyrifos	Acres Treated with Chlorpyrifos
Beans, dry	1,533,000	<1%	6,000
Brassica crops			
Broccoli	125,000	4%	6,000
Cabbage	57,000	5%	3,000
Cauliflower	41,000	<1%	200
Celery	29,000	<1%	<100
Cherry, Sweet	87,000	30%	26,000
Cherry, Tart	37,000	32%	12,000
Corn	84,700,000	1%	677,000
Cotton, seed treatment	9,270,000	5%	482,000
Cotton, foliar treatment	9,270,000	1%	126,000
Cranberry	40,000	31%	12,000
Fig	8,000	<1%	<100
Garlic	24,000	1%	200
Grapefruit	73,000	31%	22,000
Grape, Raisin	201,000	6%	11,000
Grape, Table	105,000	40%	42,800
Grape, Wine	592,000	4%	23,000
Hazelnut	29,000	11%	3,000
Lemon	55,000	28%	16,000
Mint[1]	92,000	50-100%	46,000-92,000
Onion	145,000	40%	58,000
Orange, California	177,000	22%	39,000
Orange, Florida	434,000	22%	95,000
Peach, Georgia and South Carolina	26,000	70%	18,000
Peach, other states	84,000	13%	11,000
Peanut	1,260,000	9%	114,000
Pear	52,000	12%	6,000
Peas, succulent	179,000	<1%	400
Pecan	494,000	23%	115,000
Pepper	67,000	1%	500
Pistachio	179,000	<1%	300
Plum/Prune	75,000	4%	3,000
Potato	1,070,000	<1%	400
Sorghum	6,104,000	2%	108,000
Soybean	77,100,000	4%	3,080,000
Strawberry, Oregon	1,900	32%	600
Strawberry, other states	57,000	19%	11,000
Sugarbeet, Minnesota and North Dakota	627,000	28%	140,000
Sugarbeet, other states	498,000	9%	60,000
Sunflower	1,630,000	8%	123,000
Sweet Corn[2]	554,000	10%	54,000

Crop	Acres Harvested	Percent Treated with Chlorpyrifos	Acres Treated with Chlorpyrifos
Tobacco	347,000	11%	37,000
Tomato	372,000	<1%	2,000
Walnut	272,000	46%	124,000
Wheat, Spring	14,000,000	6%	783,000
Wheat, Winter	32,600,000	2%	549,000
Total			**8,484,000**[3]

Sources: USDA NASS, 2010-2014; Kynetec, 2016 (years 2010-2014). For *Brassica*, sorghum and sugarbeet, USDA NASS, 2014-2018; Kynetec, 2019, (2014-2018). Figures are rounded.

Footnotes:

[1] No data were available for percent treated. A range of 50 – 100% is used to avoid an underestimate.

[2] Percent treated and acres treated with chlorpyrifos do not include use of seed treated with chlorpyrifos.

[3] Estimated total acreage treated from 2014-2018 is 8.8 million acres annually. This estimate in the table is lower because it excludes some crops, is based on usage from 2010-2014 for most of the crops, and because acreage for this table is based on estimates of percent crop treated and harvested acreage (see Section 2.2).

In addition to the crops listed in Table 2.2-1, there are other crops that have tolerances for chlorpyrifos. These crops include bananas, cucurbits (cantaloupe, cucumber, pumpkin, squash, and watermelon), rutabaga, sweet potato, and turnips. These crops are relatively small-acreage crops and would typically be grown in combination with other, similar crops, e.g., vegetable growers, fruit and nut growers. The benefits associated with chlorpyrifos are not estimated for these crops, so they are not included in the total.

Estimating the Difference in Cost for Chlorpyrifos Alternatives

EPA identified the primary pests targeted by chlorpyrifos through a review of the chlorpyrifos labels and from private pesticide market research data consisting of the results of marketing surveys of growers (Kynetec 2016, 2019). Growers of about 60 crops are surveyed about pesticide use on the crops they grow, and they are asked to identify the pests they are targeting with a pesticide treatment. The data were queried to identify the major target pests for chlorpyrifos applications (Kynetec 2016, 2019).

EPA identified likely alternatives to the use of chlorpyrifos using biological and economic considerations, which are based on market research data on chemicals targeting the same pests as chlorpyrifos and verified by state extension service pest management recommendations to ensure that they are effective. In some cases, possible alternatives are less expensive than chlorpyrifos, but EPA does not consider these alternatives, at least in isolation. This is based on the assumption that if a less expensive product works as well as chlorpyrifos, the grower would use it. Therefore, it is likely that a less expensive product will not be as efficacious or not used for another reason. In addition, EPA only considered currently registered alternatives to chlorpyrifos. However, existing chemicals can be registered on additional crops and new products can be developed. As a result, estimated impacts to growers may decrease over time.

Some growers, particularly those producing for export market, may be constrained in the choice of alternatives to chlorpyrifos, because maximum residue levels (MRLs) allowed for export crops may not be established for particular chemicals in key international markets, or are set at

levels not feasible to achieve. This could be more of an issue for newer chemistries in small acreage fruit and nut crops; establishment of MRLs for minor uses may take time. As a result, some growers may have to use more costly control methods than those identified in EPA's assessment below or forego an export market and potentially receive a lower domestic price for their produce.

For some crops, public comments or the USDA identified pest problems that only applied to specific regions of the country, such as strawberry in Oregon, peaches in the Southeast, and sugarbeets in specific counties in Minnesota and North Dakota. For these crops, additional analysis on costs for those regions is included in the crop-specific cost estimates presented in Section 2.3.

Estimating the Cost of Control with Chlorpyrifos and Alternatives

Market research data provide cost estimates for pesticide applications by crop and pest. Variation in the costs of a pesticide occur due to differences in application rates required for control of pests in each crop. The incremental cost of the rule is estimated as the difference in cost between a chlorpyrifos pest control program and alternative strategies. Differences in insecticide costs were estimated on a per-acre basis. In situations where crops have no alternatives or less efficacious alternatives to chlorpyrifos, yield and/or quality losses were also considered. For some crops, such as cranberry and mint, market research data are not available, and cost and usage estimates were derived from information submitted by the industry or by extrapolating cost information from other crops.

In developing scenarios for the use of alternatives, EPA generally assumes that all target pests are present on each acre treated with chlorpyrifos. Therefore, estimates of additional costs may be based on the use of multiple alternatives to control multiple pests. Data on acres treated by pest, however, indicate that problems with many pests are limited to a portion of the area treated with chlorpyrifos. Thus, estimates involving the use of multiple chemicals to replace a single chlorpyrifos treatment may significantly overestimate impacts. In some cases, such as Michigan asparagus, growers may see yield or quality losses without the ability to use chlorpyrifos. When information on those losses are available, we include yield losses in our estimates of benefits, in some cases extrapolating from one crop to similar crops. In the case of some crops, almonds, for example, there is not sufficient information to estimate quality or yield losses quantitatively.

Section 2.3 Uncertainties

The results of this analysis are subject to uncertainty. This section provides a brief description of the major sources of uncertainty, as well as simplifying assumptions and their implications.

Target Pests

For most crops, EPA identified the primary target pests based on responses of growers to market surveys on the use of pesticides. However, those responses may not fully capture the suite of pests controlled by a broad-spectrum insecticide like chlorpyrifos. Past analyses (*e.g.*, Zalom *et al*. 1999) have shown that broad-spectrum materials such as chlorpyrifos can serve a 'keystone' role in some IPM programs. Removal of such broad-spectrum insecticides from pest

management programs can result in unexpected outbreaks of previously minor pests or even the emergence of new pests. As a result, additional control costs could manifest themselves in the short term or develop over time.

Regional Differences

Most of EPA's estimates are national in scope. However, pests and pest pressure may differ across agroclimatic conditions. As a result, the assessment may be missing or underestimating losses in one or more regions of the United States due to differences in target pests and appropriate alternatives. For some crops, EPA was provided with information from crop experts that indicated that regional conditions or pest problems warranted further examination. Additional analysis on regional impacts is included for these crops, which include Michigan asparagus and cherries, Oregon strawberries, Minnesota and North Dakota sugarbeets, and Southeastern peaches. For these areas, the costs were higher than the national estimates for the same crops, but the national estimates would overstate costs in areas with low pest pressure.

New Methods of Insect Control

In this analysis, EPA only considered currently registered alternatives to chlorpyrifos. However, as pesticide markets open through the loss of a control option or new pests emerge, existing chemicals are registered on additional crops or new products are developed. EPA also assumed that growers who use chlorpyrifos will replace it with other insecticides, instead of non-chemical management tactics such as biological control with insect natural enemies. However, some growers may find these approaches to be cost effective over time as understanding of their optimal deployment improves. As a result, estimated impacts to growers may decrease over time.

Intensity of Pest Pressure

In developing scenarios for the use of alternatives, EPA has generally assumed that all target pests are present on all acres treated with chlorpyrifos. Therefore, estimates of additional costs are based on the use of multiple alternatives. Data on acres treated by pest, however, indicate that situations with many pests are limited to a proportion of acres treated with chlorpyrifos. Thus, estimates involving the use of multiple chemicals to replace a single chlorpyrifos treatment may significantly overestimate impacts.

Emerging Pest and Resistance Problems

Most of EPA's cost estimates are based on reported use of chlorpyrifos against specific pests using market research data (Kynetec, 2016) from 2010 – 2014. However, if growers of a crop face relatively new pests or pest problems that are growing in intensity, using historical data on chlorpyrifos use will underestimate any estimate of the cost of alternatives or yield loss at an aggregate level. This may be a particular problem with trunk and limb-boring insects in tree crops, for example, where the potential damage is severe. Currently, most of the affected acreage is in the Southeast, but the pest problem could spread to other areas in the future. In addition, in some crop systems that have only one or two pesticide modes of action registered, the loss of chlorpyrifos may accelerate the evolution of pest resistance against whatever alternative modes of action remain. This could be a result of growers no longer being able to rotate pesticides with different modes of action during seasonal pest management, which is a fundamental resistance management strategy. If resistance develops, unless additional modes of action are registered, the cost impact of chlorpyrifos loss will be higher.

Export Restrictions

EPA identified alternatives to the use of chlorpyrifos based on state recommendations and/or common use as reported in market surveys. However, as mentioned above, some growers may be constrained in the choice of alternatives, particularly those targeting the export market because maximum residue levels (MRLs) may not be established for particular chemicals in key international markets. This could be an issue, especially for small acreage fruit and nut crops for newer chemistries because establishment of MRLs for minor uses may take time. International MRL harmonization is a focus of several ongoing efforts between the Agency and international trade partners but in the short term some growers may have to use more costly control methods than identified in EPA's assessments. However, since EPA frequently based the assessment of impacts on the most expensive likely alternative, any underestimation of costs may be small. Further, small entities may be less likely to target the export market than large growers and those that do target the export market may have higher gross revenue per acre than the average small grower.

Data Limitations

Costs are not estimated for some uses of chlorpyrifos due to data limitations. In particular, there are registered uses of chlorpyrifos as seed treatments that may be important for some crops. However, the extent of impact from loss of chlorpyrifos seed treatments remains uncertain at this time because usage information for seed treatments is not available for chlorpyrifos and alternatives. As a result, this analysis may underestimate the acreage affected by any changes to the registration of chlorpyrifos. Any such underestimation is likely small, however, as the crops for which data are lacking are generally small acreage.

Section 2.4 Crop Benefit Estimates

This section reports estimates of the per-acre benefits of chlorpyrifos for individual crops. Crops are presented in alphabetical order. In most cases, the estimates are made at the national level, but where EPA has found important variation of pests or crop conditions in specific areas, estimates are made by state or region. For some crops, where alternatives may be substantially more costly than chlorpyrifos or there may be a yield and/or quality loss with the use of alternatives to chlorpyrifos, the benefits of chlopyrifos may be quite large. The majority of the estimates are based on reported use of chlorpyrifos against specific pests using market research data from 2010 – 2014, which were the most recently available when the majority of this analysis was initially conducted. More recent usage data (2014 – 2018) were reviewed and suggest that for the majority of crops the situation has not changed and therefore the analysis was not revised. For sugarbeets, sorghum and the *Brassica* crops, the more recent usage data suggests that the situation may have changed, so these crops are reevaluated for that time period below.

Alfalfa

Chlorpyrifos use on alfalfa is primarily targeted at the alfalfa weevil. Although nationally, use of alfalfa is low in terms of percent crop treated, in some states like Kansas, Colorado and

California, growers appear to rely on chlorpyrifos somewhat more heavily. The alternatives consist of synthetic pyrethroids (Table 2.4-1).

Table 2.4-1. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Alfalfa.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Alfalfa	$5	Alfalfa Weevil	Zeta cypermethrin	$4	($1)
			Cyfluthrin	$4	($1)
			Lambda-cyhalothrin[1]	$5	<$1

Source: Kynetec 2016 (years 2010-2014)
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

The alternative scenario to chlorpyrifos ($5/acre) consists of one application of lambda-cyhalothrin ($5/acre) to control alfalfa weevil. This alternative is essentially the same cost as chlorpyrifos, implying costs to the farmer of less than $1 per acre. Gross revenue is $546 per acre, so additional costs are less than 0.2% of gross revenue.

According to market research data (Kynetec 2016; years 2010-2014), just over one million acres of alfalfa are treated annually with chlorpyrifos. With alternatives essentially the same cost or at most one dollar more, EPA estimates the total benefit of chlorpyrifos for alfalfa to be up to one million dollars per year.

Almonds

Chlorpyrifos use on almonds is limited to three applications per year, including dormant/delayed dormant sprays, in-season foliar sprays, and trunk sprays targeting borers. Usage data, however, indicate that growers average 1.25 applications per year. While usage is significant against navel orangeworm and peach twig borer (Kynetec 2016; years 2010-2014), this is due in part to the prevalence of the pests. Numerous alternatives are available for control of these two pests and chlorpyrifos does not rank that highly, relative to these alternatives in terms of acres treated and per university extension recommendations (UC IPM 2014a, b). Substitution of alternatives would be one-for-one with chlorpyrifos.

Emerging pests of concern are leaffooted bugs (at least three species), which have been specifically identified by the almond industry in recent years (Almond Board of California 2015, UC IPM 2012a, Goodhue *et al.* 2019). While the overall average chlorpyrifos usage targeting this pest has been relatively low since 2009 (though sporadically higher in prior years), there was a sharp increase in 2013, and future usage data is likely to reflect a pest of emerging importance. The industry has identified chlorpyrifos as a very important chemical and cites clothianidin as the main effective alternative (Almond Board of California 2015), but usage data indicate that pyrethroids are also being used (Table 2.4-2). At least one recent research article indicates that pyrethroids are the main set of insecticides now used for leaffooted bugs (Daane *et al.* 2019). Extension recommendations also list bifenthrin and esfenvalerate (both pyrethroids) as chlorpyrifos alternatives, but caution against their disruption of beneficial insect populations (UC IPM, 2012a). Because the suitability of the alternatives to chlorpyrifos is questionable, there is

the potential for yield/quality losses as well under high pest population pressure in the absence of chlorpyrifos availability. Loss of chlorpyrifos as a leaffooted bug control option may also increase the risk of resistance to pyrethroids developing in pest populations as growers over-use this class of insecticides. If pyrethroids begin to lose effectiveness yield/quality losses would become inevitable.

Table 2.4-2. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Almonds.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Almonds	$17	Navel Orangeworm	Bifenthrin[1]	$12	($5)
			Methoxyfenozide	$24	$7
			Chlorantraniliprole	$31	$14
			Esfenvalerate	$6	($11)
			Lambda-cyhalothrin	$6	($11)
		Peach Twig Borer	Methoxyfenozide	$24	$7
			Esfenvalerate	$6	($11)
			Diflubenzuron	$20	$3
			Lambda-cyhalothrin	$6	($11)
			Chlorantraniliprole	$31	$14
			Bifenthrin[1]	$12	($5)
		Leaffooted Bug	Bifenthrin[1]	$9	($5)
			Esfenvalerate	$6	($11)
			Clothianidin[1]	$16	($1)

Source: Kynetec 2016, 2010-2014.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Assuming all three pests could be controlled simultaneously with one application of chlorpyrifos ($17/acre), a high-cost alternative scenario would consist of one application of bifenthrin ($12/acre) to control navel orangeworm, one application of methoxyfenozide ($24/acre) to control peach twig borer, and one application of clothianidin ($16/acre) to control leaffooted bug. Together, this strategy would cost approximately $52/acre (total is not exact due to rounding of some costs). This is about $35/acre more than one single application of chlorpyrifos. Average gross revenue is about $6,205 per acre (see Appendix A), implying impacts of about 0.6% of gross revenue per acre, for a total benefit of $5.0 million.

In the absence of the leaffooted bug, growers might apply methoxyfenozide for control of either or both the navel orangeworm and peach twig borer with additional insecticide costs of about $7-14/acre, depending on the number of applications. Methoxyfenozide is highly effective against Lepidoptera (caterpillar pests) but has little to no impact on other insect taxa.

As discussed above, using the alternatives (particularly in regard to controlling leaffooted bugs) might result in yield/quality losses, leading to impacts in addition to chemical cost increase. As a result, almond growers might face additional lost revenue from lower yield or reduced price received for lower quality.

About 144,000 acres of almond are treated with chlorpyrifos each year, on average (Kynetec 2016; years 2010-2014). Additional insecticide costs are estimated to range from $7 to $35 per

acre, implying total annual benefits of between $1.0 and $5.0 million, not considering possible yield losses.

Apples

Chlorpyrifos use on apples is limited to one application per year. For airblast applications, only a dormant or delayed dormant spray can be made to the canopy. For post-bloom applications, only trunk applications (to the lower 4 feet of trunk, not to contact fruit or foliage) are permitted. Such trunk applications would be used to target dogwood borers and black stem borers. These are mainly pests in the eastern United States and especially on young or newly planted trees. This is notable, because even though the available usage data shows little usage against borers (Kynetec 2016; years 2010-2014), most applications would only be made to very young trees that have many years of fruit productivity ahead of them. Therefore, while borers contribute little to chlorpyrifos usage in terms of market share or percent of crop treated, the control of borers is important in apple production, and chlorpyrifos is an important tool for this pest. The main alternatives are listed below in Table 2.4-3 and include hand-applied mating disruption dispensers to control dogwood borers. If mating disruption is not effective, as is the case with borers in other tree fruit, then there may be additional yield losses without chlorpyrifos. A comment from Dr. D. Breth of Cornell University stated, in part:

> "In 2013, infestations of [black stem borer] were seen for the first time in commercial apple trees, in multiple western NY sites. In these sites, growers were seeing 30% of trees in parts of their orchards collapsing. To date, at least 30 additional infestation sites have been documented, extending as far as to Long Island." (USDA OPMP, 2017).

While the description shows the seriousness of this pest problem, it does not have enough description of likely affected acreage to allow a detailed economic impact analysis.

In addition to use against the borer pests, pre-bloom dormant or delayed dormant applications on apples would typically target rosy apple aphids, San Jose scale, and overwintering pests including leafrollers, plum curculio, and codling moth. Control of leafrollers, plum curculio, and codling moth is mostly incidental, and growers are unlikely to target these pests specifically during the dormant or delayed-dormant period, but rather, would normally target control tactics for the petal-fall stage, and subsequent foliar sprays. Therefore, EPA does not examine likely alternatives for these pests, since such applications would still be made with or without the availability of chlorpyrifos during the early season.

While petroleum oil is listed as an alternative with a high percentage of crop treated for rosy aphids and San Jose scale, oil is often not an efficacious stand-alone tactic. IPM recommendations call for applications of oil with an insecticide during the dormant/delayed dormant period to target susceptible stages. If this control measure fails for rosy apple aphids, neonicotinoid applications at petal fall can be made to target them (PSU, 2013). For San Jose scale, growers may resort to trying to control the 'crawler' stage later in the growing season using spirotetramat, pyriproxyfen, or pyrethroids (PSU, 2013).

For control of rosy apple aphid and San Jose scale, the alternative active ingredients to chlorpyrifos are projected to substitute one for one with chlorpyrifos. Timing would differ (i.e., chlorpyrifos would go on at delayed dormant, whereas the alternatives would be used at petal

fall, targeting different stages of the same pest), but in either case, only one application would be necessary for season-long control. Efficacy is expected to be similar.

As mentioned above, chlorpyrifos use on apples is limited to one application per year. Growers can use it to control borers as a trunk application or the other pests pre-bloom. For the latter situation, a high-cost alternative strategy would be that chlorpyrifos ($14/acre) is replaced by one application of imidacloprid ($6/acre) to control rosy apple aphid/aphid, one application of a tank mix of petroleum oil ($15/acre) and pyriproxyfen ($38) to control San Jose scale/scale (Table 2.4-3). The total cost of the alternative regime is estimated to be $63/acre, which is about $49/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). This is likely to overestimate the cost because chlorpyrifos is already commonly tank-mixed with petroleum oil, but for this analysis it is assumed that chlorpyrifos is applied alone. A low-cost scenario would be an application of acetamiprid to control both pests, with incremental insecticides costs of about $12/acre. For borers, one application of chlorpyrifos being replaced by an application of mating disruption ($65/acre) to control borers, which is about $51/acre more expensive than chlorpyrifos ($14/acre). Average gross revenue is about $8,852 per acre (Appendix A), implying impacts of as much as 0.6% of gross revenue per acre in either scenario. Given an average of 196,000 acres treated annually with chlorpyrifos, total benefits for apples are estimated to range from $2.3 to $10.0 million per year. This may understate benefits if mating disruption cannot control borer pests and if the affected acreage and damage from borers increases over time. Based on Market Research Data from 2010 – 2014, there is little use of chlorpyrifos targeting borers in apples.

Table 2.4-3. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Apples.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Apples	$14	Rosy Apple Aphid/Aphid	Petroleum Oil	$15	$1
			Acetamiprid	$26	$12
			Imidacloprid [1]	$6	($8)
			Lambda-Cyhalothrin	$5	($9)
			Spirotetramat	$46	$32
			Thiamethoxam	$11	($3)
			Esfenvalerate	$5	($9)
		San Jose Scale/Scale	Petroleum Oil [1]	$15	$1
			Pyriproxyfen [1]	$38	$14
			Spirotetramat	$46	$32
			Acetamiprid	$26	$12
			Lambda- Cyhalothrin	$5	($9)
			Imidacloprid	$6	($8)
		Borers/ Dogwood Borers	Mating Disruption [1]	$65	$51

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the upper range of cost of control in the absence of chlorpyrifos.

Asparagus

The major pests targeted by chlorpyrifos in asparagus production are shown in Table 2.4-4. Chlorpyrifos labels allow one pre-harvest application and up to two post-harvest ("fern stage") applications per year in this crop. Based on market research data chlorpyrifos is applied 1.4 times per year, on average, to asparagus. Applications are mainly for control of the asparagus aphid in the western U.S., while in Michigan the primary pests are cutworms and asparagus beetle.

Among various aphid pests of asparagus is the European asparagus aphid. While this insect occurs throughout the United States, it appears to be a consistent problem mainly in states west of the Rocky Mountains (Natwick *et al.* 2012, USDA 2003a). According to the University of California (UC), the asparagus aphid causes damage to the plant mainly because its saliva contains toxins that cause distorted growth in the subsequent year that in turn reduces yield. In addition, heavy infestation produces honeydew and may lead to secondary infestation with ants. Major crop damage would occur during this perennial crop's second year (Natwick *et al.* 2012).

Chlorpyrifos is at the top of the University of California's list of insecticides useful in an integrated pest management (IPM) program for the asparagus aphid (Natwick *et al.* 2012), and in California it has been the most-used insecticide for this pest (Kynetec 2016; years 2010 - 2014). Based on University of California recommendations, proprietary pesticide usage data, and EPA's professional judgement, likely alternatives for chlorpyrifos use against this pest would be dimethoate. Dimethoate is a systemic organophosphate (OPs) and thus probably more attractive options than other alternatives for growers (regardless of which region/state is considered). EPA assumes that yield losses with these materials will be unlikely.

The asparagus beetle refers to either of two species, the asparagus beetle or the spotted asparagus beetle. (Natwick *et al.* 2012, USDA 1999a, 2003a). Injury to the plant is by direct feeding on shoot tips; damage is most critical in young stands of plants. For these pests, any one of the leading alternatives (identified by proprietary pesticide usage data and listed in Table 2.4-4) should work as a one-to-one replacement for chlorpyrifos, with no significant changes in yield or quality loss.

Cutworms (several species) damage young asparagus spears as they emerge from the soil surface (USDA 2000b, Natwick *et al.* 2012). Damage often occurs in the spring. Data show some use of carbaryl and permethrin. However, the 2002 Pest Management strategic plan for Michigan asparagus indicated that neither provide control equivalent to chlorpyrifos, and permethrin can fail under some conditions, such as hot weather (USDA 2000b).

Table 2.4-4 shows the difference in cost between the alternatives and chlorpyrifos for the target pests. Use of acetamiprid to control the asparagus aphid would lead to an increase in pesticide costs of $11 per acre, up to $22 per acre if two applications were needed. Average gross revenue is about $3,369 per acre, implying impacts of less than 0.5% of gross revenue per acre. The affected acreage is about 8,100 acres outside Michigan, for an annual benefit of $89,000 to $178,000.

Table 2.4-4. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Asparagus.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Asparagus, other than Michigan	$9	Asparagus Aphid	Acetamiprid[1]	$20	$11
			Dimethoate	$6	($3)
			Malathion	$7	($2)
Asparagus, Michigan	$7	Cutworms	None	25% yield loss	
		Asparagus Beetle	Carbaryl	$7	<$1

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

In Michigan, carbaryl is by far the leading insecticide for the asparagus beetle and is approximately the same cost as chlorpyrifos. Industry experts who commented on the tolerance revocation petition (Bakker, 2016) estimate that yields would be 25% lower with the use of carbaryl or permethrin than with chlorpyrifos. Gross revenue for Michigan asparagus averages $1,800 per acre from 2010 – 2014 (USDA, 2016a), so a 25% yield loss is equivalent to $450 per acre. Costs, therefore, could range from near zero for control of the asparagus beetle to $450 per acre. An average 5,700 acres of asparagus are treated with chlorpyrifos in Michigan (Kynetec 2016; years 2010-2014), so total costs, in terms of lost production, could be as much as $2.6 million per year.

The total benefit of chlorpyrifos or asparagus for the country as a whole is estimated to be $48,500 to $2.7 million per year.

Brassica: broccoli, cabbage, cauliflower

The analysis for broccoli, cabbage and cauliflower was updated more recently than other crops, using usage data from 2014-2018. At the time the original analysis was done, there was substantial use of chlorpyrifos in these crops, but more recent usage data has shown a significant decline in use. Chlorpyrifos applications primarily target cabbage root maggots in *Brassica* crops (Kynetec 2019; years 2014-2018), with over 95% of the chlorpyrifos pounds applied in broccoli and cauliflower and over 70% of the pounds applied in cabbage are targeting root maggots. These pests are in the soil, feed on the roots, and require a soil insecticide application for control. Young plants are more susceptible to damage. For *Brassica* vegetables, it appears that growers can use a diamide insecticide such as cyantraniliprole, the pyrethroid bifenthrin or the neonicotinoid clothianidin to successfully control these pests (UF 2018, Shimat and Zarate 2015).

Table 2.4-5 shows the primary target pest for chlorpyrifos in *Brassica* crops as well as potential alternatives and the difference in cost between the alternatives and chlorpyrifos.

Table 2.4-5. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, *Brassica* crops.

Crop	Cost of Chlorpyrifos ($/Acre)	Target Pest	Alternatives to Chlorpyrifos	Cost of Alternatives	Difference in Cost ($/Acre)
Broccoli	$29	Cabbage Root Maggot	Clothianidin	$21	$8
			Cyantraniliprole[1]	$97	$68
			Bifenthrin	$6	($23)
Cabbage	$12	Cabbage Root Maggot	Clothianidin	$26	$14
			Cyantraniliprole[1]	$90	$78
			Bifenthrin	$4	($8)
Cauliflower	$10	Cabbage Root Maggot	Clothianidin	$21	$11
			Cyantraniliprole[1]	$100	$90
			Bifenthrin	$9	($1)

Source: Kynetec 2019; years 2014-2018. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

The alternative scenario to chlorpyrifos for broccoli, cabbage and cauliflower consists of one application of cyantraniliprole. For broccoli, the baseline treatment of chlorpyrifos costs $29 per acre, and the replacement cyantraniliprole cost $97 per acre, resulting in an increased cost of control of $68 per acre (Table 2.4-5). Average gross revenue in broccoli is about $7,000 per acre, so the increase in cost is just under 1% of gross revenue. According to the available usage data (Kynetec 2019; years 2014-2018), about 5,100 acres of broccoli are treated with chlorpyrifos annually to control root maggots, so the benefit of chlorpyrifos is about $347,000 per year in broccoli.

For cauliflower, the baseline treatment of chlorpyrifos costs $10 per acre, and the alternative scenario of cyantraniliprole costs about $100 per acre, $90 more expensive than the baseline (Table 2.4-5). Average gross revenue in cauliflower is about $9,700 per acre, implying benefits of under 1% of gross revenue per acre. According to the available usage data (Kynetec 2019; years 2014-2018), less than 200 cauliflower acres are treated with chlorpyrifos annually, so the benefit of chlorpyrifos over alternatives is about $9,000 per year.

For cabbage, the baseline treatment of chlorpyrifos costs $12 per acre, and the alternative scenario of cyantraniliprole costs about $90, $78 per acre more expensive than the baseline chlorpyrifos treatment (Table 2.4-5). Average gross revenue in cabbage is about $7,000 per acre, implying benefits of about 1% of gross revenue per acre. According to the available usage data (Kynetec 2019; years 2014-2018), about 2,100 acres are treated with chlorpyrifos annually, so the estimated benefit of chlorpyrifos is about $164,000 per year.

These benefits of chlorpyrifos as estimated above are based on usage data from 2014 – 2018, but chlorpyrifos usage has fallen substantially, with no use reported in three of the last five years for broccoli, and two of the last five years for cauliflower, and in those years, there was substantially less use of chlorpyrifos than in prior years. The estimates here are based on usage over five years (2014 – 2018), so they may not reflect benefits going forward. In addition, California, the primary producer of broccoli and cauliflower, is eliminating the use of chlorpyrifos by the end of 2020 (CDPR, 2019).

Cherries (sweet)

In all cherries, the available pesticide usage data for 2010 to 2014 indicate that an average of 27% of all cherry acreage was treated per year with this insecticide.

The major pests targeted by chlorpyrifos in sweet cherry production are black cherry aphid, San Jose scale, and obliquebanded leafroller. Chlorpyrifos can be phytotoxic to sweet cherry foliage (Pscheidt *et al.*, 2015). Therefore, almost all of its use in sweet cherries occurs before budbreak. EPA also received information (NWHC 2016) about increasing prevalence of grape mealybug problems and the potential issues with lesser peachtree borer, but there did not appear to be much use of chlorpyrifos against these pests (Kynetec 2016; years 2010 – 2014).

Table 2.4-6 shows the primary target pests for chlorpyrifos in sweet cherries, as well as a list of the most likely alternatives to chlorpyrifos for these pests and the difference in cost between the alternatives and chlorpyrifos. As with other crops in this analysis, selection of alternatives was based on recent pesticide usage data (from Market Research Data) as well as extension service guidance and other information. There are less expensive alternatives for black cherry aphid, but EPA concluded that some of these alternatives must be used in combination with each other to get an effect similar to that of chlorpyrifos, such that there would be a modest overall cost increase. If chlorpyrifos was not available for use to control the black cherry aphid, current users would most likely replace one application of chlorpyrifos with one application of petroleum oil plus diazinon and a later in-season application of imidacloprid.

Table 2.4-6. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Sweet Cherries.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Cherries (sweet)	$16	Black Cherry Aphid	Imidacloprid [1]	$7	($9)
			Petroleum Oil [1]	$18	$2
			Diazinon [1]	$21	$5
		San Jose Scale	Petroleum Oil [1]	$18	$2
			Buprofezin	$42	$26
			Pyriproxyfen [1]	$35	$19
		Obliquebanded Leafroller	Chlorantraniliprole	$42	$26
			Spinosad	$34	$18
			Diazinon [1]	$21	$5

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. Chlorpyrifos is assumed to be mixed with petroleum oil for a total cost of $34/acre. One application of diazinon (mixed with petroleum oil) is estimated to provide control of both black cherry aphid and obliquebanded leafroller.

The likely alternatives for the San Jose scale and obliquebanded leafroller are more expensive. If chlorpyrifos was not available for use to control the San Jose scale, current users would most likely replace one application of chlorpyrifos with one application of a petroleum oil mixed with either buprofezin or pyriproxyfen. These combinations can also be used in the dormant stage but require thorough coverage to be effective (Varela *et al* 2015). For obliquebanded leafroller, extension literature suggests that another organophosphate, such as diazinon, mixed with oil, should provide control during the dormant season that is similar to chlorpyrifos (UC IPM 2015f).

Given the increased cost to control scale, however, sweet cherry growers would experience an increased cost in chemical control as a result of not being able to use chlorpyrifos to control these pests.

For the upper bound impact, EPA assumes that currently, one application of chlorpyrifos per season is used to control all three major pests in sweet cherries: black cherry aphid, San Jose scale, and obliquebanded leafroller. Although there is concern in the industry about grape mealybug and lesser peachtree borer, they do not appear to be significant targets of chlorpyrifos (Kynetec 2016; years 2010 – 2014).

The alternatives scenario consists of one application of chlorpyrifos with petroleum oil ($16 + $18 = $34/acre) being replaced by one application diazinon with petroleum oil ($21 + $18 = $39/acre); this application of diazinon to control black cherry aphid would also control the obliquebanded leafroller. Additionally, EPA estimates growers would make a later, in-season application of imidacloprid ($7/acre) to control the black cherry aphid and one additional application of pyriproxyfen with petroleum oil ($35 + $18 = $53/acre) to control San Jose scale. The baseline scenario of using chlorpyrifos is $34/acre and the cost of the alternative scenario is $99/acre ($39 + $7 + $53). Therefore, the alternative scenario is about $65/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). Average gross revenue for sweet cherry growers is about $9,530/acre (Appendix A), implying benefits of about 0.7% of gross revenue per acre.

The lower bound impact would be replacing chlorpyrifos with diazinon, at an increase in insecticide cost of $5/acre, for control of either black cherry aphid or obliquebanded leafroller. If scale were the only pest problem, the estimated cost would be about $3/acre to use pyriproxyfen instead of chlorpyrifos.

On average, about 26,900 acres of sweet cherry are treated annually with chlorpyrifos. Estimated per-acre increases in insecticide cost imply total benefits of $77,700 to $1.7 million per year for sweet cherry.

Cherries (tart)

According to the available pesticide usage data for recent years (Kynetec 2016; years 2010-2014), the major pests targeted by chlorpyrifos in tart (also called sour) cherry production are green fruitworm and plum curculio. In young orchards, insects that bore into the wood can also be targets of chlorpyrifos use (as a trunk drench) (USDA 2011). However, this use is a minor component in terms of the area of the crop treated with chlorpyrifos, according to the available pesticide usage data used by EPA to identify major target pests (Kynetec 2016; years 2010-2014). Nevertheless, as for other tree fruit crops, EPA acknowledges that borer pest control is a potentially important chlorpyrifos use.

Table 2.4-7 shows the primary target pests for chlorpyrifos in tart cherries, as well as potential alternatives and the difference in cost between the alternatives and chlorpyrifos. There are less expensive alternatives for green fruitworm as a one to one replacement for chlorpyrifos. If chlorpyrifos was not available for use to control this pest, then farmers would likely use esfenvalerate, phosmet, or zeta-cypermethrin. For plum curculio, growers could use phosmet, an organophosphate, or a neonicotinoid, while for borers, phosmet may be an option; the Table 2.4-7 lists the likely pyrethroids and neonicotinoids used by growers. Alternatives are all, on

average, lower cost than chlorpyrifos, which suggests that growers using chlorpyrifos face higher pest pressure, multiple pests, or other constraints that make these alternatives less useful than chlorpyrifos. For example, esfenvalerate, one of the cheaper alternatives, can cause outbreaks of mites, so some growers might instead prefer to use chlorpyrifos despite the higher cost.

Table 2.4-7. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Tart Cherries.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Cherries (tart)	$23	Green Fruitworm	Permethrin	$6	($17)
			Esfenvalerate	$5	($18)
			Phosmet [1]	$20	($3)
			Zeta-cypermethrin	$6	($17)
		Plum Curculio	Esfenvalerate	$5	($18)
			Phosmet [1]	$20	($3)
			Thiamethoxam	$18	($5)
		Lesser Peachtree Borer	Phosmet	$20	($3)
			Mating Disruption	$65	$42

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

For this assessment, EPA assumes that one application of chlorpyrifos ($23/acre) is used to control both green fruitworm and plum curculio simultaneously in tart cherries. The alternative scenario consists of one application of phosmet ($20/acre) to control green fruitworm and another application of phosmet ($20/acre) to control plum curculio. The baseline scenario of using chlorpyrifos is $23/acre and the cost of the alternative scenario is $40/acre. Therefore, the alternative scenario is about $17/acre more expensive than chlorpyrifos. Average gross revenue is about $1,695 per acre (Appendix A), implying impacts of about 1.1% of gross revenue per acre. On average, about 13,700 acres of tart cherries are treated with chlorpyrifos.

EPA received comments indicating that borers, particularly the lesser peach tree borer, are not effectively controlled by available insecticides (Korson, 2016). EPA agreed with the conclusion that this pest seems to be a growing problem for which effective alternatives to chlorpyrifos are not available. Michigan extension publications mention that mating disruption is a possible control strategy for lesser peachtree borer, at an additional cost of $42 per acre over chlorpyrifos. There is concern, however, that mating disruption may not be fully effective. For acreage where lesser peachtree borer is uncontrolled, EPA assumes 10% yield loss. This is based on surveys of heavily infested orchards from Michigan Extension experts reported to EPA by the USDA OPMP (USDA OPMP 2017). These surveys indicate that heavily infested orchards have about 20% of trees affected by borers, and half of those are in serious decline, with essentially no yield. The lesser peachtree borer actually reduces lifetime yield and shortens the life of infested trees, but EPA has been unable to find reliable quantitative estimates for yield losses and shortened tree lifetime. The 10% loss estimate may be on the low end, as over time borers could colonize a

larger percentage of the trees in an infested orchard. Gross revenue from tart cherries averaged $2,005 per acre from 2010 – 2014, so 10% yield loss would be $201 per acre. An average of 1,389 acres were treated with chlorpyrifos targeting borers in Michigan cherries. This average is from 2012 – 2014, since there were no treatments for borers with chlorpyrifos in 2010 or 2011 according to the available usage data. This is consistent with the lesser peachtree borer emerging as an important pest in Michigan cherries. This estimate is sensitive to the assumptions about yield loss and the share of treated acreage that will suffer those yield losses, and these are a source of substantial uncertainty. This additional cost is specific to Michigan production, and is in addition to the estimate in the previous paragraph, because this cost is specific to Michigan cherry. Cherry production in other regions east of the Rocky Mountains may also have peachtree borer problems sporadically, in which case similar economic impacts would be expected.

The tart cherry low benefits estimate is $291,900, which assumes that 11,800 acres are treated with alternatives for plum curculio and green fruitworm at an additional cost of $17 per acre, and 1,400 acres also are treated with mating disruption for lesser peachtree borer at $65 per acre. The high-end estimate is $481,500 which assumes that 11,800 acres are treated with alternatives for plum curculio and green fruitworm at an additional cost of $17 per acre, and 1,400 suffer 10% yield loss instead of mating disruption for acreage treated for borers acreage. This is based on current chlorpyrifos use patterns against borers and will understate the costs if the problem continues to grow. This estimate is sensitive to the assumptions about yield loss and the share of treated acreage that will suffer those yield losses. These are a source of substantial uncertainty; higher affected acreage or greater yield loss could increase the losses substantially.

Cotton

Chlorpyrifos use on cotton nationally is relatively low – the national average for 2010 to 2014 was about five percent of all acres treated with foliar applications and about one percent treated with seed treatments (Kynetec 2016; years, 2010 - 2014). An average of one application per year was made during those years. There is considerable year to year variation in chlorpyrifos use, likely reflecting fluctuating levels of many insect pests. Use, as measured by percent of the crop treated, is higher in California, at 28% (Kynetec 2016; years, 2010 - 2014).

Chlorpyrifos foliar use in cotton most often targets the cotton aphid, silverleaf whitefly, and stinkbugs (various species). Stinkbugs refers to several species of this type of insect and the importance of one or other individual species varies across the country. Widely distributed members of this complex include the green stinkbug, the brown stinkbug, and the southern green stinkbug. All had historically been relatively minor pests until cotton genetically modified to control insects became widespread (Stevenson and Matcoha 2005, Hebert *et al.* 2009), which reduced application of insecticides targeting other pests. Stinkbugs damage plants by attacking developing cotton bolls directly (UGA 2019).

The cotton aphid and the silverleaf whitefly not only reduce yield by their feeding activity, but also reduce the quality of harvested cotton lint by leaving sticky honeydew on it. Honeydew is the sugary excretion these insects produce from the plant sap they feed on (UC IPM 2015e, MSU 2015). Sticky or discolored lint can result in entire fields' harvests becoming unsaleable not only in the pest-heavy year but in subsequent years, because cotton mills refuse to buy from that area again (UC IPM 2015).

Seed treatments appear to target thrips, although soil pests are often difficult to identify and growers may use seed treatments because they are observed to improve stand establishment, not because of a specific pest problem. Neonicotinoid seed treatments are the most common method for thrips control. At-plant applications of imidacloprid and acephate are also possible control strategies. Aldicarb has not been available for use in cotton in recent years. However, it is registered on cotton, so it may be available for use again in the future.

Based on the available pesticide usage data and extension guidance for pest management, EPA expects that a neonicotinoid seed treatment would be used in place of a chlorpyrifos seed treatment. Dicrotophos or acephate (both organophosphates), in combination with bifenthrin (a synthetic pyrethroid) could substitute for chlorpyrifos for the control of stinkbugs. Likely alternatives for the cotton aphid are imidacloprid, thiamethoxam, or acetamiprid, and for whiteflies, they might include either acetamiprid or pyriproxyfen.

Table 2.4-8. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Cotton.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Cotton, seed treatment	$2	Thrips	Thiamethoxam	$6	$4
			Imidacloprid	$9	$7
			Clothianidin	$11	$9
			Acephate	$2	<$1
Cotton, foliar	$5	Cotton Aphid	Acetamiprid	$11	$6
			Flonicamid	$11	$6
			Imidacloprid	$5	$0
			Thiamethoxam	$6	$1
		Silverleaf Whitefly	Acetamiprid	$11	$6
			Pyriproxyfen	$15	$10
		Stinkbug	Dicrotophos [1]	$4	($1)
			Acephate	$3	($2)
			Bifenthrin	$4	($1)
			Imidacloprid	$5	$0
			Novaluron	$8	$3

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. An application of chlorpyrifos is assumed to target a single pest, given the sporadic nature of use.

The alternative scenarios depend on the application method and pests; the pests targeted by foliar applications generally appear sporadic in nature and will not frequently occur simultaneously. However, since whiteflies and aphids have been emphasized as particularly damaging to both yield and quality of the harvest (UC IPM 2015), there may be situations where simultaneous control of both pests using two alternative insecticides are needed, at least in California.

For seed treatments, acephate could be used at no increase in costs. Neonicotinoids are more likely, implying an increase in insecticide cost of $4 to $9 per acre. Average gross revenue is about $668 per acre (Appendix A), implying impacts of 0% up to 1.3% of gross revenue per

acre. About 482,000 acres of cotton are planted with chlorpyrifos-treated seeds (Kynetec 2016; years, 2010-2014), which implies from $0 to as much as $4.3 million in benefits for chlorpyrifos.

One foliar application of chlorpyrifos ($5/acre) could be replaced with one application of imidacloprid or thiamethoxam at approximately the same cost to control cotton aphid or with acetamiprid ($11/acre). Acetamiprid could also be used to control silverleaf whitefly. One application of dicrotophos and bifenthrin to control stinkbugs would cost about $8/acre in total. Thus, alternative control scenarios for foliar applications cost about the same to $6/acre more than chlorpyrifos. Costs could be up to $19/acre for control of stinkbug with whitefly or aphid together assuming use of acetamiprid; the combination would be about $14/acre more than chlorpyrifos. Average gross revenue is about $668 per acre (Appendix A), implying impacts from 0% up to 2.1% of gross revenue per acre. On average, 126,000 acres of cotton are treated with a foliar application of chlorpyrifos. Total benefit estimates range from almost nothing to as much as $1.8 million per year for replacing foliar chlorpyrifos applications.

Cranberry

Chlorpyrifos is used in cranberry to control lepidopteran (caterpillar) pests and cranberry weevil (Humfeld 2016). Public comments from the cranberry industry indicate that diazinon is an alternative to chlorpyrifos for control of both pests. Chlorantraniliprole is an alternative to control only lepidopteran pests, and cranberry weevil can be controlled with thiamethoxam. According to the industry information, chlorpyrifos treatments in cranberry control both pests with an average cost of $22 per acre, while diazinon treatments cost $36 per acre. Chlorantraniliprole treatments cost $51 per acre (Humfeld, 2016). Industry information did not identify the cost of thiamethoxam, and cranberry is not surveyed in the available market research data. Therefore, EPA estimated the cost of thiamethoxam use by taking the average cost of thiamethoxam used in all available crops in Washington and Wisconsin, the two biggest cranberry producing states (Kynetec 2016, years 2010-2014). The estimated cost of a treatment of thiamethoxam is $6 per acre.

The information on pests, alternatives, and costs is summarized in Table 2.4-9. Currently the cost of control with chlorpyrifos is $22/acre, which provides control of both lepidopterans and cranberry weevil. The alternatives scenario consists of replacing one application of chlorpyrifos with one application of chlorantraniliprole ($51/acre) to control lepidopterans and one application of thiamethoxam ($6) per acre to control cranberry weevil. The scenario is about $35/acre more expensive than chlorpyrifos. If targeting a single pest, the difference in cost between a chlorpyrifos treatment and an alternative treatment for one of the pests will be no more than $29/acre and could be as little as $14/acre with diazinon. Gross revenue averages $7,864 per acre (Appendix A), implying impacts of under 0.5% of gross revenue. According to the Census of Agriculture, there are 40,000 acres of cranberry grown in the United States (USDA 2014); the Cranberry Institute says that 31% of acres are treated with chlorpyrifos, which means about 12,400 acres would be affected. At an additional cost of $14 - $35 per acre, the estimated total benefit to the cranberry industry from chlorpyrifos is $174,000 - $434,000 annually.

Table 2.4-9. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Cranberry.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternative	Cost of Alternative ($/acre)	Difference in Cost ($/acre)

Cranberry	$22	Cutworms	Chlorantraniliprole [1]	$51	$29
			Diazinon	$36	$14
		Cranberry weevil	Thiamethoxam [1]	$6	($16)
			Diazinon	$36	$14

Sources: Cranberry Institute, 2016; Kynetec 2016; years, 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Grapefruit

In terms of pest management importance, chlorpyrifos is most likely important for control of citrus mealybug in grapefruit. University of Florida extension recommendations (Diepenbrock *et al.* 2019a) indicate that these pests are often controlled by natural enemies. However, when populations get exceedingly large, chlorpyrifos is the most efficacious material, and treatment is warranted "only in cases of severe infestations" (Diepenbrock *et al.* 2019a, b). Mealybugs are difficult to control on citrus due to feeding in concealed locations, such as crevices between foliage and fruit, that are difficult to cover with insecticides applied with airblast sprayers. Spraying is recommended immediately prior to spring flush or periods of peak egg-hatch after the flush (UF, 2012). Given the limited efficacy of alternatives, yield losses could occur under heavy outbreak situations without the use of chlorpyrifos.

While chlorpyrifos usage is reported on grapefruit for control of citrus leafminer and rust mites, it accounts for a minor proportion of all pesticide applications against these pests, with other market leaders surpassing chlorpyrifos in importance. For applications against adult Asian citrus psyllid (mainly in Florida), there are numerous alternatives and growers are currently making use of any and all insecticides at their disposal to contain outbreaks of this pest, which vectors the critical Huanglongbing disease in citrus. Use of chlorpyrifos against red scale is also reported.

EPA's projected upper bound cost scenario consists of one application of chlorpyrifos ($19/acre) per season being replaced by one application of zeta-cypermethrin ($4/acre) to control Asian citrus psyllid; one application of abamectin ($13/acre) to control citrus rust mite/mites; and one application of spirotetramat ($46/acre) to control citrus mealybug. In total, the alternatives would cost about $63/acre, which is about $44/acre more than one application of chlorpyrifos (Table 2.4-10). Lower cost scenarios would occur if only a single pest was to be targeted. For the psyllid, diflubenzuron ($31/acre) or spinetoram ($28/acre) might be used at additional insecticide cost of $9-$12/acre. Alternatives for citrus rust mites or citrus mealybug are $12-$16/acre more expensive than chlorpyrifos. Average gross revenue is about $3,731 per acre, implying impacts of about 1.2% of gross revenue per acre at the upper bound. On average, about 22,400 acres of grapefruit are treated annually with chlorpyrifos (Kynetec 2016; years, 2010-2014). Estimated total benefit for chlorpyrifos ranges from $202,000 to $987,000 per year. As discussed above, in the absence of chlorpyrifos, yield and/or quality losses could occur under heavy outbreaks of citrus mealybug.

Table 2.4-10. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Grapefruit.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Grapefruit	$19	Asian Citrus Psyllid	Zeta-cypermethrin [1]	$4	($15)
			Imidacloprid	$17	($2)
			Abamectin	$13	($6)
			Petroleum Oil	$16	($3)
			Thiamethoxam	$13	($6)
			Diflubenzuron	$31	$12
			Spinetoram	$46	$27
		Citrus Rust Mite/ Mites	Sulfur	$12	($7)
			Abamectin [1]	$13	($6)
			Petroleum Oil	$16	($3)
			Spirodiclofen	$32	$13
			Diflubenzuron	$31	$12
		Citrus Mealybug	Spirotetramat [1]	$46	$27
			Petroleum Oil	$16	($3)
			Imidacloprid	$17	($2)

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Grapes

In all grapes, the available pesticide usage data indicate that chlorpyrifos was applied once per year on average (Kynetec 2016; years 2010-2014). In table grapes, an average of 41% of the crop was treated; area treated in wine and raisin grapes was much lower (4% and 6%, respectively).

The major pests targeted by chlorpyrifos in table, wine, and raisin grape production are the vine mealybug and the grape mealybug (Kynetec 2016; years 2010-2014). These insects contaminate grape clusters by excreting sticky honeydew that allows black sooty mold, a secondary contaminant, to develop. In addition, these insects can transmit viruses (i.e., grapevine leafroll-associated viruses) that stunt plant growth and reduce yields (UC IPM 2019). Table grapes are particularly vulnerable to mealybug damage because cluster contamination results in buyer rejection. Therefore, treatment for mealybugs in table grapes is recommended at a much lower threshold (about half the mealybug infestation in samples) as compared to wine and raisin grapes.

Table 2.4-11 shows the primary target pests for chlorpyrifos in grapes, as well as likely alternatives and the difference in cost between the alternatives and chlorpyrifos. The alternatives identified for both grape and vine mealybugs are generally more expensive than chlorpyrifos. For vine mealybug, buprofezin or spirotetramat along with a subsequent application of clothianidin are the alternatives likely to be used because of the high degree of control that is probably needed. For grape mealybug, buprofezin or spirotetramat, plus imidacloprid would be the likely option of choice to replace chlorpyrifos. Grape growers would experience an increased cost in chemical control for vine and grape mealybugs as a result of switching to this method and are likely to face some economic losses.

Table 2.4-11. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Table Grapes.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Grapes (raisin)	$18	Mealybug	Imidacloprid [1]	$10	($8)
			Spirotetramat [1]	$48	$30
Grapes (table)	$18	Vine Mealybug	Buprofezin	$25	$7
			Clothianidin [1]	$14	($3)
			Spirotetramat [1]	$54	$36
		Grape Mealybug	Imidacloprid [1]	$26	$7
			Spirotetramat [1]	$54	$36
			Buprofezin	$25	$7
Grapes (wine)	$23	Vine Mealybug	Imidacloprid [1]	$14	($9)
			Buprofezin	$27	$4
			Spirotetramat [1]	$50	$27
		Grape Mealybug	Spinosyn	$36	$13
			Imidacloprid [1]	$14	($9)
			Spirotetramat [1]	$50	$27

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

For raisin grapes, the alternative is to apply spirotetramat, which costs about $30/acre more than chlorpyrifos. Average gross revenue is about $3,942/acre (USDA, 2010 – 2014), implying per-acre impacts of less than one percent of gross revenue. About 11,000 acres of raisin grapes are treated with chlorpyrifos annually (Kynetec 2016; years 2010-2014). The estimate of total benefits from chlorpyrifos are $331,000 per year.

The alternatives scenario for table grapes consists of one application of chlorpyrifos ($18/acre) per season being replaced by one application each of spirotetramat ($54/acre) and clothianidin ($14/acre) to control vine mealybug; and one application each of spirotetramat ($54/acre) and imidacloprid ($26/acre) to control grape mealybug. The baseline scenario of using chlorpyrifos is $18/acre and the cost of the alternative scenario is $148/acre. Therefore, the alternative scenario is about $130/acre more expensive than chlorpyrifos (the difference may not be exact due to rounding). This could overestimate the cost of an alternative control regime because a single application of buprofezin or spirotetramat could potentially control both vine and grape mealybugs with an increase in control cost of $7 to $36 per acre. Average gross revenue is about $11,435 per acre, implying impacts of about 1.1% of gross revenue per acre using the upper bound estimate of per-acre costs. On average, chlorpyrifos is used on 41,800 acres of table grape (Kynetec 2016; years 2010-2014) implying total benefits of $293,000 to $5.4 million annually.

The alternatives scenario for wine grape consists of one application of chlorpyrifos ($23/acre) per season being replaced by one application each of imidacloprid ($14/acre) and spirotetramat ($50/acre) to control vine mealybug and one application each of imidacloprid ($14/acre) and spirotetramat ($36/acre) to control grape mealybug. The baseline scenario of using chlorpyrifos is $23/acre and the cost of the alternative scenario is $114/acre. Therefore, the alternative

scenario is about $91/acre more expensive than chlorpyrifos (the difference may not be exact due to rounding). This may overestimate the cost of an alternative control regime if both the vine and grape mealybug can be controlled simultaneously, as is assumed with a single application of chlorpyrifos, with a single application of spirotetramat. Increased costs in the absence of chlorpyrifos could be as low as $4/acre with use of buprofezin to control vine mealybug alone. Average gross revenue is about $4,876/acre (Appendix A), implying impacts of about 1.9% of gross revenue per acre with an increase of $91/acre in control costs. The total benefit of chlorpyrifos is estimated to be between $90,000 and $2.1 million per year, given an average of 22,600 acres of wine grapes treated annually with chlorpyrifos (Kynetec 2016; years 2010-2014).

Hazelnuts

Chlorpyrifos use on hazelnuts (also called filberts) is limited to three applications per year, including dormant/delayed dormant sprays and in-season foliar sprays. Usage data, however, indicates that only about two percent of hazelnut acres are treated more than once. While a large share of chlorpyrifos usage is targeted against the leafroller complex, filbert worms, and filbert aphids, numerous alternatives are available (Wiman and Bell 2020, Pscheidt *et al.* 2015). Imidacloprid, spirotetramat, acetamiprid, and cyfluthrin are all alternatives used for aphids (Table 2.4-12). Diflubenzuron, emamectin, *Bacillus thuringiensis* (*Bt*), methoxyfenozide and spinetoram are recommended alternatives for leafrollers (Wiman and Bell 2020, Pscheidt *et al.* 2015). There is very little reported use of methoxyfenozide, and there is no use of the other alternatives (Kynetec 2016, years 2010-2014). The alternative scenario used is based on alternatives shown to target leafrollers in usage data (Kynetec, 2016; years 2010 -2014).

The alternatives scenario consists of replacing an application of chlorpyrifos ($11/acre) with an application of esfenvalerate ($9/acre) or other synthetic pyrethroid, and an application of imidacloprid ($5/acre) for season-long control of the filbert aphid, leafrollers, and filbert worms. The total cost of the alternative regime is $14/acre, or $3/acre more than using chlorpyrifos alone. Impacts could be negligible, particularly for growers that face a single pest. Gross revenue for hazelnuts averages $3,224/acre (Appendix A), implying impacts per acre well below one percent of gross revenue. On average, about 3,300 acres of hazelnut are treated with chlorpyrifos (Kynetec 2016; years 2010-2014). Total benefits to hazelnut growers could be up to $10,000 per year.

Table 2.4-12. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Hazelnuts.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Hazelnuts	$11	Filbert Aphid	Esfenvalerate [1]	$9	($2)
			Cyfluthrin	$4	($7)
			Imidacloprid [1]	$5	($6)
		Leafrollers Complex	Esfenvalerate [1]	$9	($2)
			Cyfluthrin	$4	($7)
			Imidacloprid [1]	$5	($6)
		Filbert Worm	Esfenvalerate [1]	$9	($2)
			Cyfluthrin	$4	($7)
			Imidacloprid [1]	$5	($6)

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.

[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Lemons

Chlorpyrifos is used in lemons to control several scale species, citrus bud mite and citrus mealybug. In some parts of Southern California, the soft scale species, citricola scale is controlled naturally (called biocontrol) by parasitic wasps (parasitoids) and is thus rarely a pest. However, in the Central Valley biocontrol is not effective, necessitating broad-spectrum insecticide usage. Petroleum oil can reduce populations as a stand-alone tactic but will not control large outbreaks. UC recommendations state that applications of chlorpyrifos at high rates can control populations for two to three years (UC IPM, 2015b). Alternatives such as neonicotinoids and buprofezin have moderate efficacy but can only control populations for one year. Because citricola scale is mostly susceptible to broad spectrum OP and carbamate applications, outbreaks are therefore most likely to occur in groves that have stopped using such tactics – *i.e.*, it is possible that the impact of this pest will grow over time if chlorpyrifos is removed from the system. In addition to the alternatives listed, UC IPM also recommends acetamiprid for applications in the fall following applications of other neonicotinoids in the spring via soil drench applications (UC IPM, 2015b).

For two armored scale species, California red Scale and yellow Scale, biocontrol is a viable option. UC IPM (2015c) recommends that growers should release rates of 5,000-10,000 parasitoid wasps per acre. Some areas of the state do not see outbreaks due to biocontrol. Applications of chlorpyrifos are timed to correspond with trap captures of the crawler lifestage, and efficacy is very good. Unlike citricola scale, it does not appear that OPs and carbamates confer multiple year suppression, so for comparison with alternatives, it might make more sense to consider one for one substitution of applications. In addition to the listed alternatives in the usage data, UC IPM also recommends buprofezin and carbaryl; each of these would be a one for one substitution with chlorpyrifos. However, if applications are already being made to target citricola scale, it is unlikely that additive applications would be made to also target other scale species.

The citrus bud mite has historically been a pest mainly of coastal-grown lemons but has recently been found on interior regions as well (UC IPM 2019b). Feeding damage distorts developing flower buds which can lead to lower yields and/or reduced fruit quality. While usage data indicate that chlorpyrifos has been used to an appreciable extent to manage this pest, recent extension guidelines from the University of California do not mention this insecticide as an option recommended for use in an IPM program targeting this mite pest. Several alternatives are recommended instead, often mixed with horticultural (petroleum or narrow-range) oils. These include cyantraniliprole in combination with abamectin, fenbutatin oxide, and spirotetramat (UC IPM 2019b).

University of Florida extension recommendations indicate that citrus mealybugs are often controlled by natural enemies, but that when populations get exceedingly large, chlorpyrifos is the most efficacious material and treatment is warranted 'only in cases of severe infestations' (Diepenbrock *et al.* 2019a, b). Mealybugs are difficult to control due to feeding in concealed locations, such as crevices between foliage and fruit that are difficult to cover with insecticides applied by airblast equipment, which is the typical broadcast treatment method for citrus crops. Spraying is recommended immediately prior to spring flush or during periods of peak egg-hatch after the flush (UF 2012). Given limited efficacy of alternatives (Diepenbrock *et al.* 2019b), this pest warrants consideration for yield loss analysis under heavy outbreak situations.

Table 2.4-13 shows the difference in cost between the alternatives and chlorpyrifos for the target pests. Based upon available information for control of citricola scale, one application of chlorpyrifos applied in a given year is assumed to be effective for three years. Thus, the chlorpyrifos cost of $36/acre is divided by three to obtain the annual cost of $12/acre. The alternatives scenario consists of two applications of buprofezin ($176/acre) to control citricola scale each year, and one application of a tank mix of petroleum oil ($35/acre), abamectin ($20/acre), and spirotetramat ($71/acre) to control citrus bud mite and mealybugs. In total, the alternatives would cost about $302/acre (the total is not exact due to rounding), which is about $290/acre more expensive than chlorpyrifos ($12/acre). Citricola scale accounts for about ten percent of the 15,600 acres treated with chlorpyrifos. Red and yellow scale account for over 40% of chlorpyrifos treated acres and mealybugs around 20 to 25%. Use of spirotetramat in place of chlorpyrifos to target red and yellow scale would add about $36/acre to production costs. If only the other scale ("scale complex") were targeted, cost increases might be as low as $10/acre with the use of thiamethoxam. The average gross revenue of lemon is $8,268, implying an impact of about 4% of gross revenue for citricola scale and less than 0.5% for other pests. The total benefit ranges from $156,000 to $4.5 million, but the upper bound assumes all acres are impacted by citricola scale.

Table 2.4-13. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Lemons.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Lemons	$36	Scale Complex [2]	Petroleum Oil	$35	<$1
			Thiamethoxam [1]	$45	$10
			Dimethoate	$22	($13)
		CA Red/Yellow Scale	Petroleum Oil	$35	<$1
			Spirotetramat [1]	$71	$36
			Pyriproxyfen	$63	<$1
		Citricola Scale	Petroleum Oil	$35	<$1
			Buprofezin [1]	$88	$53
			Acetamiprid	$20	($15)
			Dimethoate	$22	($13)
		Citrus Bud Mite	Petroleum Oil [1]	$35	<$1
			Abamectin [1]	$20	($15)
			Spirotetramat [1]	$71	$36
		Citrus Mealybug	Petroleum Oil [1]	$35	<$1
			Imidacloprid	$33	<$1
			Spirotetramat [1]	$71	$36
			Abamectin [1]	$20	($15)

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnotes:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. Chlorpyrifos is assumed to be used once every three years when used for citricola scale, for an average annual cost of about $12/acre. Buprofezin is expected to be used twice each year to obtain similar control.
[2] "Scale complex" does not include red scale and citricola scale

However, as discussed above, using the alternatives might result in yield/quality losses under heavy citrus mealybug outbreak situations, leading to revenue impacts in addition to chemical cost increases.

Mint

Chlorpyrifos is used in mint to control cutworms, mint root borer, and symphylans, according to comments from the Mint Industry Research Council submitted to the chlorpyrifos regulatory docket in 2015 (Salisbury 2015). EPA's earlier Small Business analysis of the petition to revoke chlorpyrifos tolerances (EPA, 2015a) did not include mint. EPA reviewed extension pest management recommendations from states with mint production (e.g., Washington, Oregon, California), and confirmed that the pests mentioned by the mint industry are potentially major problems for the crop. In addition, these recommendations suggested that chlorantraniliprole is an effective alternative for control of two of these pests (cutworms and borers) and that either 1,3-dichloropropene or ethoprop are effective alternatives for symphylan management (UC IPM 2012, Rinehold 2016). Because mint is not surveyed in the market research data that EPA uses to estimate prices, insecticide prices were estimated from national level data on pesticide costs in all crops, averaged from 2010 – 2014 (USDA, 2016b). The cost of chlorpyrifos was estimated at $10 per acre, which may be low for mint if application rates are higher than the national average. Chlorantraniliprole was estimated to cost $29 per acre, for a difference of $19 per acre (Table 2.4-14). If treatment for symphylans is needed, the cost of ethoprop would be about $19 per acre or 1,3-dichloropropene about $166 per acre with a difference in cost of $9 or $156 per acre (Table 2.4-14).

Using information from the USDA on yield and price received for peppermint and spearmint (USDA, 2016b), gross revenue is calculated at $2,080 per acre, implying impacts of 0.9% of gross revenue (Table 2.4-14). According to the Census of Agriculture, there are 92,400 acres of spearmint and peppermint grown in the United States (USDA, 2016b). In the absence of information on the share of the crop treated with chlorpyrifos, we conservatively assume that half to all acreage is treated with chlorpyrifos, and the more expensive alternative chlorantraniliprole would be applied to all the acreage. At an additional cost of $19 per acre for control of cutworms and borers, the estimated total benefits to the mint industry is $876,000 to $1.8 million annually. If the same acreage needed control of symphylans, the estimated total benefits, the additional cost of chlorantraniliprole plus ethoprop is $28, resulting in net benefits for chlorpyrifos of $1.3 to $2.6 million. The actual acreage that needs treatment for symphylans or the other mint pests is unknown.

Table 2.4-14. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Mint.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternative	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Mint	$10	Cutworms, Mint root borer	Chlorantraniliprole [1]	$29	$19
		Symphylans	Ethoprop	$19	$9
			1,3-dichloropropene	$166	$156

Source: Kynetec, 2016; years 2010-2014; Salisbury 2015. Numbers may not add due to rounding.
Footnote:
[1] Chemical used to estimate the cost of control in the absence of chlorpyrifos.

Onions

Chlorpyrifos is applied to onions as a soil application at or before planting to control a complex of maggot species, including onion maggots, seedcorn maggots, *etc.*, which are problematic pests nationally, and of particular importance in the eastern U.S.

Seed treatments with neonicotinoids, spinosad, and cyromazine are available with demonstrated efficacy (Hoepting and Nault, 2012). Neonicotinoid-treated seeds are known to be used and are effective in controlling the soil pest complex, including maggots. Since seed treatments are done before planting, a grower could save the costs of actual application for chlorpyrifos pre-plant applications, *i.e.*, one less trip across the field. In the absence of seed treatments, preliminary indications are that maggot efficacy of chlorpyrifos is superior to alternatives (SEVEW 2019), so a yield loss might occur where neonicotinoid seed treatments are not viable or available. Applications of lambda-cyhalothrin and diazinon can be substituted one-for one with chlorpyrifos, but efficacy against the maggot complex is unclear.

Based upon available information on use, cost, and efficacy, EPA projects that the most likely alternative scenario to the use of chlorpyrifos is a seed treatment that costs from $20 to $75 per acre (Utah State University, Cooperative Extension, 2011). Due to variability in available packages (*i.e.*, some seed treatment systems are only available as a package treatment that also includes fungicides), pricing for this option is difficult to estimate. Using the upper bound of this range to estimate the impact, the alternatives scenario would cost $66/acre more than the current use of chlorpyrifos ($9/acre). Average gross revenue for onions is approximately $6,322 per acre, implying an impact of about 1% of gross revenue per acre. A low-cost estimate would be about $11/acre more for an application of diazinon instead of chlorpyrifos (Table 2.4-15). About 57,800 acres of onion are treated each year with chlorpyrifos, on average (Kynetec 2016; years 2010-2014). Total benefit for chlorpyrifos is estimated to be $636,000 to $3.8 million per year.

Table 2.4-15. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Onions.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Onions	$9	Maggot Complex (onion, seed, etc.)	Lambda-cyhalothrin	$5	($4)
			Diazinon [1]	$20	$11
			Spinetoram	$39	$30

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. Data on seed treatment price from Utah State University, Cooperative Extension (2011).

Oranges (California)

The analysis for oranges was done separately for California and Florida due to significant differences in production practices and target pests for chlorpyrifos. California citrus production is driven by the sale of fresh produce, in contrast with Florida which mainly grows oranges for juice. California also has unique pest control challenges with citricola scale and katydids, which are not an issue for Florida growers. These considerations justify analyzing California oranges

separately from Florida oranges. In addition, comments received on the tolerance revocation suggest that California growers need to control a complex of ant species frequently; no similar comments were received from Florida growers or crop experts (Grafton-Cardwell 2015, Morse 2015).

In some parts of Southern California, citricola scale is under biocontrol by parasitoids and is rarely a pest. In the Central Valley, however, biocontrol is not effective which necessitates broad-spectrum insecticide usage. Petroleum oil can reduce populations as a stand-alone tactic but will not control large outbreaks. UC recommendations state that applications of chlorpyrifos at high rates can effectively control or "re-set" populations for two to three years (UC IPM, 2015b). Alternatives such as neonicotinoids and buprofezin have moderate efficacy but can only control populations for one season. Each often requires more than one application per year. Because citricola scale is usually controlled with broad spectrum organophosphate and carbamate applications, outbreaks are most likely to occur in groves that have recently stopped using such tactics—i.e., it is possible that the impact of this pest will grow over time if chlorpyrifos is removed from the system. Certain ant species, such as the Argentine ant, tend to and protect phloem-feeding insects, such as citricola scale, in order to feed on the phloem-feeders' sugary honeydew excretions. If ant control is diminished with the use of alternatives, this scale-tending behavior would also contribute to an increase in scale populations and their damage to the crop. However, the cost estimates below are based on controlling pests that are tended by ants, not direct ant control. In addition to the alternatives listed, UC IPM also recommends acetamiprid for applications in the fall following applications of other neonicotinoids in the spring via soil drench applications for citricola scale (UC IPM, 2015b). As a result, an upper bound alternatives scenario could be two to four applications of acetamiprid plus two to four applications of imidacloprid as a soil drench, or two to four applications of buprofezin plus petroleum oil.

For two armored scale species, California red scale and yellow Scale, biocontrol is a viable option. UC IPM (2015c) recommends that growers should release parasitoid wasps at rates of 5,000-10,000 per acre. Some areas of the state do not see outbreaks of these scale species due to biocontrol. In groves where insecticide treatments are required, applications of chlorpyrifos are timed to correspond with trap captures of crawlers (immature scale) and efficacy is very good. Unlike citricola scale, it does not appear that organophosphates and carbamates confer multiple year suppression for California red scale. In addition to the listed alternatives in the usage data, UC IPM (2015c) also recommends buprofezin and carbaryl; each of these would also be a one for one substitution with chlorpyrifos. However, in years where applications are already being made to target citricola scale, it is unlikely that additive applications would be made to also target other scale.

Katydids are a significant pest problem in the absence of broad-spectrum pesticide options. Katydids (e.g., forktailed bush katydid) feed directly on fruit after petal fall, leading to either fruit drop or quality loss from scar tissue formation. Since California is a primarily fresh market producer, such quality losses would be significant. Beyond the listed insecticides in Table 2.4-16, diflubenzuron and naled are additional materials recommended for katydid control and would likely be used as a one for one substitution for chlorpyrifos (UC IPM, 2015d). On average, these chemicals cost just over $20/acre (Kynetec 2016; years 2010-2014).

Table 2.4-16. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, California Oranges.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Oranges (CA)	$43	Citricola Scale	Petroleum Oil	$21	($22)
			Pyriproxyfen	$74	$31
			Acetamiprid	$61	$18
			Dimethoate	$14	($29)
			Buprofezin [1]	$93	$50
		CA Red/Yellow Scale	Petroleum Oil	$21	($22)
			Pyriproxyfen	$74	$31
			Spirotetramat	$65	$22
			Imidacloprid	$29	($14)
			Buprofezin [1]	$93	$50
			Acetamiprid	$61	$18
	$17	Katydids	Cyfluthrin	$9	($8)
			Fenpropathrin	$25	$18
			Cryolite [1]	$46	$29
			Chlorantraniliprole	$33	$16
			Dimethoate	$11	($6)

Source: Kynetec, 2016; years 2010-2014.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. Chlorpyrifos is assumed to be used once every three years against scale, for an average annual cost of about $14/acre. Buprofezin is expected to be used twice each year.

Two applications of chlorpyrifos per year are permitted on California oranges. In practice, about 13% of acres are treated more than once. Based upon available information for control of scale insects, one application of chlorpyrifos applied in a given year is conservatively assumed to be effective for three years. Thus, the chlorpyrifos cost of $43/acre is divided by three to obtain the annual cost of about $14/acre. This might be replaced by two applications of buprofezin annually ($186/acre) for an increase in insecticide costs of $172/acre. For an application of chlorpyrifos to control katydids at about $17/acre, alternatives range in price from $25/acre for fenpropathrin to $46/acre for an application of cryolite, that is, $8 to $29/acre more than chlorpyrifos. An upper bound estimate of cost would be for an acre treated for both scales and katydids for a total increase in insecticide cost of $180 to $201 per acre. Average gross revenue is about $4,278 per acre, implying impacts of less than 0.5% to as much as 4.5% of gross revenue per acre. According to market research data (Kynetec 2016; years 2010-2014), 38,800 acres of oranges are treated, on average. Total benefits, therefore, are estimated to range from $310,000 to about $7.8 million per year.

However, in addition to being more expensive than chlorpyrifos, these alternative chemicals may also be less efficacious, leading to potential yield and/or quality losses for citricola scale.

Oranges, Florida

Florida orange production is driven by the processing (juice) market, in contrast with California, which mainly grows oranges for the fresh market. While chlorpyrifos usage is reported on Florida oranges for control of rust mites, it accounts for a minor proportion of all pesticide

applications against these pests, with other market leaders far surpassing chlorpyrifos in importance. For applications against adult Asian citrus psyllids, there are numerous alternatives and growers are making use of any and all insecticides at their disposal to suppress outbreaks of this pest, which vectors the critical Huanglongbing disease in citrus.

EPA's alternative scenario consists of one application of chlorpyrifos ($13/acre) per season being replaced by one application of zeta-cypermethrin ($5/acre) to control Asian citrus psyllid and one application of a tank-mix of petroleum oil ($15/acre) and abamectin ($13/acre) to control citrus rust mites. In total, the alternatives would cost about $33/acre (the total is not exact due to rounding), which would be about $20/acre more expensive than one application of chlorpyrifos (Table 2.4-17). This may be an overestimate of cost because more than one application of chlorpyrifos may be needed to target multiple pests and here EPA assumes only one. A lower bound estimate would be applications of either imidacloprid or thiamethoxam to target either Asian citrus syllid or citrus rust mites for an increase of about $2/acre in insecticide cost relative to chlorpyrifos. Average gross revenue is about $3,352 per acre for Florida oranges, implying impacts of about 0.6% of gross revenue per acre for the more conservative substitution scenario. Given an average of 95,000 acres treated with chlorpyrifos each year (Kynetec 2016; years 2010-2014), total impact is estimated to be between $190,000 and $3.1 million annually.

Table 2.4-17. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Florida Oranges.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Oranges (FL)	$13	Asian Citrus Psyllid	Zeta-cypermethrin [1]	$5	($8)
			Abamectin	$13	<$1
			Petroleum Oil	$15	$2
			Imidacloprid	$15	$2
			Fenpropathrin	$16	$3
		Citrus. Rust Mite/ Mites	Petroleum Oil [1]	$15	$2
			Abamectin [1]	$13	<$1
			Sulfur	$12	($1)
			Spirodiclofen	$26	$13
			Thiamethoxam	$15	$2

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

According to USDA reports, from 2010-2014, an average of 24,700 acres of citrus crops (all citrus) were grown in Texas and 16,300 acres of tangelos and tangerines were cultivated in Florida (USDA 2016a). Approximately 22% of the orange crop is treated with chlorpyrifos in both Florida and California; it seems reasonable that a similar percentage of citrus in Texas and similar crops would be treated with chlorpyrifos as well. Thus, EPA estimates that almost 9,000 acres of other citrus are currently treated annually with chlorpyrifos, on average. Assuming per-acre impacts are similar to the Florida orange scenario, total benefits for these other citrus crops in Florida and all citrus in Texas are estimated to range from $18,000 to $296,000 per year.

Peaches/Nectarines

Chlorpyrifos use on peaches and nectarines is limited to one application per year. For airblast applications, only a dormant or delayed dormant season spray can be made to the canopy. For post-bloom (growing season) applications, only trunk and lower scaffold limb applications are permitted, with spray not allowed to contact fruit. Such trunk applications target the peachtree borer and lesser peachtree borer, both of which have similar biology. One application of chlorpyrifos to the trunk and lower limbs at the rate of 3.0 lbs/100 gal (dilute application) typically provides good to excellent season-long control against borers (PSU, 2013). For these pests, the main alternative is likely to be hand-applied mating disruption dispensers.

Pre-bloom dormant or delayed dormant applications to peaches typically target San Jose scale or white peach scale. Similar to apples, pears, and plums, while petroleum oil is listed as an alternative with a high percentage of crop treated for San Jose scale, oil is often not an efficacious stand-alone tactic. IPM recommendations suggest applications of oil with an insecticide during the dormant/delayed dormant period to target susceptible stages. For San Jose scale, growers may attempt to control the 'crawler' stage (immature scales) later in the growing season using spirotetramat, pyriproxyfen, or pyrethroids (PSU, 2013). Alternatives for these pests can be substitutes for chlorpyrifos on a one for one basis. A single application of one of these alternative chemicals is expected to have efficacy similar to chlorpyrifos.

Because of differences in the share of acreage treated with chlorpyrifos, Georgia and South Carolina peaches are modeled separately from the rest of the country. Chlorpyrifos use on peaches is limited to one application per year. Therefore, as in apples discussed above, two alternatives scenarios are possible. For states other than Georgia and South Carolina, chlorpyrifos applications targeting scale pests ($13/acre) would be replaced by one application of a tank mix of petroleum oil ($22/acre) and esfenvalerate ($6/acre) to control scale pests for a combined cost of about $28/acre or $15/acre more than using chlorpyrifos. For applications to control borers, one application of chlorpyrifos would be replaced with the use of mating disruption ($40/acre), which would cost about $27 per acre more than chlorpyrifos (Table 2.4-18). At the lower bound, applications of phosmet may be feasible at a cost of $8/acre in additional chemical cost. With average gross revenue per acre of about $5,916 per acre for states other than Georgia and South Carolina, this represents 0.1 to 0.5% of gross revenue per acre. Given that about 13% of peach acreage is treated with chlorpyrifos outside of Georgia and South Carolina, EPA estimates 11,100 acres are treated with leading to a benefit estimate of $88,000 to $297,000 in total.

Table 2.4-18. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Peaches and Nectarines.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Peaches/ Nectarines, GA and SC	$8	Peachtree and lesser peachtree borer	No effective alternatives		
			Mating Disruption [1]	$40	$32
			Petroleum Oil [1]	$15	7
			Phosmet	$20	$12

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
		San Jose and white peach scale	Esfenvalerate [1]	$5	($3)
Peaches/ Nectarines, other states	$13	Lesser peachtree borer	Phosmet	$21	$8
			Esfenvalerate	$6	($7)
			Mating Disruption [1]	$40	$27
		San Jose and white peach scale	Petroleum Oil [1]	$22	$9
			Phosmet	$21	$8
			Esfenvalerate [1]	$6	($7)
			Pyriproxyfen	$42	$29
			Acetamiprid	$32	$19

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

EPA received comments on the proposed tolerance revocation that discussed other pests of peach production in Georgia and South Carolina, specifically the lesser peachtree borer (Horton, 2016). EPA evaluated and verified the commenter's information about the pest and agreed with the conclusion that this pest is substantially more important in these states. Chlorpyrifos is used on a higher percentage of the peach acreage in Georgia and South Carolina, so these two states are considered separately. Information from state experts confirmed that alternatives were not effective, and usage data showed that only chlorpyrifos, not esfenvalerate or phosmet, was being used against this pest in this area. For acreage where lesser peachtree borer is uncontrolled, EPA assumes 10% yield loss for the purposes of cost estimation. Lesser peachtree borer reduces yield and shortens the life of the tree, but EPA has been unable to find reliable quantitative estimates for yield losses and shortened tree lifetime in peaches.

Based on information available for Michigan cherry (see the tart cherry section above), we model the yield loss at 10% for the affected acreage. The 10% loss estimate may be on the low end, as over time borers could colonize a larger percentage of the trees in an infested orchard. Gross revenue from peaches in Georgia and South Carolina averaged $4,178 from 2010 – 2014, so 10% yield loss would be about $418 per acre. An average of 17,900 acres were treated with chlorpyrifos in Georgia and South Carolina peaches for 2010 – 2014 (Kynetec, 2016). As a low-end estimate, we include treatments of petroleum oil ($15 per acre) and esfenvalerate ($5 per acre) to replace one treatment of chlorpyrifos at an increase $12 per acre for the control of scale pests. For the high-end estimate, we assume the same replacement at $12 per acre plus $418 per acre in lost revenue. For Georgia and South Carolina, the total benefit is from $215,100 to $7.8 million. This estimate is sensitive to the assumptions about yield loss and the share of treated acreage that will suffer those yield losses, and these are a source of substantial uncertainty. However, because most of the use of chlorpyrifos in these states seems to be targeting borer pests, the total benefit is likely to be in the higher end of this range.

Peanuts
Chlorpyrifos use in peanuts targets soil-dwelling insects: wireworms, rootworms, and borers (Kynetec 2016; years 2010-2014). The lesser cornstalk borer and the southern rootworms feed directly on the pegs and pods of the peanut plants (USDA, 2003b). Wireworms feed directly on

the roots of transplanted peanuts and the seeds (USDA, 2003b). Based on the available data, over the last five years, chlorpyrifos was the most used chemical to control borers and rootworms (Kynetec 2016; years 2010-2014). However, the insecticides used for wireworm control have been more variable. In 2009, aldicarb was the most used chemical to control wireworms, but no use of aldicarb is reported after 2010, because manufacturing ceased. While production of aldicarb has resumed recently, wireworms are not on the current label as target pests in peanut. Phorate was the major chemical used for wireworms in 2010, but use has declined since, perhaps because it can no longer be used at pegging. In 2011 and 2012, chlorpyrifos was the major insecticide for wireworms.

In peanuts, on average chlorpyrifos is applied once per season (Kynetec 2016; years 2010-2014). Table 2.4-19 shows the primary target pests for chlorpyrifos in peanuts, as well as potential alternatives and the difference in cost between the alternatives and chlorpyrifos. For the primary pests targeted by chlorpyrifos, EPA considers phorate and chlorantraniliprole as alternatives, based on market research data (Kynetec 2016; years 2010 – 2014). Of the two, phorate (an organophosphate) is less expensive. Chlorantraniliprole (a member of the relatively new diamide class of insecticides) only controls borers, while phorate controls all three, but is less effective against borers. Chlorpyrifos users would most likely replace one application of chlorpyrifos with one application of phorate to control the pests targeted with chlorpyrifos. The cost of phorate or chlorantraniliprole is lower than chlorpyrifos, but we are assuming that growers will use both chemicals to replace chlorpyrifos. The earlier EPA analysis (EPA 2015) modeled a treatment of diflubenzuron instead of chlorantraniliprole, but information received in public comments lead to revision of the analysis. Cost estimates for chlorantraniliprole are based on only one year of usage data.

Table 2.4-19. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Peanuts.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Peanuts	$21	Borers	Phorate	$14	($7)
			Chlorantraniliprole[1]	$17	($4)
		Rootworms	Phorate[1]	$14	($7)
		Wireworms	Phorate[1]	$14	($7)

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

The alternatives scenario consists of replacing one application of chlorpyrifos ($21/acre) with an application of chlorantraniliprole ($17/acre) to control borers and an application of phorate ($14/acre) to control rootworms and wireworms. The total cost of the alternative regime is $10/acre more than the cost of chlorpyrifos. Gross revenue in peanut is $1,007 per acre, so the additional cost of chlorpyrifos alternatives is about 1% of gross revenue. EPA estimates that an average 114,000 acres of peanuts are treated from 2010 - 2014, implying total benefits of $1.1 million per year. However, as discussed above, using phorate in place of chlorpyrifos might result in yield loss if there is poor control of borers, leading to higher impacts.

Pears

Chlorpyrifos use on pears is limited to one application per year, made as a dormant/delayed dormant application. While applications against pear psylla are most common in terms of acres treated with chlorpyrifos (Kynetec 2016; years 2010-2014), chlorpyrifos plays a very small role relative to other active ingredients to control of this wide-spread pest. For San Jose scale, dormant/delayed dormant applications of chlorpyrifos with oil would target susceptible stages in the early season. While petroleum oil is listed as an alternative for San Jose scale, oil is often not an efficacious stand-alone tactic but is usually mixed with other insecticides, including chlorpyrifos (Murray and DeFrancesco 2014). When early season failures result, pear growers may attempt to control the crawler stage (immature scales) later in the growing season using spirotetramat, pyriproxyfen, buprofezin, and diazinon (Murray and DeFrancesco 2014).

Table 2.4-20 shows the primary target pest for chlorpyrifos in pears, San Jose and other scales, as well as potential alternatives and the difference in cost between the alternatives and chlorpyrifos. The alternative scenario for scale control consists of one application of a tank mix of petroleum oil ($14/acre) and pyriproxyfen ($40/acre). The baseline scenario of using chlorpyrifos is $17/acre and the cost of the alternative scenario is $54/acre. Therefore, the alternative scenario is about $37/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). As chlorpyrifos may also be mixed with oil, the cost increase may only be the additional $23/acre incurred from switching to pyriproxyfen. Compared to chlorpyrifos alone, a combination of oil and lambda-cyhalothrin represents an increase in cost of $5/acre. Average gross revenue is about $8,060 per acre for pears (Appendix A), implying impacts of less than 0.5% of gross revenue per acre. EPA estimates that about 12% of pear acreage is treated with chlorpyrifos annually (Kynetec 2016; years 2010-2014) or about 6,000 acres. Thus, the benefits of chlorpyrifos is estimated to range from $30,000 to $223,000 per year.

Table 2.4-20. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Pears.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Pears	$17	San Jose Scale/Scale Complex	Petroleum Oil [1]	$14	($3)
			Pyriproxyfen [1]	$40	$23
			Lambda-cyhalothrin	$8	($9)
			Spirotetramat	$44	$27

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Pecans

Chlorpyrifos use in pecans primarily targets the pecan nut casebearer (Kynetec 2016; years 2010-2014). The casebearer is a major pest of pecan nuts throughout the pecan growing regions (USDA, 2002). One larva will consume all the nuts in a cluster (USDA, 2003c). Since 2009, growers have chosen chlorpyrifos over other chemicals, in terms of acres treated, followed by methoxyfenozide. Other pests for which chlorpyrifos has been selected include a complex of aphids (Kynetec 2016; years 2010-2014). Aphids can be a problem, especially the black pecan aphid, which possesses a toxin that induces leaf loss, usually impacting the crop the following

year (USDA, 2001). Pecan phylloxera are also targeted with chlorpyrifos, particularly in Georgia (James 2015).

Chlorpyrifos is applied as a foliar treatment to control pecan nut casebearer. Most applications in the past three years have been at application rates of 0.75 to 1 pounds (lb) of active ingredient (ai) per acre. However, the range of application rates extends up to 3.75 to 4 lbs ai/acre. An average of 1.75 chlorpyrifos applications are made per acre (Kynetec, 2016, years 2010 – 2014).

Proper timing of any effective insecticide at the first-generation larvae of pecan nut casebearer will usually prevent subsequent applications (Knutson and Ree, 2015; Mulder and Grantham, undated). Methoxyfenozide, an insect growth regulator, is effective against pecan nut casebearer larvae. Imidacloprid is the primary insecticide used to control aphids in pecans (Kynetec, 2016; years 2010-2014). Chlorpyrifos may be part of a resistance management program for aphids (USDA, 2001). The most common alternative to chlorpyrifos is imidacloprid (Kynetec 2016; years 2010 -2014).

Table 2.4-20 shows the primary target pests for chlorpyrifos in pecan production, as well as the potential alternatives and the difference in cost between the alternatives and chlorpyrifos. The alternatives scenario consists of one application of chlorpyrifos ($8/acre) being replaced by one application of methoxyfenozide ($10/acre) to control pecan nut casebearer and one application of imidacloprid ($9/acre) to control aphids and pecan phylloxera. The total cost of the alternative scenario is $19/acre, about $11/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). However, if only one pest is targeted, the increase in insecticide cost may be only $1 to $2 per acre. Average gross revenue is about $1,127 per acre (Appendix A), implying impacts of less than 1% of gross revenue per acre. Annually, an average of 115,000 pecan acres are treated with chlorpyrifos. Per-acre costs range from $1 to $11, implying total benefits of $115,000 to $1.3 million per year.

Table 2.4-20. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Pecans

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Alternatives ($/acre)	Difference in Cost ($/acre)
Pecans	$8	Pecan Nut Casebearer	Methoxyfenozide [1]	$10	$2
		Aphids and Pecan Phylloxera	Imidacloprid [1]	$9	$1

Source: Kynetec 2016; years 2010-2014, James (2015). Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Plums/Prunes

Chlorpyrifos use in plums and prunes is targeted for the control of San Jose scale. For San Jose scale, dormant/delayed dormant applications of chlorpyrifos with oil would target susceptible stages in the early season. While petroleum oil is listed as an alternative in Table 2.4-21, oil is often not an efficacious stand-alone tactic. For growers missing this early season control window, applications against crawlers later in the season would be made using a number of alternatives to chlorpyrifos.

Table 2.4-21. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Plums/Prunes

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Plums/ Prunes	$16	San Jose Scale/Scale Complex	Petroleum Oil [1]	$17	$1
			Esfenvalerate [1]	$6	($10)
			Pyriproxyfen	$45	$29
			Spirotetramat	$49	$33

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Table 2.4-21 shows the potential alternatives and the difference in cost between the alternatives and chlorpyrifos. Alternatives can be substituted on a one-for-one basis with chlorpyrifos. Both chlorpyrifos and its alternatives could be tank-mixed with oil for a dormant application, and efficacy would be comparable (UC IPM, 2009b). EPA's lower bound alternative, however, assumes that chlorpyrifos ($16/acre) is applied alone and would be replaced by a tank mix of petroleum oil ($17/acre) and esfenvalerate ($6/acre). The baseline scenario of using chlorpyrifos is $16/acre and the cost of the alternative scenario is $23/acre. Therefore, the alternative scenario is about $7/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). An upper bound of per-acre costs would be for growers to switch to spirotetramat, at an increase in insecticide cost of $33/acre. Average gross revenue is about $3,646 per acre for plums/prunes (Appendix A), implying impacts of 0.2% to 0.9% of gross revenue per acre. Chlorpyrifos use is relatively low in plums and prunes; approximately 2,900 acres are treated annually. Total benefits for chlorpyrifos is estimated to range from $20,000 to $96,000 per year.

Sorghum (milo)

The analysis for sorghum was updated more recently than other crops, using usage data from 2014-2018. Sugarcane aphids are the primary target of chlorpyrifos applications in sorghum (Kynetec 2019; years 2014-2018). This species recently became a major problem in sorghum (EPA, 2015b), particularly in southern grain sorghum production areas. Sugarcane aphids insert their piercing-sucking mouthparts into leaves to remove plant sap. Their excrement is in the form of sticky honeydew. Black sooty mold forms on the honeydew, which potentially reduces photosynthetic efficiency. Severe sugarcane aphid infestations prior to flowering or during grain development can reduce yield (Bowling et al, 2016). Harvesting efficiency can also be affected because sticky honeydew that settles on foliage and grain heads causes material to build up in the separator of a combine (see reference in Bowling et al, 2016).

Chlorpyrifos is used early in the season due to a relatively long pre-harvest interval. During 2016, two new products were first registered in sorghum that contained the active ingredients sulfoxaflor and flupyradifurone (Sorghum Checkoff 2016). If these are used in place of chlorpyrifos, there is an additional cost of $3-4 per acre (Table 2.3.22).

Table 2.4-22. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Sorghum

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Sorghum	$4	Sugarcane Aphid/Other Aphids	Sulfoxaflor[1]	$7	$3
			Flupyradifurone	$11	$7

Source: Kynetec, 2016; years 2014-2018. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Table 2.4-22 above shows the potential alternatives and the difference in cost between the alternatives and chlorpyrifos. Alternatives can be substituted on a one-for-one basis with chlorpyrifos. The cost of the baseline scenario using chlorpyrifos is $4/acre and the cost of the alternative scenario is $7/acre. Therefore, the alternative scenario is about $3/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). An upper bound of per-acre costs would be for growers to switch to flupyradifurone, at an increase in insecticide cost of $7acre. Average gross revenue is about $245 per acre for grain sorghum (Appendix A), implying impacts of 1.2% to 2.9% of gross revenue per acre. Chlorpyrifos use averages about 108,000 acres are treated annually. Total benefits for chlorpyrifos is estimated to range from $324,000 to $756,000 per year.

Soybeans

Chlorpyrifos labels allow for multiple applications per year in this crop, including pre-plant soil and post-emergence foliar applications. On average, however, chlorpyrifos is applied once per year to soybeans; only about three percent of acres are treated twice (Kynetec 2016; years 2010-2014). Nationally, the average application rate is 0.36 lb ai/acre. The major pests targeted by chlorpyrifos in soybean production are shown in Table 2.4-23.

Soybean aphid is the leading target pest for chlorpyrifos applications to soybeans, by acres treated (Kynetec 2016; years 2010-2014). This invasive insect from Asia is a sap feeding pest that occurs sporadically over much of the United States, requiring applications of one or more foliar insecticides. Likely alternatives for this pest would be foliar applications of lambda-cyhalothrin, thiamethoxam, or imidacloprid. Thiamethoxam and imidacloprid have systemic activity, while lambda-cyhalothrin has broad-spectrum knockdown activity. Spider mites and bean leaf beetles are also targeted by applications of chlorpyrifos, with similar efficacy observed among the same alternatives listed for soybean aphid: lambda-cyhalothrin, thiamethoxam, and imidacloprid (Kynetec 2016; years 2010-2014). The most likely substitution scenarios for soybean growers in the absence of chlorpyrifos would be to apply any of these available alternatives, with substitution on a one-for-one basis with chlorpyrifos.

Table 2.4-23. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Soybeans

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternative	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Soybeans	$3	Soybean Aphid	Lambda-cyhalothrin	$4	$1
			Thiamethoxam [1]	$7	$4
			Imidacloprid	$8	$5
		Bean Leaf Beetle	Lambda-cyhalothrin	$4	$1
			Thiamethoxam [1]	$7	$4
			Imidacloprid	$8	$5
		Spider Mite	Lambda-cyhalothrin	$4	$1
			Thiamethoxam [1]	$7	$4
			Imidacloprid	$8	$5

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemical used to estimate the cost of control in the absence of chlorpyrifos. One application of thiamethoxam is expected to control either or both the soybean aphid and the bean leaf beetle.

EPA's alternatives scenario consists of one application of chlorpyrifos ($3/acre) per season being replaced by one application of thiamethoxam ($7/acre) to control soybean aphid and bean leaf beetle. The baseline scenario of using chlorpyrifos is $3/acre and the cost of the alternative scenario is $7/acre. Therefore, the alternative scenario is about $4/acre more expensive than chlorpyrifos (difference may not be exact due to rounding). However, costs could be as low as $1/acre with the use of lambda-cyhalothrin. Average gross revenue is about $526 per acre, implying impacts of about 0.2% to 0.8% of gross revenue per acre. EPA estimates that almost 3.1 million acres of soybean are treated annually with chlorpyrifos, so the total benefit ranges from $3.1 million to $12.2 million.

Strawberries

Chlorpyrifos use in strawberries targets a complex of lepidopteran larvae, including cutworms and various armyworms (Kynetec 2016; years 2010-2014). Early in the season, these pests will eat foliage and even the crown of young plants. Later in the season, these larvae feed directly on the berries (Mossler, 2012; UC IPM, 2014c). Chlorpyrifos is used early in the season, as there is a 21-day pre-harvest interval.

EPA received comments on pests specific to strawberry production in Oregon, specifically the soil pest, garden symphylan (Unger, 2016). Earlier usage data confirm that symphylans are the main pest targeted with chlorpyrifos in Oregon (Kynetec 2016; years 2010-2014), although usage data are no longer collected for Oregon strawberries. Furthermore, it appears that chlorpyrifos is the only pesticide used to control garden symphylans in this crop. Extension descriptions confirm that symphylans can sometimes be significant pests of newly planted strawberries and other crops in western Oregon (Jesse and Dreves 2020).

For the lepidopteran larvae, methoxyfenozide (an insect growth regulator) is the most likely alternative to chlorpyrifos but would not have any impact on other pests that might be present, such as the strawberry bud weevil. *Bacillus thuringiensis* (*Bt*) is a biopesticide with a very short pre-harvest interval (PHI). It is used multiple times during the harvest season, especially in organic production, but also in conventional strawberry production. Therefore, *Bt* may be

applied to strawberries that have had chlorpyrifos applied earlier in the season. *Bt* is effective on only young lepidopteran larvae. As a conservative estimate, without chlorpyrifos, there may be three to five additional applications of *Bt*. There may be other pesticides needed for control of pests other than lepidopterans.

Table 2.4-24 shows the primary target pest for chlorpyrifos in strawberry as well as potential alternatives and the difference in cost between the alternatives and chlorpyrifos. For the primary pests targeted by chlorpyrifos, *Bt* and methoxyfenozide are the alternatives, as both control a variety of lepidopteran larvae. The reported cost for *Bt* represents five applications because multiple *Bt* applications that would be needed to replace one application of chlorpyrifos in strawberry. A single application of methoxyfenozide could replace one application of chlorpyrifos in strawberry to control lepidopteran larvae.

Table 2.4-24. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Strawberry.

Crop	Cost of Chlorpyrifos ($/Acre)	Target Pest	Alternatives to Chlorpyrifos	Cost of Alternatives	Difference in Cost ($/acre)
Strawberry, Other than Oregon	$10	Lepidopteran Larvae ("Worms")	*Bt* [1]	$75 ($15.50 up to 5x)	$65
			Methoxyfenozide [1]	$20	$10
			Spinetoram	$48	$38
			Chlorantraniliprole	$27	$17
Strawberry, Oregon	$12	Garden Symphylan	No Effective Alternatives		
		Weevil Complex	Carbaryl	$18	$6

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. *Bt* cost reflects multiple applications to achieve similar control.

The alternatives scenario consists of either five applications of *Bt* or one application of methoxyfenozide (states other than Oregon). The cost for one application of chlorpyrifos is $10 per acre. The cost for five applications of *Bt* to replace one application of chlorpyrifos is approximately $75 per acre while a single methoxyfenozide application is about $20 per acre. Therefore, the estimated alternative scenarios cost about $10 to $65 per acre more than chlorpyrifos. Average gross revenue is about $42,821 per acre (Appendix A), implying impacts of less than 0.1% of gross revenue per acre. On average, about 10,500 acres of strawberry are treated with chlorpyrifos outside Oregon. Total benefits for strawberry would cost growers in areas outside Oregon between $105,000 and $686,000 per year.

In Oregon, growers using chlorpyrifos to target multiple species of weevils might use carbaryl as an alternative. The average cost for chlorpyrifos is $12/acre while carbaryl averages $18/acre, an increase of $6/acre in chemical cost. Strawberry crown moth is another pest for which chlorpyrifos is recommended, but usage data show more use of carbaryl against this pest in Oregon (Kynetec 2016; years 2010 – 2014). Nearly all chlorpyrifos use, however, targets symphylans, for which there are no effective alternatives. Because there are no effective alternatives (Unger, 2016), yield loss estimates are 100% in the fields infested with symphylans without effective control. USDA yield and price data were used to calculate gross revenue per

acre of $7,813 per acre in Oregon strawberry (USDA, 2016c). The affected acreage that is treated with chlorpyrifos averages 600 acres, annually, but 545 acres of chlorpyrifos acres are targeting symphylans annually (Kynetec 2016; years 2010 - 2014). The total incremental cost estimate for Oregon strawberry ranges from a low of $3,600, which assumes all acres are only targeting weevils, to about $4.3 million. Given the high proportion of acreage treated for garden symphylan, the cost is likely near the upper bound. This cost to Oregon growers is in addition to the cost estimated in the previous paragraph to growers outside of Oregon accounts for all affected strawberry acreage nationally. The total benefit in strawberry is estimated to be $109,000 to $5.0 million annually.

Sugarbeets

The analysis for sugarbeets was updated more recently than other crops, using usage data from 2014-2018. Nationally, chlorpyrifos use in sugarbeets primarily targets sugarbeet root maggot and leafminers (Kynetec 2016; years 2014-2018). Applications targeting root maggots are likely to be made at planting, while applications targeting leafminers would be foliar sprays or post crop emergence. Published extension recommendations (Hollingsworth 2019) indicate that there are several foliar insecticides that can control leafminer outbreaks, such as zeta-cypermethrin, azadirachtin, clothianidin, thiamethoxam, and spinosad, so substitution for alternatives with chlorpyrifos would be one-for-one to control that pest. For maggots, neonicotinoid seed treatments are registered, used widely, and known to be effective. For a seed treatment scenario, there would also be a potentially saving in the cost of applying chlorpyrifos (*i.e.*, no equipment and fuel costs for a separate at-planting application). For the other alternatives applied to soil, substitution would be one-for-one with chlorpyrifos.

Particularly important problems with sugarbeet root maggot were identified by industry experts in a few counties in the Minnesota counties of Clay, Kittson, Marshall, Norman, Polk and Wilkin, and the North Dakota counties of Grand Fork, Pembina, Traill and Walsh (Kahn, 2016). Experts estimate that without adequate control, infestation of sugarbeet root maggot in these areas can lead to yield losses of 45% (Boetel, 2016).

Outside Minnesota and North Dakota, an alternative scenario in the absence of chlorpyrifos consists of one application of a clothianidin seed treatment ($22/acre) at-planting to control sugarbeet root maggot and one foliar application of zeta-cypermethrin ($4/acre) to control leafminers, replacing two applications of chlorpyrifos ($6/acre each) (Table 2.4-25). The baseline scenario of using chlorpyrifos is $12/acre and the cost of the alternative scenario is $26/acre. Therefore, the alternative scenario is about $14/acre more expensive than chlorpyrifos. Per-acre cost would be similar for a single pest, with a clothianidin seed treatment costing $10 more than a single treatment of chlorpyrifos (Table 2.4-25). Average gross revenue from 2014 - 2018 outside of Minnesota and North Dakota is about $1,440 per acre (Appendix A), implying impacts of 0.9% of gross revenue per acre. On average, 140,000 acres are treated with chlorpyrifos in states other than Minnesota and North Dakota, implying total benefits of $1.8 million per year.

Table 2.4-25. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Sugarbeets.

Crop	Cost of Chlorpyrifos ($/Acre)	Target Pest	Alternatives to Chlorpyrifos	Cost of Alternatives	Difference in Cost ($/acre)
Sugarbeets, other states	$6	Leafminer	Zeta-cypermethrin [1]	$4	($2)
			Cyfluthrin (ST)	$4	($2)
			Clothianidin (ST)	$22	$16
		Sugarbeet Root Maggot	Clothianidin (ST) [1]	$22	$16
			Cyfluthrin (ST)	$4	($2)
			Terbufos	$17	$11
			Zeta-cypermethrin	$3	($3)
Sugarbeets, MN	$6	Cutworm	Clothianidin (ST)	$22	$16
			Cyfluthrin (ST)	$4	($2)
			Terbufos[1]	$17	$11
			Zeta-cypermethrin	$4	($2)
		Sugarbeet Root Maggot	Clothianidin (ST)	$22	$16
			Cyfluthrin (ST)	$4	($2)
			Terbufos	$17	$11
			Zeta-cypermethrin	$3	($3)
			No effective alternatives in heavily infested areas[1]	45% yield loss	
Sugarbeets, ND	$6	Sugarbeet Root Maggot	Clothianidin (ST)	$22	$16
			Cyfluthrin (ST)	$4	($2)
			Terbufos	$17	$11
			Zeta-cypermethrin	$3	($3)
			No effective alternatives in heavily infested areas[1]	45% yield loss	

Source: Kynetec 2016; years 2014-2018. Numbers may not add due to rounding. ST denotes a seed treatment. Kynetec no longer tracks the cost of seed treatments, so the seed treatment cost data are based on use from 2010 – 2014.

Footnote:

[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

In Minnesota and North Dakota, sugarbeet root maggot is the primary pest, and cutworm appears to be a target of chloropyrifos in MN. Alternatives to chlorpyrifos for maggot and cutworm control would be clothianidin seed treatments, costing $16 per acre more than chlorpyrifos, or a soil application of terbufos, costing about $11 acre more than chlorpyrifos (Table 2.4-25). To target adults of the root maggots, growers in heavily affected counties might use a foliar application of a pyrethroid, but instead we model yield losses of 45% from poor control, based on Boetel (2016). Gross revenues are calculated from USDA yield and revenue data, and average about $1,100 per acre in both states from 2014-2018 (USDA 2020), so yield losses are estimated at $498 per acre in North Dakota and Minnesota. The total estimated incremental costs from chlorpyrifos tolerances, given an average of 61,200 affected acres in Minnesota and North Dakota, is $900,000 to $30.5 million per year. However, acres in the counties identified as severely affected by root maggot account for less than 20% of chlorpyrifos-treated acres in Minnesota and about 10% of chlorpyrifos-treated acres in North Dakota (Kynetec 2016; years 2014-2018), so total annual costs are likely to be about $5.1 million annually. These costs are in addition to the costs in other states estimated in the previous paragraph. The total benefit of chlorpyrifos for all sugarbeet is estimated to be $2.6 to $32.2 million per year. However, the benefit is likely closer to $6.8 million when considering the limited extent of severe sugarbeet root maggot problems that would remain uncontrolled without chlorpyrifos.

Sunflowers

Chlorpyrifos use in sunflower targets a mix of lepidopteran larvae, or caterpillars (Kynetec 2016; years 2010-2014). There are several moth pests in the sunflower growing regions. Cutworms live in the soil and reduce the establishment of the stand (USDA, 1999b). Chlorpyrifos has been used as a soil treatment at plant for these soil pests, but in more recent years, neonicotinoid seed treatments are more likely to be used to control cutworms. Other moths that feed on foliage or sunflower heads are treated with foliar applications.

Table 2.4-26 shows the primary target pest for chlorpyrifos in sunflower as well as the potential alternatives and the difference in cost between the alternatives and chlorpyrifos. For the primary foliar pests targeted by chlorpyrifos, lambda-cyhalothrin and esfenvalerate, among other synthetic pyrethroids, are the alternatives used to control lepidopteran larvae. Costs are essentially the same but the synthetic pyrethroids are used more than chlorpyrifos in terms of acres treated.

Table 2.4-26. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Sunflower.

Crop	Cost of Chlorpyrifos ($/Acre)	Target Pest	Alternatives to Chlorpyrifos	Cost of Alternatives	Difference in Cost ($/acre)
Sunflower	$4	Lepidopteran Larvae	Lambda-cyhalothrin	$4	<$1
			Esfenvalerate [1]	$4	<$1

Source: Kynetec, 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

The alternatives scenario consists of one application of chlorpyrifos ($4/acre) being replaced with one application of esfenvalerate ($4/acre) to control lepidopteran larvae. The alternatives scenario costs approximately the same as, or about $1/acre more than, chlorpyrifos. Average gross revenue is about $352 per acre (Appendix A), implying impacts of less than 0.1% of gross revenue per acre. EPA estimates that about 123,000 acres of sunflower are treated annually with chlorpyrifos, which signifies a total benefit nationally of less than $123,000 per year.

Sweet Corn

Chlorpyrifos is used to control several sweet corn pests, primarily soil pests that include corn rootworms, seedcorn maggot, garden symphylan, and wireworms but also foliar pests such as cutworms and armyworms (Kynetec 2016; years 2010-2014). Most chlorpyrifos usage targets soil pests with pre-plant or at-planting applications to soil. Some small amount of usage are foliar applications, which could also control adult rootworms (beetles) during the growing season. About 10% of the treated area is treated more than once (Kynetec 2016; years 2010-2014).

Chlorpyrifos is also registered as a seed treatment use on sweet corn. Because seed treatment usage data were not available for sweet corn, the percent of the crop treated is underestimated and thus the benefits of chlorpyrifos may also be underestimated.

Garden symphylan is mainly a regional concern in the Pacific Northwest, particularly Oregon. While this pest accounts for a small amount of chlorpyrifos usage nationally, the data suggest that this is a significant pest targeted by chlorpyrifos applications in Oregon, again via soil applications at planting.

Substitution with other at-plant soil-applied materials would be one-for-one with chlorpyrifos. Besides other broad-spectrum insecticide applications, seed treatments with neonicotinoid insecticides provide control of the soil pest complex, though control of rootworm is highly rate-dependent. Usage of neonicotinoid seed treatments could potentially save the additional cost of an at-plant application. However, if growers are making soil applications, it is likely that they would substitute a soil application of bifenthrin, tefluthrin (except in California), or terbufos for chlorpyrifos (Table 2.4-27). For foliar pests, replacement of chlorpyrifos with a foliar alternative like methomyl or a synthetic pyrethroid would be likely. Neonicotinoid seed treatments are available as a possible replacement for chlorpyrifos-treated seed for sweet corn, but EPA does not have data on their use or any cost differences as compared to chlorpyrifos treatments.

Table 2.4-27. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Sweet Corn.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Sweet Corn	$15 (soil application)	Rootworm	Bifenthrin	$12	($3)
			Lambda-cyhalothrin	$5	($7)
			Tefluthrin [1]	$16	$1
		Seed Maggot/ Wireworm	Bifenthrin	$12	($3)
			Phorate	$15	<$1
			Tefluthrin [1]	$16	$1
		Garden Symphylan	Bifenthrin	$12	($3)
			Terbufos	$17	$2
			Chlorethoxyfos	$15	(<$1)
			Tefluthrin [1]	$16	$1
	$8 (foliar application)	Armyworm/ Cutworm	Methomyl [1]	$10	$2
			Lambda-cyhalothrin	$5	($3)
			Zeta-cypermethrin	$5	($3)

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. One application of tefluthrin is expected to control all soil pests. However, this insecticide is not registered in California.

EPA's projected alternatives scenario consists of replacing one soil application of chlorpyrifos ($15/acre) with one application of tefluthrin ($16/acre) to control corn rootworms, garden symphylan, seedcorn maggot, and wireworms. Replacing one foliar application of chlorpyrifos ($8) would entail one foliar application of methomyl ($10/acre) to control cutworms and/or armyworms. In total, the chlorpyrifos regime would cost $23/acre per year while the alternative strategy of tefluthrin and methomyl would cost about $26/acre per year. This implies an increase in pest control costs of about $3/acre per year. For any single application, increases in cost may range from $1 to $2/acre. Gross revenue in sweet corn, considering both fresh and processing, averages $1,890/acre. The increase in cost represents about 0.2% of gross revenue. An average of 54,300 acres of sweet corn are treated with chlorpyrifos each year. Total benefits are estimated to range from $54,000 to $163,000 annually. Tefluthrin is not registered in California,

so growers there would need to use another alternative. As the other alternatives are less expensive, the national estimates are overestimates for California. There may be somewhat different impacts for growers replacing seed treatments, but they are unlikely to be significant. In field corn, neonicotinoid seed treatments are less expensive and much more widely used that chlorpyrifos, so they may be a viable alternative in sweet corn.

Tobacco

Chlorpyrifos use in tobacco is to control cutworm caterpillars and wireworms (beetle larvae), both soil insect pests (Kynetec, 2016; years 2010-2014). These insect pests occur more often when tobacco follows sod, tobacco, or corn (USDA, 2008). These insects are considered minor or occasional pests in most tobacco growing regions (USDA, 1999c). In past years, chlorpyrifos and acephate have been used as a soil treatment prior to transplant to control these pests. More recently, fumigations and ethoprop, applied for nematode control, also controls wireworms (USDA, 1999c; USDA, 2008). Newer chemicals, such as imidacloprid, that target major lepidopteran (caterpillar) pests will also control cutworms.

Currently one application of chlorpyrifos ($11/acre) is used to control cutworms and wireworms in tobacco. The alternatives scenario consists of replacing one application of chlorpyrifos with one application of imidacloprid ($15/acre) to control cutworms and/or wireworms. The scenario is about $4/acre more expensive than chlorpyrifos. Gross revenue averages $4,247 per acre (Appendix A), implying impacts of less than 0.1% of gross revenue. On average, about 37,300 acres of tobacco are treated annually with chlorpyrifos. The total benefit of chlorpyrifos tolerance is estimated to be $149,000 per year.

Table 2.4-28. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Tobacco.

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternative	Cost of Alternative ($/acre)	Difference in Cost ($/acre)
Tobacco	$11	Cutworms and Wireworms	Acephate	$7	($4)
			Imidacloprid [1]	$15	$4

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
Footnote:
[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos.

Walnuts

Chlorpyrifos use on walnuts is limited to two applications per year, including dormant/delayed dormant sprays and in-season foliar sprays. On average, about half the acreage treated with chlorpyrifos is treated once per year, and the other half is treated twice per year Chlorpyrifos is applied once on about half of the treated acreage, while the other half is treated twice per year (Kynetec 2016; years 2010-2014). Most chlorpyrifos usage, in terms of acres treated, is for walnut husk fly and/or codling moth. There are numerous effective alternatives available for both pests (Kynetec 2016; years 2010-2014). For walnut husk fly, a bait-based attract-and-kill strategy is recommended with a number of effective insecticide components mixed with a fly attractant (UC IPM, 2013a). For codling moth, early and mid-season foliar chlorpyrifos applications are made to target egg hatch, but several alternatives are available for effective

control of this pest (UC IPM, 2013b). For navel orangeworm, another chlorpyrifos-target pest, cultural control tactics are recommended as a primary management strategy in walnuts, with insecticidal treatments mostly considered for applications targeting the third flight of adult moths (UC IPM, 2011a).

Table 2.4-29 shows the primary target pests for chlorpyrifos in walnuts as well as potential alternatives and the difference in cost between the two. EPA projects that one application of bifenthrin with bait ($16/acre) would replace one application of chlorpyrifos with bait ($19/acre) for control of walnut husk fly. A second application of bifenthrin would also replace one separate application of chlorpyrifos for control of codling moth at some point in the season. Since bifenthrin is less expensive than chlorpyrifos, no impact is projected, but EPA cannot explain why growers do not already follow this program. Given that usage data (Kynetec, 2016 years 2010 – 2014) indicates an overall preference by growers for chlorpyrifos over similarly priced or even less expensive pyrethroid and neonicotinoid alternatives, uncertainty remains as to whether efficacy or other IPM considerations may drive other potential benefits of chlorpyrifos usage on walnuts. More reasonable alternatives for walnut husk fly might be malathion ($2/acre more than chlorpyrifos – lower bound impact) or acetamiprid or spinosad at $18/acre more than chlorpyrifos. Methoxyfenozide ($6/acre more than chlorpyrifos) or chlorantraniliprole ($18/acre more than chlorpyrifos) could replace chlorpyrifos for control of codling moth or navel orangeworm. At the upper bound, one application each of acetamiprid and chlorantraniliprole could replace two chlorpyrifos applications for $36/acre increase in insecticide cost. Average gross revenue is about $5,591 per acre (Appendix A). EPA estimates that 124,000 acres of walnut are treated annually; the total benefit of chlorpyrifos for walnuts is estimated to range from $248,000 to $4.5 million per year.

Table 2.4-29. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Walnuts

Crop	Cost of Chlorpyrifos ($/acre)	Target Pest	Alternatives	Cost of Alternatives ($/acre)	Difference in Cost ($/acre)
Walnuts	$19	Walnut Husk Fly	Bifenthrin	$16	($3)
			Acetamiprid	$37	$18
			Esfenvalerate	$9	($11)
			Spinosyn	$37	$18
			Imidacloprid	$8	($11)
			Malathion[1]	$21	$2
			Spinetoram	$38	$19
		Codling Moth	Bifenthrin [1]	$16	($3)
			Chlorantraniliprole	$37	$18
			Esfenvalerate	$8	($11)
			Lambda-cyhalothrin	$6	($13)
			Acetamiprid	$37	$18
			Methoxyfenozide	$25	$6
			Imidacloprid	$8	($11)
			Spinetoram	$38	$19
		Navel Orangeworm	Chlorantraniliprole	$37	$18
			Bifenthrin	$16	($3)
			Permethrin	$6	($13)

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding. *Footnote*:

[1] Chemicals used to estimate the cost of control in the absence of chlorpyrifos. Two applications of chlorpyrifos are permitted and bifenthrin could be used for either.

Other Crops
Chlorpyrifos is also registered on sites for which use is relatively small in terms of acres treated compared to acres grown. A low proportion of treated acres frequently indicates that cost-effective alternatives are available and/or that targeted pests are not particularly damaging. Table 2.4-30 presents information on the pests targeted by chlorpyrifos and some potential alternatives in order to estimate benefits for chlorpyrifos on these crops.

Table 2.4-30. Chlorpyrifos Target Pests, Alternatives, and Chemical Costs, Various Sites

Crop	Target Pest	Control method	Cost ($/acre)	Difference in Cost Between Control Method and Chlorpyrifos ($/acre)
Apricot	Borers	Chlorpyrifos	$7	
		Esfenvalerate	$5	($2)
		Methoxyfenozide	$21	$14
Beans, succulent	Symphylans, Maggots	Chlorpyrifos	$9	
		Ethoprop	$38	$29
		Bifenthrin	$3	($6)
Beans, dry	Red Spider Mite, Wireworms	Chlorpyrifos	$5	
		Malathion	$5	($<1)
		Zeta-cypermethrin	$2	($3)
		Ethoprop	$24	$19
Corn, field	Corn Rootworm	Chlorpyrifos	$9	
		Tefluthrin	$17	$8
		Tebupirimphos*	$15	$6
		Bifenthrin	$7	($2)
Peas, succulent	Maggots	Chlorpyrifos	$10	
		Esfenvalerate	$5	($5)
		Bifenthrin	$3	($7)
		Neonicotinoid Seed Treatment	$20-$75	$10-$65
Peppers	Aphids and Thrips	Chlorpyrifos	$8	
		Imidacloprid	$18	$10
		Spinetoram	$38	$30
Tomato	Caterpillars	Chlorpyrifos	$10	
		Methoxyfenozide	$17	$7
Wheat, Spring	Aphids	Chlorpyrifos	$3	
		Lambda-Cyhalothrin	$3	<$1
		Cyfluthrin	$3	(<$1)
		Thiamethoxam	$4	$1
		Imidacloprid	$2	($1)
Wheat, Winter	Aphids and Mites	Chlorpyrifos	$4	
		Imidacloprid	$4	(<$1)
		Thiamethoxam	$4	<$1

Source: Kynetec 2016; years 2010-2014. Numbers may not add due to rounding.
*Another common name for this active ingredient is phostebupirim; not available in California.

The benefits of chlorpyrifos in apricot are probably similar to other stone fruit, especially plums and prunes since most commercial production is in California. Insecticide costs in plums and prunes are expected to range between $7 and $33/acre more than with use of chlorpyrifos (Table

2.4-23). Borers are the primary chlorpyrifos target in apricot, but it is not a primary method of control (Kynetec 2016; years 2010-2014). Synthetic pyrethroids, such as esfenvalerate, tend to be less expensive than chlorpyrifos; methoxyfenozide is about $14/acre more expensive. EPA estimates that about 100 acres of apricot are treated each year, implying total benefits of $1,000 to $3,000 annually, using the range in cost estimated for plums and prunes.

Soil-dwelling pests are targeted by chlorpyrifos in green and other succulent beans (Kynetec 2016; years 2010-2014). Some of these pests, for example symphylans, are reported to be particularly problematic in other vegetables or in crops like strawberry. Symphylans appear to be a rare problem in beans, however; less than two percent of the crop is treated with chlorpyrifos. Alternatives may be expensive; ethoprop costs $29/acre more than a chlorpyrifos treatment. On average, about 4,700 acres of beans are treated annually, implying total benefits of chlorpyrifos in beans of $137,000 per year.

In dry beans, chlorpyrifos targets red spider mite and wireworms (Kynetec 2016; years 2010 – 2014). For both pests, there are multiple alternatives in use that are similar in cost to chlorpyrifos, although growers also use ethoprop to target wireworms at a cost of $19 per acre more than chlorpyrifos. On average, about 6,200 acres of dry beans are treated with chlorpyrifos annually, implying the total benefits of $0 to $118,000 annually.

Chlorpyrifos is mainly used for corn rootworm control in field corn (Kynetec 2016; years 2010-2014). Most of the acres treated with chlorpyrifos are treated at planting, but some are treated later in the season. Rootworm is mainly controlled at planting with plant incorporated protectants (PIPs) or seed treatments, including seed treated with chlorpyrifos. Chlorpyrifos may be used with PIPs, but it is often applied to conventional corn or herbicide-tolerant corn without traits for rootworm control. Due to restrictions on acreage planted to PIPs for resistance management purposes, they are unlikely to provide an alternative for chlorpyrifos. Neonicotinoid seed treatments may provide an option, but they tend to be less expensive, which implies chlorpyrifos is used in situations where neonicotinoids are inappropriate. As shown in Table 2.4-30, tefluthrin and tebupirimphos, as a soil application, are the most likely alternatives and cost $6 to $8 per acre more than chlorpyrifos. Either could also be used to replace a chlorpyrifos application later in the season. On average, 677,000 acres per year of corn are treated with chlorpyrifos. The total benefits for corn is estimated to be $4.1 to $5.4 million annually.

For green peas, the main target pests of chlorpyrifos use are seed maggots (Kynetec 2016; years 2010-2014). Alternative insecticides used in peas for control of seed maggots are synthetic pyrethroids, which are generally cheaper than chlorpyrifos. EPA assumes that chlorpyrifos is chosen in situations when pyrethroids would not provide adequate control. As with onion (Table 2.4-15), neonicotinoid-treated seeds may be a feasible option, implying an increase in control cost of $10 to $65 per acre. This assumes onion seed treatments are a reasonable approximation of seed cost. Maggots may be particularly damaging at crop germination, similar to *Brassica* crops, and control failure could lead to substantial losses. If yield loss is similar to the situation in *Brassica*, i.e., about 48%, impacts could be as high as $370 per acre. Less than 500 acres of green peas are treated annually, so total benefit to producers of green peas might range from $4,000 to $166,000 per year.

Chlorpyrifos is primarily used to control aphids and thrips in peppers (Kynetec 2016; years 2010-2014). As shown in Table 2.4-30, alternatives such as imidacloprid and spinetoram cost,

on average, $10 to $30 per acre more than does chlorpyrifos. Given an average of about 500 acres of peppers treated each year with chlorpyrifos, estimates of the total benefit to pepper producers range from $5,000 to $15,000 per year.

Very little chlorpyrifos is used in tomato production; caterpillars, such as armyworms and cutworms, appear to be the primary target pests. There are numerous alternatives registered, with methoxyfenozide the most commonly used chemical control. As shown in Table 2.4-30, use of methoxyfenozide instead of chlorpyrifos may increase costs to the grower by about $7/acre. As only about 1,600 acres of tomato are treated with chlorpyrifos per year, on average, the benefits of chlorpyrifos is about $11,000 annually.

Chlorpyrifos is largely used for aphid control in spring and winter wheat (Kynetec 2016; years 2010-2014). There are several alternatives, particularly neonicotinoid insecticides like imidacloprid and thiamethoxam, that are similar in cost. Per acre, any increase in cost is likely to be under $1/acre. About 783,000 acres of spring wheat and 549,000 acres of winter wheat are treated annually with chlorpyrifos. Total benefit, therefore, ranges from $0 to $783,000 for spring wheat and up to $549,000 for winter wheat.

There are three sites for which chlorpyrifos is registered, figs, kiwifruit, and pistachio, that are primarily grown in California. California pesticide use reports show that less than 10 fields, covering just over 100 acres of these three crops, were treated with chlorpyrifos in the five years between 2010 and 2014. Similarly, market research data (Kynetec 2016; years 2010 – 2014) show negligible use of chlorpyrifos on celery and garlic (also primarily grown in California) from 2010 to 2014. Given the lack of consistent chlorpyrifos usage, EPA concludes that there is likely no significant benefit to growers of these crops.

Finally, chlorpyrifos is registered as a seed treatment for several vegetable crops, most notably cantaloupe, watermelon, cucumber, pumpkin, and squash. EPA does not have data as to the extent that chlorpyrifos-treated seeds are used and received no public comments regarding usage. In place of chlorpyrifos-treated seeds, growers could use seeds treated with other insecticides or make soil applications at planting. According to Kynetec (2016) years 2010-2014), there are numerous pesticides used for these vegetables at planting, ranging in cost from $3 to $36/acre. The most commonly used insecticide, imidacloprid, costs about $18/acre (Kynetec 2016). These costs would overstate the incremental cost of the chemical replacing chlorpyrifos, since it does not account for the cost of the seed treatment. There may be some increase in application costs if growers switched from seed treatment to a soil application, but since the application would accompany the planting operation, additional labor and machinery costs may be small. EPA has no information regarding the acreage that might be affected.

In addition to these crops, EPA did not estimate costs of control for livestock uses of chlorpyrifos. Most livestock-related active registrations of chlorpyrifos are for treatment of housing and processing premises. The only direct use of chlorpyrifos in U.S. livestock production is for a cattle ear tag to repel and kill flies. The benefits of chlorpyrifos for this use are discussed qualitatively in a separate assessment by BEAD (US EPA, 2020c).

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Appendix A. Grower Revenue

EPA utilized data on area cultivated and value of production from the National Agricultural Statistics Service (NASS) of USDA to calculate average gross revenue per acre. A five-year (2010 – 2014) average is used unless recent price increases indicate substantially higher revenues currently.

Crop	Acres Harvested (Avg. Annual)	Gross Revenue (Avg. Annual)	Gross Revenue (Avg. Annual $ per acre)
ALFALFA (hay)	18,375,000	$10,038,403,600	$546
ALMONDS	822,000	$5,100,158,000	$6,205
APPLES	326,730	$2,892,088,600	$8,852
APRICOTS	11,404	$45,578,800	$3,997
ASPARAGUS	25,680	$86,513,000	$3,369
BEANS/PEAS (Dry)	1,533,180	989,730,200	$646
BEANS (Snap, Bush, Pole, String)	157,464	$249,372,100	$1,584
BROCCOLI[1]	124,920	$878,913,800	$7,036
CABBAGE[1]	57,434	$401,307,200	$6,987
CANOLA	1,400,560	$469,069,600	$335
CAULIFLOWER[1]	40,976	$396,934,600	$9,687
CELERY	28,580	$376,764,000	$13,183
CHERRIES (sweet)	87,378	$786,386,200	$9,000
CHERRIES (tart)	37,070	$74,307,600	$2,005
CORN (grain)	84,655,400	$66,043,095,400	$780
COTTON	9,274,520	$6,192,680,600	$668
CRANBERRIES	39,980	$314,384,800	$7,864
CUCUMBERS (fresh market)	39,980	$191,819,200	$4,877
CUCUMBERS (processing)	39,328	$174,862,000	$2,074
GARLIC	84,324	$255,807,200	$10,514
GRAPEFRUIT	24,330	$270,440,800	$3,731
GRAPES (raisin)	72,480	$792,405,000	$3,942
GRAPES (table)	201,000	$1,200,629,600	$11,435
GRAPES (wine)	105,000	$2,887,594,600	$4,876
HAZELNUTS	592,200	$94,470,000	$3,224
LEMONS	29,300	$454,421,000	$8,268
MINT	54,960	$191,789,600	$2,080
ONIONS	92,160	$919,155,000	$6,322
ORANGES (FL)	434,460	$1,456,223,400	$3,352
ORANGES (CA)	177,444	$759,065,600	$4,278
PEACHES	83,656	$493,190,600	$5,495
PEANUTS	1,261,020	$1,269,374,000	$1,007
PEARS	51,720	$416,869,800	$8,060
PEAS (Fresh/Green/Sweet)	179,700	$138,392,200	$770
PECANS (in shell)	4,938,401	$556,737,800	$1,127

Crop	Acres Harvested (Avg. Annual)	Gross Revenue (Avg. Annual)	Gross Revenue (Avg. Annual $ per acre)
PEPPERS (bell)	45,940	$589,605,400	$12,834
PEPPERS (chile)	20,920	$163,307,000	$7,806
PISTACHIOS	179,200	$1,389,330,000	$7,753
PLUMS / PRUNES	74,800	$272,710,000	$3,646
POTATOES	1,065,580	$3,990,486,000	$3,745
PUMPKINS	49,060	$133,716,800	$2,726
SORGHUM[1]	6,104,000	$1,497,555,800	$245
SOYBEANS	77,074,800	$40,578,872,000	$526
SQUASH	41,306	$218,161,600	$5,282
STRAWBERRIES	58,551	$2,507,214,000	$42,821
SUGARBEETS[1] (Except MN and ND)	498,260	718,550,000	$1,442
SUGARBEETS[1] (MN and ND)	627,400	693,810,400	$1,106
SUNFLOWER	1,629,260	$572,820,200	$352
SWEET CORN (fresh market)	223,326	$734,824,200	$3,290
SWEET CORN (processing)	330,912	$312,695,800	$945
SWEET CORN (combined)	554,238	$1,047,520,000	$1,890
TOBACCO	346,564	$1,471,710,200	$4,247
TOMATOES (fresh market)	100,302	$1,125,381,200	$11,220
TOMATOES (processing)	283,220	$1,093,076,600	$3,859
WALNUTS	272,000	$1,520,686,000	$5,591
WATERMELON	120,988	$488,717,800	$4,039
Wheat (Spring)	13,978,000	$4,377,700,800	$313
Wheat (Winter)	32,631,000	$9,772,478,200	$299

Sources: USDA NASS, 2010 – 2014
[1] USDA NASS, 2014 – 2018

EXHIBIT F

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

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.

* * * * * * *

(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.

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PENALTIES

SEC. 303. (a) * * *

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(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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