UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations	Docket Nos. FIFRA-HQ-2023-0001; EPA-HQ-OPP-2022-0417

REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS

by

Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America

INDEX OF EXHIBITS

Exhibit No.	Description
1	EPA, Chlorpyrifos; Tolerance Revocations; Final Rule; 86 Fed. Reg. 48,315 (Aug. 30, 2021); EPA-HQ-OPP-2021-0523
2	EPA, *Chlorpyrifos: Proposed Interim Registration Review Decision, Case Number 0100, December 2020* (Dec. 3, 2020), EPA-HQ-OPP-2008-0850-0971
3	EPA, Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations; Notice; 87 Fed. Reg. 76,474 (Dec. 14, 2022); EPA-HQ-OPP-2022-0417

Exhibit No.	Description
4	Letter from Venus Eagle, Product Manager (01), Insecticide-Rodenticide Branch, Registration Division (7505P), to Frank E. Sobotka, IPM Resources LLC, "Amended labeling to modify the directions for use; Product Name: Chlorpyrifos Technical; EPA Reg. No.: 33658-17; EPA Decision No.: 456408; Your submission dated 10/3/11; resubmission dated 11/21/11" (Nov. 28, 2011)
5	Letter from Venus Eagle, Product Manager (01), Insecticide-Rodenticide Branch, Registration Division (7505P), to Gharda Chemicals, Ltd. c/o Dr. Frank E. Sobotka, IPM Resources LLC, "Amended labeling to implement required spray drift mitigation measures; Product Name: Pilot 4E Chlorpyrifos Agricultural Insecticide; EPA Registration Number: 33658-26; Submission dated August 28, 2012; resubmission dated December 18, 2012" (Dec. 20, 2012)
6	Letter from Venus Eagle, Product Manager 01, Insecticide-Rodenticide Branch, Registration Division (7505P), to Gharda Chemicals, Ltd. c/o Dr. Frank E. Sobotka, IPM Resources LLC, "Amended labeling to implement required spray drift mitigation measures; Product Name: Pilot 15G Chlorpyrifos Agricultural Insecticide; EPA Registration Number: 33658-27; Submission dated August 28, 2012; resubmission dated December 18, 2012" (Dec. 20, 2012)
7	Letter from South Dakota Soybean Association and 18 additional Grower Groups, to The Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 6, 2023)
8	Letter from Julie Gordon, President/Managing Director, Cherry Marketing Institute, to the Honorable Michael S. Regan, Administrator, EPA, "Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos" (Jan. 9, 2023)
9	Letter from Michael Goodis, EPA, to Carrie Meadows, U.S. Beet Sugar Association and 20 additional Grower Groups, declining request for stay/withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos (Jan. 11, 2023)
10	Brief of Respondents, *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. July 26, 2022)
11	Petitioners' Opening Brief, *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. May 24, 2022)

Exhibit No.	Description
12	Petitioners' Reply Brief, *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022)
13	Letter from Cassie Bladlow, President, U.S. Beet Sugar Association, and Luther Markwart, Executive Vice President, American Sugarbeet Growers Association, to U.S. Environmental Protection Agency, Office of Administrative Law Judges, "Objections to Decision Revoking All Chlorpyrifos Tolerances" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0029
14	Letter from Richard Gupton, Senior Vice President of Public Policy & Counsel, Agricultural Retailers Association, et al., to EPA, "Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 19, 2021), EPA-HQ-OPP-2021-0523-0007
15	Letter from David Milligan, President, National Association of Wheat Growers (Oct. 28, 2021), EPA-HQ-OPP-2021-0523-0016
16	Letter from Kevin Scott, President, American Soybean Association, "Formal Written Objections, Request for Evidentiary Hearing, and Request to Stay Tolerance Revocations: Chlorpyrifos" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0022
17	Letter from Kyle Harris, Director, Grower Relations, Cherry Marketing Institute, "Formal Written Objections and Request for Evidentiary Hearing for chlorpyrifos Tolerance Revocation" (Oct. 29, 2021), EPA-HQ-OPP-2021-0523-0024
18	Memorandum from Danette Drew, Chemist, Risk Assessment Branch V/VII (RAB V/VII), et al., EPA, to Patricia Biggio, Chemical Review Manager, Risk Management and Implementation Branch I (RMIB I), EPA, "**Chlorpyrifos**: Third Revised Human Health Risk Assessment for Registration Review" (Sept. 21, 2020), EPA-HQ-OPP-2008-0850-0944
19	Memorandum from Rochelle F.H. Bohaty, Ph.D., Senior Chemist, et al., EPA, to Patricia Biggio, Chemical Review Manager, et al., EPA, "Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (Sept. 15, 2020), EPA-HQ-OPP-2008-0850-0941
20	EPA, Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule; Order; 87 Fed. Reg. 11,222 (Feb. 28, 2022); EPA-HQ-OPP-2021-0523

Exhibit No.	Description
21	EPA, "Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)" (Nov. 18, 2020), EPA-HQ-OPP-2008-0850-0969
22	Petition for Review, Attachment 2, Exhibits A-W, Supporting Declarations of Grower Petitioners, *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. Feb. 28, 2022)
23	*Amicus Curiae* Brief of the State of North Dakota in Support of Petitioners, *Red River Valley Sugarbeet Growers Ass'n et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. June 1, 2022)
24	Letter from The Honorable Thomas J.Vilsack, Secretary, U.S. Department of Agriculture, to The Honorable Rep. Vicky Hartzler (Sept. 20, 2022)

EXHIBIT 1

(2) Tolerances are established for residues of thiabendazole, including its metabolites and degradates, in or on the commodities in table 2 to paragraph (a)(2). Compliance with the tolerance levels specified to table 2 to paragraph (a)(2) is to be determined by measuring only the sum of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite 5-hydroxythiabendazole (free and conjugated) calculated as the stoichiometric equivalent of thiabendazole, in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

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[FR Doc. 2021–18390 Filed 8–27–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; FRL–5993–04–OCSPP]

Chlorpyrifos; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 29, 2021, the United States Court of Appeals for the Ninth Circuit ordered EPA to issue a final rule concerning the chlorpyrifos tolerances by August 20, 2021. Based on the currently available data and taking into consideration the currently registered uses for chlorpyrifos, EPA is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA). Accordingly, EPA is revoking all tolerances for chlorpyrifos.

DATES: This final rule is effective October 29, 2021. The tolerances for all commodities expire on February 28, 2022.

Written objections, requests for hearings, or requests for a stay identified by the docket identification (ID) number EPA–HQ–OPP–2021–0523 must be received on or before October 29, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** unit in this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room are closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 703–347–0206; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0523 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 29, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although at this time, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges (OALJ) are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA OALJ, a person should utilize the OALJ e-filing system, at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.,* the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178 and above, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0523, using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

If you would like to submit CBI with your hearing request, please first contact the Pesticide Re-Evaluation Division by telephone, 703–347–0206, or by email address: *OPPChlorpyrifosInquiries@epa.gov.* Do not submit CBI to EPA through the Federal eRulemaking Portal or email.

D. What can I do if I want the Agency to maintain a tolerance that the Agency has revoked?

Any affected party has 60 days from the date of publication of this order to file objections to any aspect of this order with EPA and to request an evidentiary hearing on those objections (21 U.S.C. 346a(g)(2)). A person may raise objections without requesting a hearing.

The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objection (40 CFR 178.25). While 40 CFR 180.33(i) indicates a fee is due with each objection, EPA currently cannot collect such fees per 21 U.S.C. 346a(m)(3). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27).

Although any person may file an objection, EPA will not consider any legal or factual issue presented in objections, if that issue could reasonably have been raised earlier in the Agency's review of chlorpyrifos relative to this petition. Similarly, if you fail to file an objection to an issue resolved in the final rule within the time period specified, you will have waived the right to challenge the final rule's resolution of that issue (40 CFR 178.30(a)). After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings on this rule. See Nader v EPA, 859 F.2d 747 (9th Cir. 1988), cert denied 490 U.S. 1931 (1989).

EPA will review any objections and hearing requests in accordance with 40 CFR 178.30, and will publish its determination with respect to each in the **Federal Register**. A request for a hearing will be granted only to resolve factual disputes; objections of a purely policy or legal nature will be resolved in the Agency's final order, and will only be subject to judicial review pursuant to 21 U.S.C. 346a(h)(1), (40 CFR 178.20(c) and 178.32(b)(1)). A hearing will only be held if the Administrator determines that the material submitted shows the following: (1) There is a genuine and substantial issue of fact; (2) There is a reasonable probability that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims to the contrary; and (3) Resolution of the issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.30*).*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0523 in the subject line on the first page of your submission. All requests must be in writing and must be received by the Hearing Clerk as required by 40 CFR part 178 on or before October 29, 2021.

II. Background

A. What action is the Agency taking?

EPA is revoking all tolerances for residues of chlorpyrifos. In 2007, the Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC) filed a petition with EPA under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), requesting that EPA revoke all chlorpyrifos tolerances. (Ref. 1). In an April 29, 2021 decision concerning the Agency's orders denying that 2007 Petition and the subsequent objections to that denial, the Ninth Circuit ordered EPA to ''(1) grant the 2007 Petition; (2) issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA 'has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information,' including for 'infants and children'; and (3) modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. 346a(a)(1).'' *League of United Latin Am. Citizens* v. *Regan,* 996 F.3d 673 (9th Cir. 2021) (the *LULAC* decision).

In today's action, EPA is granting the 2007 Petition, which requested revocation of the tolerances. While EPA previously responded to and denied the individual claims in the original petition, the Court found EPA's denial, at least with regard to the issues raised in the litigation, to be unsupported by the record before the Court and ordered EPA to grant the 2007 Petition and issue a final rule revoking or modifying tolerances. EPA is granting the petition by granting the relief sought by the petition, *i.e.,* the revocation of the chlorpyrifos tolerances, for the reasons stated in this rulemaking. Moreover, the Court expressly ordered EPA to respond to the petition by issuing a final rule under FFDCA section 408(d)(4)(A)(i). 996 F.3d at 702. That provision of the statute involves the issuance of a final rule ''without further notice and without further period for public comment.'' 21 U.S.C. 346a(d)(4)(A)(i). While the FFDCA provides an option for EPA to respond to a petition with the issuance of a proposed rule under FFDCA section 408(d)(4)(A)(ii) and thereafter to finalize the proposal, the Court did not direct EPA to exercise its authority to finalize its 2015 proposal to revoke tolerances pursuant to subparagraph (d)(4)(A)(ii). Nothing in the Ninth Circuit's opinion reflects an expectation that, in complying with the Court's order, EPA would or should finalize the 2015 proposed rule. As such, EPA is viewing this action as independent from the 2015 proposal, and this final rule is based on the Agency's current assessment of the available scientific information, rather than a continuation of and finalization of the Agency's proposal in 2015 to revoke chlorpyrifos tolerances.

In this final rule, EPA is revoking all tolerances for residues of chlorpyrifos contained in 40 CFR 180.342. This includes tolerances for residues of chlorpyrifos on specific food and feed commodities (180.342(a)(1)); on all food commodities treated in food handling and food service establishments in accordance with prescribed conditions (180.342(a)(2) and (a)(3)); and on specific commodities when used under regional registrations (180.342(c)).

EPA finds that, taking into consideration the currently available information and the currently registered uses of chlorpyrifos, EPA cannot make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA section 408(b)(2). 21 U.S.C. 346a(b)(2). As described in greater detail below, the Agency's analysis indicates that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels, when relying on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment and including the statutory tenfold (10X) margin of safety to account for uncertainties related to the potential for neurodevelopmental effects to infants, children, and pregnant women. Accordingly, the Agency is therefore revoking all tolerances because given the currently registered uses of chlorpyrifos, EPA cannot determine that there is a reasonable certainty that no harm will result from aggregate exposure to residues, including all anticipated dietary (food and drinking water) exposures and all other exposures for which there is reliable information.

B. What is the Agency's authority for taking this action?

EPA is taking this action pursuant to the authority in FFDCA sections 408(b)(1)(A), 408(b)(2)(A), and 408(d)(4)(A)(i). 21 U.S.C. 346a(b)(1)(A), (b)(2)(A), (d)(4)(A)(i).

C. Overview of Final Rule

When assessing pesticides, EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA, see *https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act,* and for a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program* and *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/epas-risk-assessment-process-tolerance-reassessment.*

In general, to assess the risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps: (1) Identification of the toxicological hazards posed by a pesticide; (2) Determination of the exposure "level of concern" for humans, which includes choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide, as well as uncertainty factors; (3) Estimation of human exposure to the pesticide through all applicable routes; and (4) Characterization of human risk based on comparison of the estimated human exposure to the level of concern. For tolerances, if aggregate exposure to humans is greater than the Agency's determined level of concern, the Agency's determination is the tolerances are not safe.

The following provides a brief roadmap of the Units in this rule.

- Unit III. contains an overview of the statutory background, including the safety standard in FFDCA, and the registration standard under FIFRA. FFDCA provides the statutory basis for evaluating tolerances and directs the Agency to revoke tolerances that are not safe.
- Unit IV. provides an overview of the FFDCA petition that requested that EPA revoke chlorpyrifos tolerances on the grounds that those tolerances were not safe under the FFDCA. While that petition raised numerous issues, the primary scientific challenge to the chlorpyrifos tolerances that was before the Ninth Circuit related to whether EPA had selected the correct PoD for assessing risk. While EPA's PoD was based on inhibition of the enzyme acetylcholinesterase (AChE), petitioners asserted that the most sensitive health endpoint was neurodevelopmental outcomes from exposure to chlorpyrifos. A summary of that petition, EPA's response to that petition, and the subsequent litigation and Ninth Circuit's order directing EPA to revoke or modify the chlorpyrifos tolerances is included in this section.
- Unit V. provides an overview of the regulatory background for chlorpyrifos, including the numerous human health risk assessments EPA has conducted and FIFRA Scientific Advisory Panels (SAPs) that were convened to discuss the complex scientific issues associated with chlorpyrifos.
- Units VI. through VIII. summarizes EPA's risk assessment, which reflect the four-step process described above.
- Unit VI, which focuses on the hazard assessment of chlorpyrifos, combines the first two steps to provide a full picture of how EPA conducts its hazard assessment. After describing the process generally, this unit discusses EPA's analysis of the hazards posed by chlorpyrifos, including a discussion of the available data on AChE inhibition and the potential for neurodevelopmental outcomes in the young. Unit VI. also discusses the Agency's process for determining the endpoint on which to regulate chlorpyrifos exposure and the rationale for basing the PoD analysis on 10% AChE inhibition. Finally, this Unit includes a discussion of the FQPA safety factor and the Agency's reasons for retaining the default 10X value.
- Unit VII. describes EPA's exposure assessment for chlorpyrifos. The unit includes a description of the general approach for estimating exposures to pesticide residues in or on food and in drinking water, as well as exposures that come from non-occupational and non-dietary sources, also referred to as residential exposures. The unit walks through how EPA conducted those exposure assessments for chlorpyrifos, including a detailed discussion of the recent refinements to the drinking water analysis conducted by EPA for chlorpyrifos.
- Unit VIII. describes the Agency's process for assessing aggregate risk based on the hazard discussed in Unit VI. and the exposure discussed in Unit VII. and provides the Agency's rationale and conclusions concerning the overall risks posed by chlorpyrifos based on the currently registered uses. Unit VIII. concludes that the aggregate risks exceed the level of concern and therefore the chlorpyrifos tolerances must be revoked.

Units IX. and X. address procedural matters, international obligations, statutory and executive order review requirements, and the specific revisions that will be made to the Code of Federal Regulations with this final rule.

III. Statutory Background

A. Federal Food, Drug, and Cosmetic Act (FFDCA) Tolerances

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications of tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, pesticide residues in or on food is considered unsafe, 21 U.S.C. 346a(a)(1), and such food, which is then rendered ''adulterated'' under FFDCA section 402(a), 21 U.S.C. 342(a), may not be distributed in interstate commerce, 21 U.S.C. 331(a).

Section 408(b)(2) of the FFDCA directs that EPA may establish or leave in effect a tolerance for a pesticide only if it finds that the tolerance is safe, and EPA must revoke or modify tolerances determined to be unsafe. FFDCA 408(b)(2)(A)(i) (21 U.S.C. 346a(b)(2)(A)(i)). Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through food, drinking water and all non-occupational exposures (*e.g.,* in residential settings), but does not include occupational exposures to workers (*i.e.,* occupational). Risks to infants and children are given special consideration. Specifically, pursuant to section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

This provision further directs that ''in the case of threshold effects, . . . an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to ''use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' (21 U.S.C. 346a(b)(2)(C)). Due to Congress's focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to prenatal exposure as well as to exposure during childhood years. This section providing for the special consideration of infants and children in section 408(b)(2)(C) was added to the FFDCA through the Food Quality Protection Act (FQPA) (Pub. L. 104–170, 110 Stat. 1489 (1996)); therefore, this additional margin of safety is often referred to as the ''FQPA safety factor (SF)''.

Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), authorizes EPA to revoke tolerances in response to an administrative petition submitted by any person. As explained in more detail in Unit IV, PANNA and NRDC submitted a petition in 2007 requesting revocation of all chlorpyrifos tolerances. The Ninth Circuit has directed EPA to grant that petition and issue a rule revoking or modifying those tolerances. EPA is issuing this rule in response to that petition and revoking all chlorpyrifos tolerances because EPA is unable to determine, based on data available at this time, that aggregate exposures to chlorpyrifos are safe.

B. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Registration Review

Under FIFRA, a pesticide may not be sold or distributed in the United States unless it is registered. (7.U.S.C. 136a(a)). EPA must determine that a pesticide ''will not generally cause unreasonable adverse effects on the environment in order to register a pesticide.'' 7 U.S.C. 136a(c)(5). The term ''unreasonable adverse effects on the environment'' is defined to include ''a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.'' 7 U.S.C. 136(bb). Thus, the FIFRA registration standard incorporates the FFDCA safety standard and requires consideration of safety at the time of registration and during the registration review process.

Under section 3(g) of FIFRA (7 U.S.C. 136(a)(g)), EPA is required to re-evaluate existing registered pesticides every 15 years in a process called ''registration review.'' The purpose of registration review is ''to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration,'' 40 CFR 155.40(a)(1), taking into account changes that have occurred since the last registration decision, including any new relevant scientific information and any changes to risk-assessment procedures, methods, and data requirements. 40 CFR 55.53(a). To ensure that a pesticide continues to meet the standard for registration, EPA must determine, based on the available data, including any additional information that has become available since the pesticide was originally registered or re-evaluated, that the pesticide does not cause ''unreasonable adverse effects on the environment.'' 7 U.S.C. 136a(c)(1), (5); *see also* 40 CFR 152.50.

Chlorpyrifos is currently undergoing registration review, which must be completed by October 1, 2022. 7 U.S.C. 136a(g)(1)(A)(iv). For information about the ongoing registration review process for chlorpyrifos, see *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0850.*

IV. FFDCA Petition and Related Litigation

A. 2007 FFDCA Petition

In 2006, EPA issued the Registration Eligibility Decision (RED) for chlorpyrifos, which concluded that chlorpyrifos was eligible for reregistration as it continued to meet the FIFRA standard for registration. In September 2007, PANNA and NRDC submitted to EPA a petition (the Petition) seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA. (Ref. 1). That petition raised several claims regarding EPA's 2006 FIFRA reregistration decision for chlorpyrifos and the active registrations in support of the request for tolerance revocations and product cancellations. Those claims are described in detail in EPA's earlier order denying the petition (82 FR 16581, April 5, 2017) (FRL–9960–77).

B. Agency Responses and 2017 Order Denying Petition

On March 29, 2017, EPA denied the Petition in full (82 FR 16581, April 5, 2017) (FRL–9960–77). Prior to issuing that order, EPA provided the Petitioners with two interim responses on July 16, 2012 and July 15, 2014, which denied six of the Petition's claims. EPA made clear in both the 2012 and 2014 responses that, absent a request from Petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request, and EPA therefore finalized its response to those claims in the March 29, 2017 Denial Order.

As background, three of the Petition's claims all related to the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% RBC AChE inhibition). Because the claims relating to the potential for neurodevelopmental effects in children raised novel, highly complex scientific issues, EPA originally decided it would be appropriate to address these issues in connection with the registration review of chlorpyrifos under FIFRA section 3(g) and decided to expedite that review, intending to finalize it in 2015, well in advance of the October 1, 2022 registration review deadline (Ref. 2). EPA decided as a policy matter that it would address the Petition claims raising these matters on a similar timeframe. Id. at 16583.

The complexity of these scientific issues precluded EPA from finishing its review according to EPA's original timeline, and the Petitioners brought legal action in the Ninth Circuit Court of Appeals to compel EPA to either issue an order denying the Petition or to grant the Petition by initiating the tolerance revocation process. The result of that litigation was that on August 10, 2015, the Court ordered EPA to ''issue either a proposed or final revocation rule or a full and final response to the administrative [P]etition by October 31, 2015.'' *In re Pesticide Action Network N. Am.,* 798 F.3d 809, 815 (9th Cir. 2015).

In response to that 2015 order, EPA issued a proposed rule to revoke all tolerances for chlorpyrifos on October 28, 2015 (published in the **Federal Register** on November 6, 2015 (80 FR 69080)), based on its unfinished registration review risk assessment. EPA acknowledged that it had had insufficient time to complete its drinking water assessment and its review of data addressing the potential for neurodevelopmental effects. Although EPA noted that further evaluation might enable more tailored risk mitigation, EPA was unable to conclude, based on the information before EPA at the time, that the tolerances were safe, since the aggregate exposure to chlorpyrifos exceeded safe levels.

On December 10, 2015, the Ninth Circuit issued a further order requiring EPA to take final action on its proposed revocation rule and issue its final response to the Petition by December 30, 2016. *In re Pesticide Action Network N. Am.,* 808 F.3d 402 (9th Cir. 2015). In response to EPA's request for an extension of the deadline in order to be able to fully consider the July 2016 FIFRA Scientific Advisory Panel (SAP) report regarding chlorpyrifos toxicology, the Ninth Circuit ordered EPA to complete its final action by March 31, 2017. *In re Pesticide Action Network of North America* v. *EPA,* 840 F.3d 1014 (9th Cir. 2016). Following that order, EPA published a Notice of Data Availability (NODA), seeking comment on EPA's revised risk assessment and water assessment and reopening the comment period on the proposal to revoke tolerances. (81 FR 81049, November 17, 2016) (FRL–9954–65).

On March 29, 2017, and as published in the **Federal Register** on April 5, 2017, the EPA issued an order denying the Petition (the Denial Order) (82 FR 16581). The specific responses are described in full in that Denial Order and summarized again in the Agency's denial of objections (84 FR 35555, July 24, 2019) (FRL–9997–06). EPA's Denial Order did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA concluded that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. EPA therefore denied the remaining Petition claims, concluding that it was not required to complete—and would not complete—the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without resolution of those issues during the ongoing FIFRA registration review of chlorpyrifos.

C. Objections and EPA's Denial of Objections

In June 2017, several public interest groups and states filed objections to the Denial Order pursuant to the procedures in FFDCA section 408(g)(2). Specifically, Earthjustice submitted objections on behalf of the following 12 public interest groups: Petitioners PANNA and NRDC, United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens, Learning Disabilities Association of America, National Hispanic Medical Association and Pineros y Campesinos Unidos del Noroeste. Another public interest group, the North Coast River Alliance, submitted separate objections. With respect to the states, New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submitted a joint set of objections (Ref. 1). The objections focused on three main topics: (1) The Objectors asserted that the FFDCA requires that EPA apply the FFDCA safety standard in reviewing any petition to revoke tolerances and that EPA's decision to deny the Petition without making a safety finding failed to apply that standard; (2) The Objectors contended that the risk assessments EPA conducted in support of the 2015 proposed rule and the 2016 Revised Human Health Risk Assessment (HHRA) demonstrated that chlorpyrifos results in unsafe drinking water exposures and adverse neurodevelopmental effects and that EPA therefore was required to issue a final rule revoking all chlorpyrifos tolerances; and (3) The Objectors claimed that EPA committed procedural error in failing to respond to comments, and they specifically pointed to comments related to neurodevelopmental effects, inhalation risk, and Dow AgroSciences' (now doing business as Corteva AgriScience) physiologically based pharmacokinetic model (PBPK model) used in EPA's 2014 and 2015 human health risk assessments, which are discussed further in Unit V.

On July 18, 2019, EPA issued a final order denying all objections to the Denial Order and thereby completing EPA's administrative denial of the Petition (the Final Order) (84 FR 35555). Again, the Final Order did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA denied the objections in part on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the petitioners' burden.

D. Judicial Challenge to Objections Denial and 2021 Ninth Circuit Order

On August 7, 2019, the Objectors (LULAC Petitioners) and States petitioned the Ninth Circuit for review of the Denial Order and the Final Order. The LULAC Petitioners and States argued that EPA was compelled to grant the 2007 Petition and revoke chlorpyrifos tolerances because (1) EPA lacked authority to maintain chlorpyrifos tolerances without an affirmative finding that chlorpyrifos is safe, (2) EPA's findings that chlorpyrifos is unsafe in the Agency's risk assessments from 2014 and 2016, compel it to revoke chlorpyrifos tolerances, and (3) The 2007 Petition provided a sufficient basis for EPA to reconsider the question of chlorpyrifos's safety and was not required to prove that a pesticide is unsafe.

On April 29, 2021, the Ninth Circuit issued its decision, finding that when EPA denied the 2007 Petition to revoke chlorpyrifos tolerances, it was essentially leaving those chlorpyrifos tolerances in effect, which, the Court noted, the FFDCA only permits if EPA has made a determination that such tolerances were safe. *League of United*

Latin Am. Citizens v. *Regan,* 996 F.3d. 673 (9th Cir. 2021). Although EPA argued that it was not compelled to reconsider its safety determination because the 2007 Petition had failed to meet the threshold requirement of providing reliable evidence that the tolerances were unsafe, the Court found that the Petition provided the necessary ''reasonable grounds,'' which triggered EPA's duty to ensure the tolerances were safe. *Id.* at 695. Since EPA's Denial Order and Final Order failed to make any safety determinations for chlorpyrifos, the Court concluded that EPA violated the FFDCA by leaving those tolerances in place without the requisite safety findings. *Id.* at 695–96. Moreover, in light of the record before the Court, including the 2016 HHRA indicating that the current chlorpyrifos tolerances are not safe, the Court found EPA's denial of the 2007 Petition to be arbitrary and capricious. *Id.* at 697. Based on the available record, the Court concluded that EPA must grant the Petition and issue a final rule modifying or revoking the tolerances under FFDCA section 408(d)(4)(A)(i). *Id.* at 701.

The Court recognized that EPA had been continuing to evaluate chlorpyrifos in registration review and had issued additional regulatory documents concerning chlorpyrifos after the record closed in the litigation, *e.g.,* the 2020 Proposed Interim Registration Review Decision and 2020 SAP, both of which are discussed in more detail in Unit V. below, and noted that such information could be relevant to a safety determination. *Id.* at 703. The Court allowed that if the new information could support a safety determination, EPA might issue a final rule modifying chlorpyrifos tolerances rather than revoking them, although the Court directed EPA to act ''immediately'' and not engage in ''further factfinding.'' *Id.* at 703. As a result, the Court ordered EPA to: (1) Grant the 2007 Petition; (2) Issue a final rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances, provided that such modification is supported by a safety finding, and (3) Modify or cancel related FIFRA registrations for food use in a timely fashion. *Id.* at 703–04. Since the mandate was issued on June 21, 2021, the deadline for issuing this final rule is August 20, 2021.

V. Chlorpyrifos Background and Regulatory History

Chlorpyrifos (0,0-diethyl-0–3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide. Given the complex scientific nature of the issues reflected in this rule, EPA is alerting the reader that many of the technical terms used in this unit will be described more fully in a subsequent unit.

Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting acetylcholinesterase (AChE), an enzyme necessary for the proper functioning of the nervous system. This can ultimately lead to signs of neurotoxicity. As discussed in more detail below, while there are data that indicate an association between chlorpyrifos and neurodevelopmental outcomes, there remains uncertainty in the dose-response relationship and the levels at which these outcomes occur. In an effort to resolve this scientific uncertainty, evaluation of toxicology and epidemiology studies of chlorpyrifos, specific to determining the appropriate regulatory endpoint, has been the focus of EPA's work on chlorpyrifos for over a decade.

Chlorpyrifos has been registered for use in the United States since 1965. Currently registered use sites include a large variety of food crops (including fruit and nut trees, many types of fruits and vegetables, and grain crops), and non-food use settings (*e.g.,* golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products). Public health uses include aerial and ground-based fogger mosquito adulticide treatments, roach bait products, and individual fire ant mound treatments. In 2000, the chlorpyrifos registrants reached an agreement with EPA to voluntarily cancel all residential use products except those registered for ant and roach baits in child-resistant packaging and fire ant mound treatments. *See, e.g.,* 65 FR 76233, December 6, 2000) (FRL–6758–2); 66 FR 47481, September 12, 2001) (FRL–6799–7).

In 2006, EPA completed FIFRA section 4 reregistration and FFDCA tolerance reassessment for chlorpyrifos and the OP class of pesticides, concluding that the existing tolerances were safe and that chlorpyrifos continued to meet the FIFRA standard for registration. In that effort, EPA relied on RBC AChE inhibition as the endpoint for examining risk.

Subsequently, given ongoing scientific developments in the study of the OPs generally, EPA chose to prioritize the FIFRA section 3(g) registration review (the subsequent round of re-evaluation following reregistration) of chlorpyrifos and the OP class. The registration review of chlorpyrifos and the OPs has presented EPA with numerous novel scientific issues which the Agency has taken to multiple independent FIFRA SAP reviews. (*Note:* The SAP is a federal advisory committee created by FIFRA section 25(d), 7 U.S.C. 136w(d), and serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides.)

These SAPs, which have included the review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, and the evaluation of a chlorpyrifos-specific physiologically-based pharmacokinetic-pharmacodynamic (PBPK–PD, see Unit VII. for definitions) model. These FIFRA SAP reviews have resulted in significant developments in EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. In particular, and partly in response to the issues raised in the 2007 Petition, EPA has conducted extensive reviews of available data to evaluate the possible connection between chlorpyrifos and adverse neurodevelopmental effects, and to assess whether the neurodevelopmental effects could be used to determine points of departure (PoDs) for assessing chlorpyrifos. On this particular topic, EPA has convened three FIFRA SAP reviews. EPA has taken FIFRA SAP recommendations into consideration as it has developed risk assessments and regulatory documents for chlorpyrifos. The remainder of this Unit provides a brief regulatory overview for chlorpyrifos by presenting a summary of the chronology of the FIFRA SAPs and Agency assessments of chlorpyrifos.

The 2008 FIFRA SAP evaluated the Agency's preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action. (Ref. 3) The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the points of departure (PoDs, see Unit VII. for definitions), but noted that despite some uncertainties, the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies ''is epidemiologically sound'' and ''provided extremely valuable information'' for evaluating the potential neurodevelopmental effects of chlorpyrifos (Ref. 3). See Unit VI.A.2. for neurodevelopmental toxicity.

The 2010 FIFRA SAP favorably reviewed EPA's 2010 draft epidemiology framework. (Ref. 4, 5) This draft framework, titled ''Framework for Incorporating Human

Epidemiologic & Incident Data in Risk Assessments in Pesticides,'' described the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. As suggested by the 2010 FIFRA SAP, EPA did not immediately finalize the draft framework but instead used it in several pesticide evaluations prior to making revisions and finalizing it. EPA's Office of Pesticide Program's (OPP) finalized this epidemiology framework in December 2016 (Ref. 5).

In 2011, EPA released its preliminary human health risk assessment (2011 HHRA) for the registration review of chlorpyrifos. The 2011 HHRA used 10% RBC AChE inhibition from laboratory rats as the critical effect (or PoD) for extrapolating risk. It also used the default 10X uncertainty factors for inter- and intra-species extrapolation. The 10X FQPA SF was removed with a note to the public that a weight of evidence (WOE) evaluation would be forthcoming, as described in the 2010 draft ''Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment.''

In 2011, EPA convened a meeting of the FIFRA SAP to review the PBPK–PD model for chlorpyrifos. The panel made numerous recommendations for the improvement of the model for use in regulatory risk assessment, including the inclusion of dermal and inhalation routes. From 2011–2014, Dow AgroSciences, in consultation with EPA, refined the PBPK–PD model, and those refinements were sufficient to allow for use of the PBPK–PD model in the next HHRA.

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to RBC AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the United States, including those from the CCCEH, Mount Sinai, and University of California, Berkeley. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies.

The 2012 FIFRA SAP described the Agency's epidemiology review as ''very clearly written, accurate'' and ''very thorough review''. (Ref. 6 at 50–52, 53) It went further to note that it ''believes that the [Agency's] epidemiology review appropriately concludes that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7–9 years, and attention and behavior problems at 3 and 5 years of age. . . . .'' The 2012 FIFRA SAP concluded that the RBC AChE inhibition remained the most robust dose-response data, though expressed significant concerns about the degree to which 10% RBC AChE inhibition is protective for neurodevelopmental effects, pointing to evidence from epidemiology, *in vivo* animal studies, and *in vitro* mechanistic studies, and urged the EPA to find ways to use the CCCEH data.

In 2014, EPA released a revised human health risk assessment (2014 HHRA. (Ref. 7). The revised assessment used the chlorpyrifos PBPK–PD model for deriving human PoDs for RBC AChE inhibition, thus obviating the need for the inter-species extrapolation factor (as explained later in this Unit) and providing highly refined PoDs which accounted for gender, age, duration and route specific exposure considerations. The PBPK–PD model was also used to develop data derived intra-species factors for some lifestages. The 10X FQPA SF was retained based on the outcome of the 2012 FIFRA SAP and development of a WOE analysis on potential for neurodevelopmental outcomes according to EPA's ''Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides.'' The 2014 HHRA, taken together with the Agency's drinking water assessment, identified estimated aggregate risks exceeding the level of concern for chlorpyrifos.

On November 6, 2015, EPA issued a proposed rule to revoke all tolerances of chlorpyrifos, based on the aggregate risks exceeding the level of concern (80 FR 69079) (FRL–9935–92). In this proposed rulemaking, EPA specified that it was unable to conclude that aggregate exposures from use of chlorpyrifos met the FFDCA's ''reasonable certainty of no harm'' standard due to risks identified from the drinking watering using a national-scale assessment (*i.e.,* using default values and conservative assumptions). At that time, the EPA had not completed a refined drinking water assessment (*i.e.,* a higher-tier and more resource-intensive assessment relying on more targeted inputs) or an additional analysis of the hazard of chlorpyrifos that was suggested by several commenters to the 2014 HHRA. Those commenters raised the concern that the use of 10% RBC AChE inhibition for deriving PoDs for chlorpyrifos may not provide a sufficiently health protective human health risk assessment given the potential for neurodevelopmental outcomes.

In 2015, EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood reported by the CCCEH study investigators. The Agency convened another meeting of the FIFRA SAP in April 2016 to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for the PoDs. The 2016 SAP did not support the ''direct use'' of the cord blood and working memory data for deriving the regulatory endpoint, due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations, and lack of raw data from the epidemiology study. (Ref. 8)

Despite its critiques of uncertainties in the CCCEH studies, the 2016 FIFRA SAP expressed concern that 10% RBC AChE inhibition is not sufficiently protective of human health. Specifically, the FIFRA SAP stated that it ''agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition (*i.e.,* toxicity at lower doses).'' (Id. at 18). (Ref. 8)

Taking into consideration the conclusions of the 2016 SAP, EPA issued another HHRA using a dose reconstruction approach to derive the PoD based on the neurodevelopmental effects observed in the CCCEH study. In 2016, EPA also issued a revised drinking water assessment (2016 DWA). EPA issued a Notice of Data Availability seeking public comment on the 2016 HHRA and 2016 DWA. (81 FR 81049, November 17, 2016) (FRL–9954–65).

In 2017, in response to a Ninth Circuit order, EPA denied the 2007 Petition on the grounds that ''further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos.'' (82 FR at 16583). As part of this commitment to further evaluate the science, EPA evaluated the new laboratory animal studies with results suggesting effects on the developing brain occur at doses lower than doses that cause AChE inhibition, and concluded that they are not sufficient for setting a PoD. While EPA sought to verify the conclusions of the epidemiology studies conducted by Columbia University it has been unable to confirm the findings of the CCCEH papers or conduct alternative statistical analyses to evaluate the findings. In summary, while EPA sought to address the potential neurodevelopmental effects associated with chlorpyrifos exposure over the past decade, these efforts ultimately concluded with the lack of a suitable regulatory endpoint based on these potential effects. However, these efforts do not alleviate the Agency's concerns regarding potential neurodevelopmental effects.

In October 2020, EPA released its latest human health risk assessment (2020 HHRA) and drinking water assessment (2020 DWA). (Ref. 9 and 10) Due to the shortcomings of the data upon which the 2016 HHRA was based and the uncertainty surrounding the levels around which neurodevelopmental effects may occur, the 2020 HHRA uses the same endpoint and PoDs as those used in the 2014 HHRA (*i.e.,* the PBPK–PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon). The 2020 HHRA retained the default 10X FQPA SF, but also presented risk estimates at a reduced 1X FQPA SF, though it did not adopt or attempt to justify use of this approach.

Then, in December 2020, as part of its FIFRA registration review, EPA issued its Proposed Interim Registration Review Decision (2020 PID) for chlorpyrifos (85 FR 78849, December 7, 2020) (FRL–10017–13). The 2020 PID was based on comparing estimates in the 2020 HHRA with the values from the 2020 DWA, and retaining the 10X FQPA safety factor, the PID proposed to limit applications of chlorpyrifos in this country would be reduced to certain uses in certain regions of the United States. The PID proposed to conclude that the Agency could make a safety finding for the approach in this path forward, as risk would be based on limited uses in limited geographic areas, as specified. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos, which the Agency had determined would exceed risk levels of concern without the proposed use restrictions.

In December 2020, EPA requested public comment on the 2020 PID, 2020 HHRA, and 2020 DWA. EPA extended the 60-day comment period by 30 days and it closed on March 7, 2021.

VI. EPA's Hazard Assessment for Chlorpyrifos

A. General Approach to Hazard Identification, Dose-Response Assessment, and Extrapolation

Any risk assessment begins with an evaluation of a chemical's inherent properties, and whether those properties have the potential to cause adverse effects (*i.e.,* a hazard identification). In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. The animal toxicity database for a conventional, food use pesticide usually consists of studies investigating a broad range of endpoints including potential for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and neurotoxicity. These studies include gross and microscopic effects on organs and tissues, functional effects on bodily organs and systems, effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential), effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransferase and cholinesterases), and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). Further, EPA evaluates potential adverse effects in different age groups (adults as well as fetuses and juveniles). (Ref. 11 at 8–10).

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). In evaluating a chemical's dietary risks, EPA uses a reference dose (RfD) approach, which typically involves a number of considerations including:

- *A ''point of departure'' (PoD):* Typically, the PoD is the value from a dose-response curve that is at the low end of the observable data in laboratory animals and that is the toxic dose that serves as the 'starting point' in extrapolating a risk to the human population, although a PoD can also be derived from human data as well. PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario, and are chosen from toxicity studies that show clearly defined No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Adverse Effect Levels (LOAELs), dose-response relationships, and relationships between the chemical exposure and effect. EPA will select separate PoDs, as needed, for each expected exposure duration (*e.g.,* acute, chronic, short-term, intermediate-term) and route of exposure (*e.g.,* oral, dermal, inhalation). For chlorpyrifos, as discussed later in this Unit, EPA derived PoDs based on 10% RBC AChE inhibition.
- *Interspecies extrapolation:* Because most PoDs are derived from toxicology studies in laboratory animals, there is a need to extrapolate from animals to humans. In typical risk assessments, a default tenfold (10X) uncertainty factor is used to address the potential for a difference in toxic response between humans and animals used in toxicity tests. For chlorpyrifos, as described further below, EPA used a sophisticated model called a physiologically based pharmacokinetic-pharmacodynamic (PBPK–PD) model that accounts for differences in laboratory animals and humans, thereby obviating the need for the default interspecies factor.
- *Intraspecies extrapolation:* To address the potential for differences in sensitivity in the toxic response across the human population, EPA conducts intraspecies extrapolation. In typical risk assessments, a 10X default uncertainty factor is used. For chlorpyrifos, the PBPK–PD model used to derive PoDs also accounts for differences in metabolism and toxicity response across the human population for some age groups and some subpopulations, which allows the default factor of 10X to be refined in accordance with EPA's 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.*

• *Food Quality Protection Act safety factor (FQPA SF)):* The FFDCA section 408(b)(2)(C) instructs EPA, in making its ''reasonable certainty of no harm'' finding, that in ''the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of data with respect to exposure and toxicity to infants and children.'' Section 408(b)(2)(C) further states that ''the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' For chlorpyrifos, as discussed later in this Unit, EPA is retaining the default 10X FQPA SF.

In the human health risk assessment process, as indicated above, EPA uses the selected PoD to calculate a RfD for extrapolating risk. The RfD is calculated by dividing the selected PoD by any applicable interspecies and intraspecies factors and other relevant uncertainty factors such as LOAEL to NOAEL factor or database uncertainty factor.

After calculating the RfD, as indicated above, EPA retains an additional safety factor of 10X to protect infants and children (the FQPA safety factor), unless reliable data support selection of a different factor, as required under the FFDCA. As described in EPA's policy for determining the appropriate FQPA safety factor, this additional safety factor often overlaps with other traditional uncertainty factors (*e.g.,* LOAEL to NOAEL factor or database uncertainty factor), but it might also account for residual concerns related to pre- and postnatal toxicity or exposure. (Ref. 35 at 13–16) In implementing FFDCA section 408, EPA calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD), by dividing the RfD by the FQPA SF. Risk estimates less than 100% of the PAD are safe.

B. Toxicological Effects of Chlorpyrifos

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information for chlorpyrifos in support of this action. For over a decade, EPA has evaluated the scientific evidence surrounding the different health effects associated with chlorpyrifos. The Agency has conducted extensive reviews of the scientific literature on health outcomes associated with chlorpyrifos and presented approaches for evaluating and using that information to the FIFRA SAP on several occasions, as discussed above in Unit V. Chlorpyrifos has been tested in toxicological studies for the potential to cause numerous different adverse outcomes (*e.g.,* reproductive toxicity, developmental toxicity, cancer, genotoxicity, dermal toxicity, endocrine toxicity, inhalation toxicity, and immunotoxicity). The inhibition of AChE leading to cholinergic neurotoxicity and the potential for effects on the developing brain (*i.e.,* neurodevelopmental effects) are the most sensitive effects seen in the available data. (2020 HHRA p. 6). The SAP reports have rendered numerous recommendations for additional study and sometimes conflicting advice for how EPA should consider (or not consider) the data in conducting EPA's registration review human health risk assessment for chlorpyrifos.

Unit VI. discusses the Agency's assessment of the science relating to AChE inhibition and the potential for neurodevelopmental effects. Other adverse outcomes besides AChE inhibition and neurodevelopment are less sensitive and are thus not discussed in detail here. Further information concerning those effects can be found in the 2000 human health risk assessment which supported the RED and the 2011 preliminary human health risk assessment. (Ref. 12 and 13).

1. Acetylcholinesterase (AChE) Inhibition

Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting AChE, an enzyme necessary for the proper functioning of the nervous system and ultimately leading to signs of neurotoxicity. This mode of action, in which AChE inhibition leads to neurotoxicity, is well-established, and thus has been used as basis for the PoD for OP human health risk assessments, including chlorpyrifos. This science policy is based on decades of work, which shows that AChE inhibition is the initial event in the pathway to acute cholinergic neurotoxicity.

The Agency has conducted a comprehensive review of the available data and public literature regarding this adverse effect from chlorpyrifos. (Ref. 8 at 24–25, Ref. 13 at 25–27) There are many chlorpyrifos studies evaluating RBC AChE inhibition or the brain in multiple lifestages (gestational, fetal, post-natal, and non-pregnant adult), multiple species (rat, mouse, rabbit, dog, human), methods of oral administration (oral gavage with corn oil, dietary, gavage via milk) and routes of exposure (oral, dermal, inhalation via vapor and via aerosol). In addition, chlorpyrifos is unique in the availability of AChE data from peripheral tissues in some studies (*e.g.,* heart, lung, liver). There are also literature studies comparing the *in vitro* AChE response to a variety of tissues which show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral AChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues. Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

Female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.,* developmental neurotoxicity (DNT), reproductive, and subchronic data).

In addition, studies are available in juvenile pups which show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon. As discussed above, this sensitivity is not derived from differences in the AChE enzyme itself but instead are derived largely from the immature metabolic clearance capacity in the juveniles.

2. Neurodevelopmental Toxicity

In addition to information on the effects of chlorpyrifos on AChE, there is an extensive body of information (in the form of laboratory animal studies, epidemiological studies, and mechanistic studies) studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos.

There are numerous laboratory animal studies on chlorpyrifos in the literature that have evaluated the impact of chlorpyrifos exposure in pre- and post-natal dosing on the developing brain. These studies vary substantially in their study design, but all involve gestational and/or early postnatal dosing with behavioral evaluation from adolescence to adulthood. The data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain with adverse outcomes in several neurological domains including cognitive, anxiety and emotion, social interactions, and neuromotor function. It is, however, important to note that there is little consistency in patterns of effects across studies. In addition, most of these studies use doses that far exceed EPA's 10% benchmark response level for RBC AChE inhibition. There are only a few studies with doses at or near the 10% brain or RBC AChE inhibition levels;

among these only studies from Carr laboratory at Mississippi State University are considered by EPA to be high quality. EPA has concluded that the laboratory animal studies on neurodevelopmental outcomes are not sufficient for quantitatively establishing a PoD. Moreover, EPA has further concluded that the laboratory animal studies do not support a conclusion that adverse neurodevelopmental outcomes are more sensitive than 10% RBC AChE inhibition. (Ref. 8 at 25–31, Ref. 9 at 88–89).

EPA evaluated numerous epidemiological studies on chlorpyrifos and other OP pesticides in accordance with the ''Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment.'' (Ref. 8, 14, and 15) The most robust epidemiologic research comes from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University; (2) the Mount Sinai Inner-City Toxicants, Child Growth and Development Study or the ''Mt. Sinai Child Growth and Development Study;'' and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley. (Ref. 8 at 32–43).

In the case of the CCCEH study, which specifically evaluated the possible connections between chlorpyrifos levels in cord blood and neurodevelopmental outcomes on a specific cohort, there are a number of notable associations. (Ref. 8 at 36–38). Regarding infant and toddler neurodevelopment, the CCCEH authors reported statistically significant deficits of 6.5 points on the Psychomotor Development Index at three years of age when comparing high to low exposure groups. Notably, these decrements persist even after adjustment for group and individual level socioeconomic variables. These investigators also observed increased odds of mental delay and psychomotor delay at age three when comparing high to low exposure groups. The CCCEH authors also report strong, consistent evidence of a positive association for attention disorders, attention deficit hyperactivity disorder (ADHD), and pervasive development disorder (PDD) when comparing high to low chlorpyrifos exposure groups. Moreover, it was reported that for children in the CCCEH cohort at age seven for each standard deviation increase in chlorpyrifos cord blood exposure, there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In addition, the CCCEH authors evaluated the relationship between prenatal chlorpyrifos exposure and motor development/movement and reported elevated risks of arm tremor in children around 11 years of age in the CCCEH cohort.

Notwithstanding the observed associations, EPA and the 2012 and 2016 FIFRA SAPs identified multiple uncertainties in the CCCEH epidemiology studies (Ref. 6 and 8). Some of these include the relatively modest sample sizes, which limited the statistical power; exposure at one point in prenatal time with no additional information regarding postnatal exposures; representativeness of a single point exposure where time-varying exposures or the ability to define cumulative exposures would be preferable; lack of specificity of a critical window of effect and the potential for misclassification of individual exposure measures; and lack of availability of the raw data from the studies that would allow verification of study conclusions.

One of the notable uncertainties in the CCCEH epidemiology studies identified by EPA and the 2016 FIFRA SAP is the lack of specific exposure information on the timing, frequency, and magnitude of chlorpyrifos application(s) in the apartments of the women in the study. Despite extensive effort by EPA to obtain or infer this exposure information from various sources, the lack of specific exposure data remains a critical uncertainty. EPA made efforts in 2014 and 2016 to develop dose reconstruction of the exposures to these women. These dose reconstruction activities represent the best available information and tools but are highly uncertain. In addition, the pregnant women and children in the CCCEH studies were exposed to multiple chemicals, including multiple potent AChE inhibiting OPs and *N*-methyl carbamates. Moreover, using EPA's dose reconstruction methods from 2014 suggest that the pregnant women likely did not exhibit RBC AChE inhibition above 10%. The 2012 and 2016 FIFRA SAP reports expressed concern that it is likely that the CCCEH findings occurred at exposure levels below those that result in 10% RBC AChE inhibition (Ref. 6 and 8). However, given the available CCCEH exposure information and the exposures to multiple potent AChE inhibiting pesticides, EPA cannot definitively conclude the level of AChE inhibition. EPA remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by CCCEH investigators. (Ref. 8) Moreover, given the uncertainties, particularly in the exposure information available from CCCEH (single timepoints, lack of time varying exposure, lack of knowledge about application timing), uncertainties remain about the dose-response relationships from the epidemiology studies.

Finally, there are several lines of evidence for actions of chlorpyrifos distinct from the classical mode of action of AChE inhibition. This information has been generated from model systems representing different levels of biological organization and provide support for molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling), and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Among the many *in vitro* studies on endpoints relevant to the developing brain available for chlorpyrifos, only three have identified outcomes in picomole concentrations, including concentrations lower than those that elicit AChE inhibition *in vitro.* However, as is the case for many other developmental neurotoxicants, most of these studies have not been designed with the specific goal of construction or testing an adverse outcome pathway. Thus, there are not sufficient data available to test rigorously the causal relationship between effects of chlorpyrifos at the different levels of biological organization in the nervous system. (Ref. 8 at 27–31)

Due to the complexity of nervous system development involving the interplay of many different cell types and developmental timelines, it is generally accepted that no single *in vitro* screening assay can recapitulate all the critical processes of neurodevelopment. As a result, there has been an international effort to develop a battery of new approach methodologies (NAMs) to inform the DNT potential for individual chemicals. This DNT NAM battery is comprised of *in vitro* assays that assess critical processes of neurodevelopment, including neural network formation and function, cell proliferation, apoptosis, neurite outgrowth, synaptogenesis, migration, and differentiation. In combination the assays in this battery provide a mechanistic understanding of the underlying biological processes that may be vulnerable to chemically-induced disruption. It is noteworthy, however, that to date the quantitative relationship between alterations in these neurodevelopmental processes and adverse health outcomes has not been fully elucidated. Moreover, additional assays evaluating other critical neurodevelopmental processes such as myelination are still being developed (Ref. 15).

In September 2020, EPA convened a FIFRA SAP on developing and implementing NAMs using methods such as *in vitro* techniques and computational approaches. Included in that consideration was use of the DNT NAM battery to evaluate OP compounds as a case study. These methods presented to the 2020 FIFRA SAP provide a more systematic approach to evaluating pharmacodynamic effects on the developing brain compared to the existing literature studies. Initial data from the NAM battery were presented to the SAP for 27 OP compounds, including chlorpyrifos and its metabolite, chlorpyrifos oxon, and, when possible, compared to *in vivo* results (by using *in vitro* to *in vivo* extrapolation). On December 21, 2020, the SAP released its final report and recommendations on EPA's proposed use of the NAMs data. (Ref. 16). The advice of the SAP is currently being taken into consideration as EPA develops a path forward on NAMs, but analysis and implementation of NAMs for risk assessment of chlorpyrifos is in progress and was unable to be completed in time for use in this rulemaking. The Agency is continuing to explore the use of NAMs for the OPs, including chlorpyrifos, and intends to make its findings available as soon as it completes this work.

C. Hazard Identification: Using AChE as the Toxicological Endpoint for Deriving PADs

The RED for chlorpyrifos was completed in 2006 and relied on RBC AChE inhibition results from laboratory animals to derive PoDs and retained the FQPA 10X safety factor due to concerns over age-related sensitivity and uncertainty associated with potential neurodevelopmental effects observed in laboratory animals. Based on a review of all the studies (guideline data required, peer reviewed literature, mechanistic), AChE inhibition remains the most robust quantitative dose-response data and thus continues to be the critical effect for the quantitative risk assessment. This approach is consistent with the advice of the SAP from 2008 and 2012. The Agency typically uses a 10% response level for AChE inhibition in human health risk assessments. This response level is consistent with the 2006 OP cumulative risk assessment and other single chemical OP risk assessments. (Ref. 17 and 18).

In response to the 2015 proposed rule to revoke chlorpyrifos tolerances, as noted above, the Agency received some comments raising a concern that the use of the 10% AChE inhibition may not be sufficiently health protective. Taking those comments into consideration, EPA conducted an additional hazard analysis and convened the 2016 FIFRA SAP to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for PoDs. The 2016 FIFRA SAP did not support the ''direct use'' of the cord blood and working memory data for deriving the regulatory endpoint, due to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, and lack of a second laboratory to reproduce the analytical blood concentrations. (Ref. 8) Despite their critiques regarding uncertainties in the CCCEH studies, the 2016 SAP expressed concern that 10% RBC AChE inhibition is not sufficiently protective of human health.

The 2016 FIFRA SAP, however, did present an alternative approach for EPA to consider. First, it is important to note that this SAP was supportive of the EPA's use of the PBPK–PD model as a tool for assessing internal dosimetry from typical OPP exposure scenarios. Use of the PBPK–PD model coupled with typical exposure scenarios provides the strongest scientific foundation for chlorpyrifos human health risk assessment. Given that the window(s) of susceptibility are currently not known for the observed neurodevelopmental effects, and the uncertainties associated with quantitatively interpreting the CCCEH cord blood data, this SAP recommended that the Agency use a time weighted average (TWA) blood concentration of chlorpyrifos for the CCCEH study cohort as the PoD for risk assessment. Thus, in 2016 EPA attempted, using the PBPK–PD model, to determine the TWA blood level expected from post-application exposures from the chlorpyrifos indoor crack-and-crevice use scenario. Despite that effort, EPA's position is that the shortcomings of the data with regard to the dose-response relationship and lack of exposure information discussed above, continue to raise issues that make quantitative use of the CCCEH data in risk assessment not scientifically sound.

Thus, taking into consideration the robustness of the available data at this time, EPA has determined that the most appropriate toxicological endpoint for deriving points of departure for assessing risks of chlorpyrifos is 10% RBC AChE inhibition. The Agency is not ignoring or dismissing the extensive data concerning the potential for adverse neurodevelopmental outcomes, however. As discussed later in this Unit, the Agency is addressing the uncertainties surrounding the potential for adverse neurodevelopmental outcomes by retaining the default 10X FQPA safety factor.

1. Durations of Exposure

As noted in Unit VI.A., EPA establishes PoDs for each expected exposure duration likely to result from pesticide exposure. For chlorpyrifos, exposure can occur from a single event or on a single day (*e.g.,* eating a meal) or from repeated days of exposure (*e.g.,* residential). With respect to AChE inhibition, effects can occur from a single exposure or from repeated exposures. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute exposures. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with most OPs show a consistent pattern of inhibition reaching a ''steady state'' of inhibition at or around 2–3 weeks of exposure in adult laboratory animals (Ref. 19). This pattern observed with repeated dosing is a result of the amount of inhibition coming to equilibrium with production of new enzyme. As such, AChE studies of 2–3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.,* up to 2 years of exposure). Thus, for most of the human health risk assessments for the OPs, the Agency is focusing on the critical durations ranging from a single day up to 21 days (*i.e.,* the approximate time to reach steady state for most OPs). As such, EPA has calculated PoDs for the acute and steady-state durations. As described below, these PoDs have been derived for various lifestages, routes, and exposure scenarios.

2. Deriving PODs, Inter- and Intra-Species Extrapolation: Use of the PBPK Model

The process for developing RfDs and PADs typically involves first deriving PoDs directly from laboratory animal studies, followed by dividing the PoD by the default uncertainty factors of 10X for interspecies extrapolation and intraspecies extrapolation, and the FQPA safety factor. For chlorpyrifos, as discussed previously in Unit V, there is a sophisticated PBPK–PD model available for chlorpyrifos. Numerous

Federal Advisory Committees and external review panels have encouraged the use of such a modeling approach to reduce inherent uncertainty in the risk assessment and facilitate more scientifically sound extrapolations across studies, species, routes, and dose levels. The PBPK–PD model for chlorpyrifos has undergone extensive peer review by various individual or groups, including the FIFRA SAPs. Significant improvements have been made to the model over the years in response to recommendations from the 2008, 2011, and 2012 FIFRA SAPs and comments from both internal and external peer reviewers. (Ref. 9 at 20). As a result, EPA has concluded that the current PBPK–PD model is sufficiently robust and is using it for deriving PoDs for chlorpyrifos.

a. Derivation of PoDs

As noted above, the PoDs for chlorpyrifos are based on the levels at which 10% RBC AChE inhibition is observed. The PBPK–PD model accounts for pharmacokinetic and pharmacodynamic characteristics to derive age-, duration-, and route-specific PoDs. Separate PoDs have been calculated for dietary (food, drinking water) and residential exposures by varying inputs on types of exposures and populations exposed. Specifically, the following characteristics have been evaluated: Duration [24-hour (acute), 21-day (steady state)]; route (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency [events per day (eating, drinking)]. For each exposure scenario, the appropriate body weight for each age group or sex was modeled as identified from the Exposure Factors Handbook (Ref. 21) for residential exposures and from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey (NHANES)/What We Eat in America (WWEIA) Survey for dietary exposures.

Within the PBPK–PD model, the Agency evaluated the following exposure scenarios: Oxon (chlorpyrifos metabolite) exposures via drinking water (acute and steady-state exposures for infants, children, youths, and female adults); chlorpyrifos exposures via food (acute and steady-state exposures for infants, children, youths, and female adults); steady-state residential exposures to chlorpyrifos via skin for children, youths, and female adults; steady-state residential exposures to chlorpyrifos via hand-to-mouth ingestion for children 1–2 years old; steady-state residential exposures to chlorpyrifos via inhalation for children 1–2 years old and female adults. (Ref. 9 at 22–25).

Steady-state dietary exposure was estimated daily for 21 days. For drinking water exposure, infants and young childrens (infants <1 year old, children between 1–2 years old, and children between 6–12 years old) were assumed to consume water 6 times per day, with a total consumption volume of 0.69 L/day. For youths and female adults, they were assumed to consume water 4 times per day, with a total consumption volume of 1.71 L/day.

For all residential dermal exposures to chlorpyrifos the dermal PoDs were estimated assuming 50% of the skin's surface was exposed. Exposure times for dermal exposure assessment were consistent with those recommended in the 2012 Residential Standard Operating Procedures (SOPs) (Ref. 18). For residential inhalation exposures following public health mosquitocide application, the exposure duration was set to 1 hour per day for 21 days. The incidental oral PoDs for children 1 to <2 years old for other turf activities were estimated assuming that there were six events, 15 minutes apart, per day.

The PBPK-modeled PoDs derived for the various lifestages, routes, and exposure scenarios discussed above, can be found in Table 4.2.2.1.2 of the 2020 HHRA (Ref 8).

b. Inter-Species Extrapolation

As indicated above, the PBPK–PD model directly predicts human PoDs based on human physiology and biochemistry, and thus there is no need for an inter-species uncertainty factor to extrapolate from animal PoDs.

c. Intra-Species Extrapolation

The PBPK–PD model can account for variability of critical physiological, pharmacokinetic, and pharmacodynamic parameters in a population to estimate, using the Monte Carlo analysis, the distribution of doses that result in 10% RBC AChE inhibition. Therefore, Data-Derived Extrapolation Factors (DDEF) for intra-species extrapolation have been estimated to replace the default intra-species uncertainty factor for some groups (Ref. 22).

According to EPA's DDEF guidance (Ref. 22), when calculating a DDEF intra-species extrapolation factor, administered doses leading to the response level of interest (in the case of chlorpyrifos, the 10% change in RBC AChE inhibition) are compared between a measure of average response and response at the tail of the distribution representing sensitive individuals. The tail of the distribution may be selected at the 95th, 97.5th, and 99th percentile.

As to chlorpyrifos, the 99th percentile was used in risk assessment to provide the most conservative measure (Ref. 7). In addition to estimating DDEF using the above approach for specific age groups, intra-species DDEF was also calculated by comparing between average responses between adults and 6-month old infants. For the 2020 HHRA, the largest calculated DDEFs, 4X for chlorpyrifos and 5X for the oxon metabolite, were used for intraspecies extrapolation for all groups except women of childbearing age. There was a slightly higher variability between adults and infants when considering the distributions for the oxon metabolite, thus, the slightly higher intra-species factor. For women of childbearing age, the Agency is applying the standard 10X intra-species extrapolation factor due to limitations in the PBPK–PD model to account for physiological, anatomical, and biochemical changes associated with pregnancy. (Ref. 9 at 21–22).

d. Summarizing the PoDs, Inter- and Intra-Species Extrapolation Factors

In summary, for assessing the risks from exposure to chlorpyrifos, the human PBPK–PD model has been used to derive PoDs based on 10% RBC AChE inhibition for various populations, durations, and routes. The model, which calculates a human PoD directly, obviates the need for an interspecies extrapolation factor since animal data are not used. To account for variations in sensitivities, the Agency has determined that an intra-species factor of 4X for chlorpyrifos and 5X for the oxon is appropriate for all groups except women of childbearing age. For women of childbearing age, the typical 10X intra-species factor is being applied, due the lack of appropriate information and algorithms to characterize physiological changes during pregnancy.

3. FQPA Safety Factor

As noted above, the FFDCA requires EPA, in making its ''reasonable certainty of no harm'' finding, that in ''the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children.'' 21 U.S.C. 346A(b)(2)(C). Section 408(b)(2)(C) further states that ''the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.''

In applying the FQPA safety factor provision, EPA has interpreted it as imposing a presumption in favor of retaining it as an additional 10X safety factor. (Ref. 5 at 4, 11). Thus, EPA generally refers to the 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the 10X is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (Id.). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in FFDCA section 408(b)(2)(C)—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Id. at 24–25, 35).

EPA's 2020 HHRA assessed the potential risks from exposures to chlorpyrifos in two ways—with one scenario being the retention of the default 10X FQPA SF, and the other scenario being the reduction of the FQPA SF to 1X. The purpose of using both values was to provide an indication of what the potential risk estimates would be under either scenario. The 2020 document, however, retained the 10X and did not adopt or offer support for reducing to 1X. To reduce the FQPA safety factor to 1X, the FFDCA requires that EPA determine that reliable data demonstrate that the 1X would be safe for infants and children. The 2020 document did not make that determination. For chlorpyrifos, of the three factors mentioned in the previous paragraph, the primary factor that undercuts a determination that a different safety factor would be safe for children is the uncertainty around the potential for pre- and post-natal toxicity for infants and children in the area of neurodevelopmental outcomes.

Based on the weight of the evidence concerning the potential for neurodevelopmental outcomes as discussed in Unit VI.B.2. above, there is ample qualitative evidence of a potential effect on the developing brain; however, there remains uncertainty around the levels at which these potential neurodevelopmental outcomes occur. Although the laboratory animal studies do not support a conclusion that neurodevelopmental outcomes are more sensitive than AChE inhibition, the mechanistic data are, at this time, incomplete in their characterization of dose-response. This conclusion may be further evaluated upon EPA's completion of the review of the 2020 FIFRA SAP report concerning NAMs; however, due to the time constraints of this rule, EPA has not been able to include that information in the current assessment of chlorpyrifos. Finally, while the epidemiology data indicates an association between chlorpyrifos and adverse neurodevelopmental outcomes, there remains some uncertainty in the dose-response relationship. As such, because the data available at this time indicate remaining uncertainties concerning pre- and post-natal toxicity due to insufficient clarity on the levels at which these outcomes occur, the Agency is unable to conclude, at this time, that a different safety factor would be safe for infants and children; thus, the Agency is retaining the default 10X FQPA safety factor.

4. Total Uncertainty Factors and PADs

In conclusion, the Agency used a total uncertainty factor of 100X for determining the food and drinking water PADs for females of childbearing age (1X interspecies factor, 10X intra-species factor, and 10X FQPA safety factor); 40X for determining the food PADs for remaining populations (1X interspecies factor, 4X intra-species factor, and 10X FQPA safety factor); and 50X for determining the PADs for drinking water for remaining populations (1X interspecies factor, 5X intra-species factor, and 10X FQPA safety factor).

Taking into consideration the PoDs, intra-species extrapolation factors, and FQPA safety factor, the Agency calculated acute PADs (aPADs) and steady state PADs (ssPADs) for infants (less than 1 year old), children (1 to 2 years old), children (6 to 12 years old), youths (13 to 19 years old), and females (13–49 years old); these subpopulations will be protective of other subpopulations. (Ref. 9 at 30–32.) Values may be found in table 5.0.1 in the 2020 HHRA.

VII. EPA's Exposure Assessment for Chlorpyrifos

Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological endpoints for those hazards is estimating human exposure. Under FFDCA section 408, EPA must evaluate the aggregate exposure to a pesticide chemical residue. This means that EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)).

Pursuant to FFDCA section 408(b), EPA has evaluated chlorpyrifos's risks based on ''aggregate exposure'' to chlorpyrifos. By ''aggregate exposure,'' EPA is referring to exposure to chlorpyrifos by multiple pathways of exposure, *i.e.,* food, drinking water, and residential. EPA uses available data and standard analytical methods, together with assumptions designed to be protective of public health, to produce separate estimates of exposure for a highly exposed subgroup of the general population, for each potential pathway and route of exposure.

The following reflect a summary of the Agency's exposure assessment from the 2020 HHRA unless otherwise specified. (Ref. 10).

A. Exposure From Food

1. General Approach for Estimating Food Exposures

There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed; and (2) The residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the U.S. Department of Agriculture (USDA), (Ref. 11 at 12). Information on residue values can come from a range of sources including crop field trials; data on pesticide reduction (or concentration) due to processing, cooking, and other practices; information on the extent of usage of the pesticide; and monitoring of the food supply. (Id. at 17).

Data on the residues of chlorpyrifos in foods are available from both field trial data and monitoring data, primarily the USDA's Pesticide Data Program (PDP) monitoring data. Monitoring data generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide immediately after harvest.

EPA uses a computer program known as the Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database

(DEEM–FCID version 3.16/Calendex) to estimate exposure by combining data on human consumption amounts with residue values in food commodities. The model incorporates 2003–2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods ''as consumed'' (*e.g.,* apple pie) are linked to EPA-defined food commodities (*e.g.,* apples, peeled fruit—cooked; fresh or N/S (Not Specified); baked; or wheat flour—cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA Agricultural Research Service (ARS) and EPA. For chronic exposure assessment (or in the case of chlorpyrifos, for steady-state exposure assessment), consumption data are averaged for the entire U.S. population and within population subgroups; however, for acute exposure assessment, consumption data are retained as individual consumption events. Using this consumption information and residue data, the exposure estimates are calculated for the general U.S. population and specific subgroups based on age, sex, ethnicity, and region.

For chlorpyrifos, EPA determined that acute and steady-state exposure durations were relevant for assessing risk from food consumption. EPA calculates potential risk by using probabilistic techniques to combine distributions of potential exposures in sentinel populations. The resulting probabilistic assessments present a range of dietary exposure/risk estimates.

Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the aPAD, the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. (The same assumptions apply to estimates for steady state dietary exposure and the ssPAD.) To the extent that one or a few values seem to ''drive'' the exposure estimates at the high-end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making (Ref. 20).

2. Estimating Chlorpyrifos Exposures in Food

The residue of concern, for tolerance expression and risk assessment, in plants (food and feed) and livestock commodities is the parent compound chlorpyrifos. EPA has determined that the metabolite chlorpyrifos oxon is not a residue of concern in food or feed, based on available field trial data and metabolism studies that indicate that the oxon is not present in the edible portions of the crops. In addition, the chlorpyrifos oxon is not found on samples in the USDA PDP monitoring data. Furthermore, the oxon metabolite was not found in milk or livestock tissues (Ref. 9 at 33).

Acute and steady-state dietary (food only) exposure analyses for chlorpyrifos were conducted using the DEEM–FCID version 3.16/Calendex software (Ref. 23). These analyses were performed for the purpose of obtaining food exposure values for comparison to the chlorpyrifos doses predicted by the PBPK–PD model to cause RBC AChE Inhibition. The acute and steady-state dietary (food only) exposure analyses do not include drinking water exposures, which were assessed separately, see Unit VII.B.2.

Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed. EPA also used food processing factors from submitted studies as appropriate. In addition, EPA's acute and steady state dietary exposure assessments used percent crop treated (PCT) information. (Ref. 23)

The chlorpyrifos acute dietary exposure analysis was conducted using the DEEM–FCID, version 3.16, which incorporates 2003–2008 survey consumption data from USDA's NHANES/WWEIA. The acute risk estimates were presented for the sentinel populations for infants (less than 1 yr old); children (1–2 years old); youths (6–12 years old); and adults (females 13–49 years old). The assessment of these index lifestages is protective of other population subgroups.

The chlorpyrifos steady-state dietary exposure analysis was conducted using the Calendex component of DEEM–FCID (with 2003–2008 survey consumption data from USDA's NHANES/WWEIA). Calendex provides a focus detailed profile of potential exposures to individuals across a calendar year. A calendar-based approach provides the ability to estimate daily exposures from multiple sources over time to an individual and is in keeping with two key tenets of aggregate risk assessment: (1) That exposures when aggregated are internally consistent and realistic; and (2) that appropriate temporal and geographic linkages or correlations/associations between exposure scenarios are maintained.

The chlorpyrifos steady state assessment considers the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year. For this assessment, the same food residue values used in the acute assessment were used for the 21-day duration. In the Calendex software, one diary for each individual in the WWEIA is selected to be paired with a randomly selected set of residue values for each food consumed. The steady-state analysis calculated exposures for the sentinel populations for infants (less than 1 year old); children (1–2 years old); youths (6–12 years old); and adults (females 13–49 years old). The assessment of these index lifestages is protective of other population subgroups.

B. Exposure From Drinking Water

1. General Approach for Assessing Exposure From Drinking Water

a. Modeling and Monitoring Data

Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (*i.e.,* the locations of sampling, the times of the year samples were taken, and the frequency by which samples were collected). Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use water exposure models as the primary means to estimate pesticide exposure levels in drinking water. Modeling is a useful tool for characterizing vulnerable sites and can be used to estimate upper-end pesticide water concentrations from infrequent, large rain events. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label (Ref. 24 at 27–28). EPA's models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground water and surface water. Depending on the modeling algorithm (*e.g.,* surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and groundwater. The most common model used to conduct drinking water assessments is the Pesticide in Water Calculator (PWC). PWC couples the Pesticide Root Zone Model (PRZM) and Variable Volume Water Model (VVWM) models together to simulate pesticide fate and transport from the field of application to an adjacent reservoir. (Ref. 24 at 27–28). The PWC estimates pesticide concentrations for an index reservoir that is modeled for site-specific scenarios (*i.e.,* weather and soil data) in different areas of the country. A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Aquatic Models website: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model ''typical'' concentrations occurring across the nation. Consequently, EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

When monitoring data meet certain data quantity criteria, EPA has tools available to quantify the uncertainty in available monitoring data such that it can be used quantitively to estimate pesticide concentrations in drinking water. (Ref. 25) Furthermore, monitoring data can be used in a weight of evidence approach with model estimated concentrations to increase confidence in the conclusions of a drinking water assessment.

b. Drinking Water Level of Comparison (DWLOC)

The drinking water level of comparison (DWLOC) is a benchmark that can be used to guide refinements of the drinking water assessment (DWA). This value relates to the concept of the ''risk cup,'' which EPA developed to facilitate risk refinement when considering aggregate human health risk to a pesticide. (Ref. 26). The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration and population being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (*e.g.,* acute, short-term, chronic). The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for AChE reversible inhibition from exposure to carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to OP insecticides is usually 21-days based on steady-state kinetics. (Ref. 19)

In practice, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect. Knowing this allowable remaining exposure and the water consumption for each population subgroup (*e.g.,* infants), the Agency can calculate the DWLOC, which is the estimate of safe concentrations of pesticides in drinking water. Using this process of DWLOC calculation allows EPA to determine a target maximum safe drinking water concentration, thereby identifying instances where drinking water estimates require refinement. (Ref. 24 at 19–20).

c. Scale of Drinking Water Assessment

Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly because of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location, and characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure, which influences the application timing, rate used, and number of treatments in a crop production cycle.

EPA may conduct a drinking water assessment (DWA) for a national scale depending on the pesticide use under evaluation. A national scale DWA may use a single upper-end pesticide concentration as a starting point for assessing whether additional refinements are needed or estimated pesticide concentrations for certain site-specific scenarios that are associated with locations in the United States vulnerable to pesticide contamination based on pesticide use patterns. (Ref. 24 at 22.)

EPA may also conduct a regional scale DWA to focus on areas where pesticide concentrations may be higher than the DWLOC. Under this assessment, EPA estimates pesticide concentrations across different regions in the United States that are subdivided into different areas called hydrologic units (HUCs). There are 21 HUC 2 regions with 18 in the contiguous United States. These areas contain either the drainage area of a major river or a combined drainage of a series of rivers. This information can eb found at: *https://water.usgs.gov/GIS/huc.html.* Estimated pesticide concentrations under this approach would be associated with a vulnerable pesticide use area somewhere within the evaluated region. (Ref. 24 at 23).

d. Drinking Water Refinements

EPA has defined four assessment tiers for drinking water assessments. Lower tiered assessments are more conservative based on the defaults or upper bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the certainty in the estimated pesticide concentration. Tier 1 requires the least amount of effort and the least amount of data, whereas Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit, resulting in high confidence in the reported pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. The order in which refinements are considered (*i.e.,* the order in which the assessment is refined) is pesticide-specific and depends on the nature and quality of the available data used to support the refinement. Additional information on the conduct of drinking water assessments can be found in the ''Framework for Conducting Pesticide Drinking Water Assessment for Surface Water'' (USEPA, 2020).

As discussed in the Framework document, EPA can incorporate several refinements in higher tiered modeling. Two such refinements are the percent cropped area (PCA) and the percent crop treated (PCT). These are described in the recently completed document titled ''*Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment*'' (Ref. 27) The PCA refers to the amount of area in a particular community water system that is planted with the crop of interest (*e.g.,* the default assumption is that the entire watershed is planted with a crop of interest). The PCT refers to the amount of the cropped area that is treated with the pesticide of interest (*e.g.,* the default is that the entire cropped area is treated with the pesticide of interest). With additional use and usage data, EPA can refine assumptions about the application rate and PCT for use in modeling to generate estimated drinking water concentrations (EDWCs) that are appropriate for human health risk assessment and more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations.

2. Drinking Water Assessment for Chlorpyrifos.

For the chlorpyrifos drinking water assessment, the metabolite chlorpyrifos oxon, which forms because of drinking water treatment and is more toxic than chlorpyrifos, was chosen as the residue of concern. (Ref. 28 and 29) The range of conversion from parent to oxon depends upon the type of water treatment and other conditions. Based on available information regarding the potential effects of certain water treatments (*e.g.,* chlorination appears to hasten transformation of chlorpyrifos to chlorpyrifos oxon), EPA assumed that all chlorpyrifos in source water is converted to chlorpyrifos oxon upon treatment.

The Agency used a DWLOC approach for assessing aggregate risk from chlorpyrifos. As such, EPA calculated DWLOCs for different age groups for both the acute aggregate assessment and the steady-state aggregate assessment, taking into consideration the food and residential contributions to the risk cup. These numbers were provided as a benchmark for evaluating drinking water contributions from uses of chlorpyrifos across the United States, and whether such concentrations would result in aggregate exposures to chlorpyrifos that exceeded the Agency's levels of concern. The lowest acute DWLOC calculated was for exposure to chlorpyrifos oxon to infants (<1 year old) at 23 ppb; the lowest steady state DWLOC calculated was also for exposure to chlorpyrifos oxon to infants (<1 year old) at 4.0 ppb. (Ref. 9 at 45–45). In other words, EDWCs of chlorpyrifos oxon greater than 4.0 ppb for a 21-day average would exceed EPA's DWLOC and present a risk that exceeds the Agency's level of concern.

In its 2014 drinking water assessment, EPA concluded that there were multiple uses of chlorpyrifos that could lead to exposures to chlorpyrifos oxon in drinking water that exceed the DWLOC identified at that time. (Ref. 29). This assessment provided the basis for the Agency's proposal to revoke tolerances in 2015. (Ref. 30). In 2016, EPA conducted a refined drinking water assessment that estimated drinking water concentrations based on modeling of all registered uses, as well as all available surface water monitoring data. That assessment considered several refinement strategies in a two-step process to derive exposure estimates for chlorpyrifos and chlorpyrifos oxon across the country. The first step was an assessment of potential exposure based on the current maximum label rates at a national level. This indicated that the EDWCs could be above the DWLOC.

Because estimated concentrations at the national level exceeded the DWLOC, the Agency conducted a more refined assessment of uses on a regional level. (Ref. 28 at 73–86). This more refined analysis derived EDWCs using the PWC modeling for maximum labeled rates and 1 pound per acre by region for each use. The analysis indicated that approved uses of chlorpyrifos in certain vulnerable watersheds in every region of the country would result in EDWCs that exceed the DWLOC. For example, Table 25 of EPA's 2016 DWA, which provides the range of estimated concentrations of chlorpyrifos in drinking water from uses on golf courses and agricultural or production crops, shows EDWCs that exceed the DWLOC in vulnerable watersheds in every region in the country. While the lower end of some of the ranges provided in that table are below the DWLOC, those lower numbers reflect a single use (*i.e.,* single crop) and do not reflect potential exposure from other uses where applications occur at higher rates, more frequently, or in more locations made more vulnerable due to soil type, weather, or agronomic practices. The relevant estimated concentration for risk assessment purposes is the highest concentration across all uses because it reflects concentrations that may occur in vulnerable sources of drinking water (Ref. 28 at 73–74).

In addition, a robust quantitative analysis of the monitoring data was conducted resulting in concentrations consistent with model-estimated concentrations above the DWLOC. (Ref. 28 at 90–121). Considering both monitoring data and modeling estimates together supports the conclusion that drinking water concentrations in regions across the country will exceed the DWLOC. (Ref. 28 at 121–123).

After the EPA's 2016 DWA showed that the DWLOC exceedances are possible from several uses, EPA developed refinement strategies to examine those estimated regional/watershed drinking water concentrations to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At that time, EPA was anticipating that a more refined drinking water assessment might allow EPA to better identify where at-risk watersheds are located throughout the country to support more targeted risk mitigation through the registration review process. The refinements better account for variability in the use area treated within a watershed that may contribute to a drinking water intake (referred to as PCA or percent use area when considering non-agricultural uses) and incorporate data on the amount of a pesticide that is actually applied within a watershed for agricultural and non-agricultural uses (referred to as PCT). These refinement approaches underwent external peer review and were issued for public comment in January 2020: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.* In addition, EPA used average application rates, average numbers of annual applications for specific crops, and estimated typical application timing at the state-level based on pesticide usage data derived from a statistically reliable private market survey database, publicly available survey data collected by the USDA, and state-specific scientific literature from crop extension experts.

The recently developed refinements were integrated in the *Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review,* which was issued in September 2020. (2020 DWA) (Ref. 10) The updated assessment applied the new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state level PCT data, incorporated refined usage and application data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information. In addition, given the 2016 DWA calculation of estimated drinking water concentrations exceeding the DWLOC of 4.0 ppb, the Agency decided to focus its refinements for the 2020 updated drinking water assessment on a subset of uses in specific regions of the United States. The purpose of the focus on this subset of uses was to determine, if these were the only uses permitted on the label, whether or not the resulting estimated drinking water concentrations would be below the DWLOC. The subset of uses assessed were selected because they were identified as critical uses by the registrant and/or high-benefit uses to growers. That subset of currently registered uses included alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. The results of this analysis indicated that the EDWCs from this subset of uses limited to certain regions are below the DWLOC. (Ref. 10 at 16–17). However, the 2020 DWA refined estimates did not include chlorpyrifos exposures from uses beyond that subset. In the 2020 DWA, EPA stated that if additional uses were added or additional geographic areas included, a new separate assessment would need to be prepared in order to evaluate whether concentrations would remain below the DWLOC. In addition to the modeling of the EDWCs for the specific subset of uses, the 2020 DWA conducted a quantitative surface water monitoring data analysis. That analysis indicated that monitored chlorpyrifos concentrations, which reflect existing uses, are above the DWLOC. (Ref. 10 at 62, 75). These data would need to be considered in the context of any additional uses beyond the subset evaluated.

C. Residential Exposure to Pesticides

1. General Approach to Assessing Non-Occupational Exposures

Residential assessments examine exposure to pesticides in non-occupational or residential settings (*e.g.,* homes, parks, schools, athletic fields or any other areas frequented by the general public), based on registered uses of the pesticide. Exposures to pesticides may occur to persons who apply pesticides (which is referred to as residential handler exposure) or to persons who enter areas previously treated with pesticides (which is referred to as post-application exposure). Such exposures may occur through oral, inhalation, or dermal routes and may occur over different exposure durations (*e.g.,* short-term, intermediate-term, long-term), depending on the type of pesticide and particular use pattern.

Residential assessments are conducted through examination of significant exposure scenarios (*e.g.,* children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To regularize this process, EPA has prepared SOPs for conducting residential assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment (*e.g.,* homes, schools, parks, athletic fields, or other publicly accessible locations). (Ref. 18) The SOPs identify relevant generic data and construct algorithms for calculating exposure amounts using these generic data in combination with pesticide-specific information. The generic data generally involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities) and transfer coefficient data. Transfer coefficient data measure the amount of pesticide that transfers from the environment to humans from a defined activity (*e.g.,* hand contact with a treated surface or plant). Specific information on pesticides can include information on residue levels as well as information on environmental fate such as degradation data.

Once EPA assesses all the potential exposures from all applicable exposure scenarios, EPA selects the highest exposure scenario for each exposed population to calculate representative risk estimates for use in the aggregate exposure assessment. Those specific exposure values are then combined with the life stage appropriate exposure values provided for food and drinking water to determine whether a safety finding can be made.

2. Residential Exposure Assessment for Chlorpyrifos

Most chlorpyrifos products registered for residential treatment were voluntarily cancelled or phased out by the registrants between 1997 and 2001; however, some uses of chlorpyrifos remain that may result in non-occupational, non-dietary (*i.e.,* residential) exposures. Based on the remaining registered uses, the Agency has determined that residential handler exposures are unlikely. Chlorpyrifos products currently registered for residential use are limited to roach bait products or ant mound treatments. Exposures from the application of roach bait products are expected to be negligible. The roach bait product is designed such that the active ingredient is contained within a bait station, which eliminates the potential for contact with the chlorpyrifos containing bait material. Since the ant mound treatments can only be applied professionally, residential handler exposure is also not anticipated. (Ref. 9 at 36–44).

There is a potential for residential post-application exposures. Chlorpyrifos is registered for use on golf courses and as an aerial and ground-based ultra-low volume (ULV) mosquito adulticide applications made directly in residential areas. Based on the anticipated use patterns reviewed under the SOP, EPA assessed these exposures as steady-state residential post-application exposures, which would be protective of shorter durations of exposure. There is a potential for dermal post-application exposures from the golf course uses for adults (females 13–49 years old); youths (11 to less than 16 years old); and children (6 to less than 11 years old). There is also a potential for dermal, incidental oral, and inhalation post-application exposures for children (1 to less than 2 years old) and dermal and inhalation post-application exposures for adults from exposure to mosquitocide uses. The Agency combined post-application exposures for children (1 to less than 2 years old) for dermal, inhalation, and incidental oral exposure routes because these routes all share a common toxicological endpoint. EPA used the post-application exposures and risk estimates resulting from the golfing scenarios in its aggregate exposure and risk assessment.

VIII. Aggregate Risk Assessment and Conclusions Regarding Safety for Chlorpyrifos

The final step in the risk assessment is the aggregate exposure assessment and risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern (LOC)/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. The aggregated exposure assessment process considers exposure through multiple pathways or routes of exposure (*e.g.,* food, water, and residential) for different sub-populations (*e.g.,* infants, children ages 1–6) and exposure duration or types of effects (*e.g.,* acute noncancer effects (single dose), chronic noncancer effects, and cancer). The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and are dependent on the level of refinement or assessment tier.

As noted above, EPA evaluates aggregate exposure by comparing combined exposure from all relevant sources to the safe level. Where exposures exceed the safe level, those levels exceed the risk cup and are of potential concern. There are risk cups for each pertinent duration of exposure for a pesticide because the amount of exposure that can be incurred without adverse health effects will vary by duration (*e.g.,* acute, short-term, chronic). The risk cup is equal to the PAD (either acute, chronic, or steady-state), or the maximum safe exposure for short- and intermediate-term durations.

Whether risks will exceed the risk cup (*i.e.,* whether exposures are expected to exceed safe levels) is expressed differently, depending on the type of level of concern the Agency has identified. For dietary assessments, the risk is expressed as a percentage of the acceptable dose (*i.e.,* the dose which EPA has concluded will be ''safe''). Dietary exposures greater than 100% of the percentage of the acceptable dose are generally cause for concern and would be considered ''unsafe'' within the meaning of FFDCA section 408(b)(2)(B). For non-dietary (and combined dietary and non-dietary) risk assessments of threshold effects, the toxicological level of concern is typically not expressed as an RfD/PAD, but rather in terms of an acceptable (or target) Margin of Exposure (MOE) between human exposure and the PoD. The ''margin'' that is being referred to in the term MOE is the ratio between the PoD and human exposure which is calculated by dividing human exposure into the PoD. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, when the Agency retains the default uncertainty factors for dietary or aggregate risk (a 10X interspecies uncertainty factor, a 10X intraspecies uncertainty factor, and a 10X FQPA safety factor), the total uncertainty factors (or level of concern) is 1000, and any MOE above 1000 represents exposures that are not of concern. Like RfD/PADs, specific target MOEs are selected for exposures of different durations and routes. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral. Target MOEs for a given pesticide can vary depending on the characteristics of the studies relied upon in choosing the PoD for the various duration and route scenarios.

In addition, in a DWLOC aggregate risk assessment, the calculated DWLOC is compared to the EDWC. Where EPA has calculated a DWLOC, EPA can determine whether drinking water exposures will result in aggregate risks of concern by comparing estimated pesticide concentrations in drinking water to the DWLOC. As noted above, an aggregate DWLOC represents the amount of allowable safe residues of pesticide in drinking water because it represents the room remaining in the risk cup after accounting for the food and residential exposures. The DWLOC provides an estimate of the allowable safe concentrations of pesticides in drinking water for comparison to EDWCs. When the EDWC is less than the DWLOC, there are no risk concerns for aggregate exposures because the Agency can conclude that the contribution from drinking water when aggregated with food and non-occupational exposures will not exceed save levels of exposure. Conversely, an EDWC at or exceeding the DWLOC would indicate a risk of concern, as those exposures to chlorpyrifos in drinking water, when aggregated with exposures from food and residential exposures, would exceed safe levels of exposure. (Ref. 31).

A. Dietary Risks From Food Exposures

As noted above, EPA's acute and steady state dietary exposures assessments for chlorpyrifos were highly refined and incorporated monitoring data for almost all foods. The Agency assessed food exposures based on approved registered uses of chlorpyrifos. This includes field uses of chlorpyrifos but not potential exposure from food handling establishment uses since the Agency did not identify any registered food handling establishment uses. (Ref. 9 at 33–36).

Considering food exposures alone, the Agency did not identify risks of concern for either acute or steady state exposures. Acute dietary (food only) risk estimates, which are based on risk from a single exposure event in the 2020 HHRA were all below 100 percent of the acute population adjusted dose for food ($aPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. The population with the highest risk estimate was females (13–49 years old) at 3.2% $aPAD_{food}$. Steady-state dietary (food only) risk estimates, which are based on the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year, were also all below 100% of the steady state PAD for food ($ssPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. The population with the highest risk estimate was children (1–2 years old) at 9.7% $ssPAD_{food}$.

Although EPA's most recent risk assessment calculated two sets of risk estimates as a result of the dual approach to assess the range of risks that would occur if the Agency determined reliable data existed to support a 1X FQPA safety factor, EPA has determined that it is appropriate to retain the 10X FQPA safety factor, see Unit VI.C.3. Therefore, the risk estimates associated with the 1X FQPA are not relevant to today's action.

B. Non-Occupational, Non-Dietary (Residential) Risks

Because there are some uses of chlorpyrifos that may result in residential exposures, EPA assessed risk from those uses. All residential post-application risk estimates for the registered uses of chlorpyrifos were below the Agency's level of concern. (Ref. 9 at 38). The residential post-application LOC for children is 40, and the lowest risk estimate for children (11 to less than 16 years old) was 1,200; the residential post-application LOC for adults is 100, and the MOE is 1,000. Because the calculated MOEs are above the Agency's level of concern, there are no risks of concern from residential exposures.

C. Risks From Drinking Water

As noted above, the Agency aggregated exposures to chlorpyrifos from food and residential exposures and calculated the DWLOC, *i.e.,* the amount of drinking water exposures that would be considered safe. The Agency calculated acute and steady state DWLOCs for infants (less than 1 year old); children (1 to 2 years old); youths (6–12 years old), and adults (females 13–49 years old), which would be protective of other subpopulations. The most sensitive acute DWLOC was 23 ppb chlorpyrifos oxon, and the most sensitive steady state DWLOC was 4 ppb.

As indicated above in Unit VII.B.2., the Agency estimated drinking water contributions from registered uses of chlorpyrifos in its 2016 DWA. That document indicated that EDWCs exceed the DWLOC of 4.0 ppb on a national level and in every region of the United States. (Ref. 28).

While the 2020 DWA produced estimated drinking water concentrations that were below the DWLOC of 4.0 ppb, those EDWCs were contingent upon a limited subset of chlorpyrifos use. When assessing different combinations of only those 11 uses in specific geographic regions, the modeling assumed that chlorpyrifos would not be labeled for use on any other crops and would not otherwise be used in those geographic regions. At this time, however, the currently registered chlorpyrifos uses go well beyond the 11 uses in the specific regions assessed in the 2020 DWA. Because the Agency is required to assess aggregate exposure from *all* anticipated dietary, including food and drinking water, as well as residential exposures, the Agency cannot rely on the 2020 DWA to support currently labeled uses. When one assesses the potential of all currently registered uses nationwide and in specific geographical areas, as was done in the 2016 DWA, the estimates of drinking water concentrations exceed the DWLOC of 4.0 ppb, in certain vulnerable watersheds across the United States.

D. Aggregate Exposure and Determination Concerning Safety

As noted above, in accordance with FFDCA section 408(b)(2), EPA must, when establishing or leaving in effect tolerances for residues of a pesticide chemical, determine that the tolerances are safe. That is, EPA must determine that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' (21 U.S.C. 346a(b)(2)).

As discussed earlier in this Unit, exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern. The Agency determined that risks from exposures to chlorpyrifos residues in food comprised 3.2% of the aPAD for females (13–49 years old) and 9.7% of the ssPAD for children (1–2 years old), the highest exposed subpopulations. Combining those exposures with relevant residential exposures, the Agency calculated the allowable levels of drinking water concentrations. Based on the Agency's assessment of drinking water concentrations based on the currently registered uses, however, drinking water exposures significantly add to those risks. When considering the drinking water contribution from currently registered uses, the Agency's levels of concern are exceeded when combined with food and residential exposures.

As indicated above, the Agency calculated acute and steady-state DWLOCs, and the lowest DWLOC is for steady-state exposures to infants at 4.0 ppb; therefore, any EDWCs of chlorpyrifos oxon exceeding 4.0 ppb indicate that aggregate exposures of chlorpyrifos would be unsafe. The Agency's 2016 DWA demonstrates that DWLOC will be exceeded for some people whose drinking water is derived from certain vulnerable watersheds throughout the United States, which means that drinking water contributions will result in aggregate exposures that exceed the Agency's determined safe level of exposure. When taking into consideration aggregate exposures based on current labeled uses, the EDWCs exceed the DWLOC of 4.0 ppb. For example, as noted above in Unit VII.B.2., the 2016 DWA presented EDWCs for uses of chlorpyrifos, including concentrations based on use on golf courses and agricultural crops. For those uses alone, the Agency estimated concentrations exceeding 4.0 ppb in every region in the country; See Table 25 of the 2016 DWA. (Ref. 28 at 73–74.) Comparing the calculated EDWCs from the 2016 DWA with the DWLOC calculated in the 2020 HHRA shows that drinking water concentrations from chlorpyrifos uses will exceed the safe allowable level for contributions from drinking water. This means that aggregate exposure (food, drinking water, and residential exposures) exceeds the Agency's safe level for chlorpyrifos exposure. Because the FFDCA requires EPA to aggregate all dietary and non-occupational exposure, EPA cannot conclude that there is a reasonable certainty that no harm will result from aggregate exposure to chlorpyrifos residues when taking into consideration all labeled uses.

It is worth noting that the Agency's Proposed Interim Registration Review Decision (PID) recognized that there might be limited combinations of uses in certain geographic areas that could be considered safe, if the assessment only includes those specific uses in those areas. The PID noted that ''[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern. If considering only the uses that result in DWLOCs below the EDWCs, aggregate exposures are not of concern.'' (Ref. 32 at 19). The PID proposed limiting chlorpyrifos applications to specific crops in certain regions where the EDWCs for those uses were calculated to be lower than the DWLOC. (*Id.* at 40). The Agency's ability to make the safety finding for any remaining uses would be contingent upon significant changes to the existing registrations, including use cancellations, geographical limitations, and other label changes.

Consequently, while the 2020 PID suggested that there may be limited combinations of uses that could be safe, FFDCA section 408(b)(2) requires EPA to aggregate all dietary and non-occupational exposures to chlorpyrifos in making a safety finding. Without effective mitigation upon which to base a reduced aggregate exposure calculation, the products as currently registered present risks above the Agency's levels of concern. Based on the data available at this time and the aggregate exposures expected from currently registered uses, the Agency cannot, at this time, determine that aggregate exposures to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe. Accordingly, as directed by the statute and in compliance with the Court's order, EPA is revoking all chlorpyrifos tolerances.

IX. Procedural Matters

A. When do these actions become effective?

The revocations of the tolerances for all commodities will become effective on February 28, 2022. The Agency has set the expiration date for these tolerances to satisfy its international trade obligations described in Unit X.

Any commodities listed in this rule treated with the pesticide subject to this rule, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(l)(5). Under this section, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

B. Response to Comments

Today's action responds to the Ninth Circuit's order to issue a final rule in response to the 2007 Petition. As such this rule is not finalizing the proposal published in the **Federal Register** issue of November 6, 2015, nor is it implementing or resolving any registration review activity. Thus, this document is not responding to comments received on the 2015 proposal or the most recent registration review documents. Those activities are separate and apart from the procedural posture of this final rule action. Moreover, as the registration review process is ongoing, including a separate review of the comments submitted, the Agency intends to respond to the most recent comments in as part of that process, rather than in this rule.

C. Are the Agency's actions consistent with international obligations?

The tolerance revocations in this final rule are not discriminatory and are designed to ensure that both domestically produced and imported foods meet the food safety standard established by the FFDCA. The same food safety standards apply to domestically produced and imported foods.

EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. Codex MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. The FFDCA requires EPA to take Codex MRLs into consideration when establishing new tolerances, and it is EPA's policy to harmonize U.S. tolerances with Codex MRLs to the extent possible, provided that the MRLs achieve the level of protection required under FFDCA. In the current instance, EPA has determined that the current U.S. tolerances for chlorpyrifos are not safe and must be revoked. EPA has developed guidance concerning submissions for import tolerance support (65 FR 35069, June 1, 2000) (FRL–6559–3).

Under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), to which the United States is a party, Members are required to, except in urgent circumstances, ''allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.'' (Ref. 33). The WTO has interpreted the phrase ''reasonable interval'' to mean normally a period of not less than six months. (Ref. 34). In accordance with its obligations, EPA intends to notify the WTO of this regulation and is providing a ''reasonable interval'' by establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule. After the six-month period expires, the tolerances for residues chlorpyrifos in or on food will no longer be in effect.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

The Office of Management and Budget (OMB) has exempted tolerance regulations from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This final rule does not contain any information collection activities subject to OMB review and approval under the PRA, 44 U.S.C. 3501 *et seq.* An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute. Since this rule, which is issued under FFDCA section 408(d)(4)(A)(i) (21 U.S.C. 346a(d)(4)(A)(i)) directly in response to a petition under FFDCA section 408(d), does not require the issuance of a proposed rule, the RFA requirements do not apply.

D. Unfunded Mandates Reform Act (UMRA)

EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

For the same reasons, this action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994). Nevertheless, the revocation of the tolerances will reduce exposure to the pesticide and lead to a reduction in chlorpyrifos use on food crops. While EPA has not conducted a formal EJ analysis for this rule, the revocation of tolerances will likely reduce disproportionate impacts on EJ communities that are impacted by chlorpyrifos applications on crops.

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

XI. References

The following is a list of the documents that are specifically referenced in this document. The docket, identified by docket ID number docket number EPA–HQ–OPP–2021–0523, includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. All records in docket are part of the record for this rulemaking. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. The Petition from NRDC and PANNA, EPA's various responses to it, and the objections submitted on the Petition denial are available in docket number EPA–HQ–OPP–2007–1005 available at *https://www.regulations.gov.*
2. U.S. EPA. Chlorpyrifos Final Work Plan. 2009. Available at: *https://www.regulations.gov/document/EPA–HQ-OPP-2008-0850-0020.*
3. FIFRA Scientific Advisory Panel (2008). ''The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos.'' Report from the FIFRA Scientific Advisory Panel Meeting of September 16–19, 2008. Available at: *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0274/document.*
4. U.S. EPA (2010). Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2009-0851-0004.*
5. U.S. EPA (2016). Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides. (2016) Available at: *https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.*
6. FIFRA Scientific Advisory Panel (2012). ''Scientific Issues Associated with Chlorpyrifos''. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2012-0040-0029.*
7. U.S. EPA (2014). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0195.*
8. U.S. EPA (2016). Scientific Advisory Panel for Chlorpyrifos: Analysis of Biomonitoring Data. Available at: *https://www.epa.gov/sites/default/files/2016-07/documents/chlorpyrifos_sap_april_2016_final_minutes.pdf.*
9. U.S. EPA (2020). Chlorpyrifos Human Health Risk Assessment. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944.*
10. U.S. EPA (2020). Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.*
11. A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food (June 21, 2000). Available at: *https://www.doh.wa.gov/Portals/1/Documents/4000/PASW_exposurefood.pdf.*
12. U.S. EPA (2000). Chlorpyrifos Human Health Risk Assessment. Available at: *https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf.*
13. U.S. EPA (2011). Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0025.*
14. U.S. EPA (2016). Summary Reviews for Additional Epidemiological Literature Studies from Prospective Birth Cohort Studies. Available in docket number EPA–HQ–OPP–2015–0653 at *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0438.*
15. U.S. EPA (2020). The Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment. Available in docket number EPA–HQ–OPP–2020–0263 at *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0033.*
16. U.S. EPA (2020). Transmittal of Meeting Minutes and Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act, Scientific Advisory Panel (FIFRA SAP) Virtual Meeting held on September 15–18, 2020. Available in docket number EPA–HQ–2020–0263 at *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0054.*
17. U.S. EPA (2006). Revised Organophosphorous Pesticide Cumulative Risk Assessment. Available at *http://www.epa.gov/pesticides/cumulative/2006-op/index.htm.*
18. U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment *https://www.epa.gov/sites/default/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.*
19. FIFRA Scientific Advisory Panel (2002). ''Organophosphate Pesticides: Preliminary OP Cumulative Risk Assessment.'' Information on how to obtain the meeting report is available at *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
20. U.S. EPA (2000). Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern. Available at:

https://www.epa.gov/sites/production/files/2015-07/documents/trac2b054_0.pdf.
21. EPA's Exposure Factors Handbook. Available at: *https://www.epa.gov/expobox/about-exposure-factors-handbook.*
22. U.S. EPA (2014). Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation. Available at: *https://www.epa.gov/sites/default/files/2015-01/documents/ddef-final.pdf.*
23. U.S. EPA (2014). Chlorpyrifos Acute and Steady Dietary (Food Only) Exposure Analysis to Support Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0197.*
24. U.S. EPA (2020). Framework for Conducting Pesticide Drinking Water Assessments for Surface Water. Environmental Fate and Effects Division. Office of Pesticide Programs. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at: *https://www.epa.gov/sites/default/files/2020-09/documents/framework-conducting-pesticide-dw-sw.pdf.*
25. FIFRA Scientific Advisory Panel (2019) ''Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments.'' Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2019-0417-0019.*
26. U.S. EPA (2001). General Principles for Performing Aggregate Exposure and Risk Assessments. Available at: *https://www.epa.gov/sites/default/files/2015-07/documents/aggregate.pdf.*
27. U.S. EPA (2020). Appendix B. Case Study for Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0279-0002.*
28. U.S. EPA (2016). Chlorpyrifos Refined Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437.*
29. U.S. EPA (2014). Chlorpyrifos Updated Drinking Water Assessment for Registration Review. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0198.*
30. U.S. EPA (2015). Proposed Rule: Tolerance Revocations: Chlorpyrifos. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0001.*
31. U.S. EPA (2011). Finalization of Guidance on Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Drinking Water Exposure Assessments. Available at: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/finalization-guidance-incorporation-water-treatment.*
32. U.S. EPA (2020). Chlorpyrifos Proposed Interim Registration Review Decision. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971.*
33. For more information on World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), please see: *https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.*
34. For more information on World Trade Organization (2001) Implementation-Related Issues and Concerns, please see: *https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/Min01/17.pdf&Open=True.*

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 18, 2021.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons set forth in the preamble, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.342, add introductory text to read as follows:

§ 180.342 Chlorpyrifos; tolerances for residues.

This section and all tolerances contained herein expire and are revoked on February 28, 2022.

* * * * *

[FR Doc. 2021–18091 Filed 8–27–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225 and 252

[Docket DARS–2020–0039]

RIN 0750–AL15

Defense Federal Acquisition Regulation Supplement: Improved Energy Security for Main Operating Bases in Europe (DFARS Case 2020–D030)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020. This section prohibits contracts for the acquisition of furnished energy for a covered military installation in Europe that is sourced from inside the Russian Federation.

DATES: Effective August 30, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 86 FR 3935 on January 15, 2021, to amend the DFARS to implement section 2821 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 2821 prohibits use of energy sourced from inside the Russian Federation in an effort to promote energy security in Europe. The prohibition applies to all forms of energy ''furnished to a covered military installation'' as that term is defined in the statute. No public comments were received in response to the proposed rule.

II. Discussion and Analysis

A. Summary of Significant Changes

No changes are made to the final rule as a result of public comments.

B. Other Changes

One change is made to the rule as proposed to clarify the same language that appears in section 225.7019–2, paragraph (b); the provision 252.225–7053, paragraph (b)(2); and clause 252.225–7054, paragraph (b)(2). In all three locations, the statement ''Does not apply to a third party that uses it to create some other form of energy (*e.g.,* heating, cooling, or electricity)'' is changed to read ''Does not apply to energy converted by a third party into another form of energy and not directly delivered to a covered military installation.'' No other changes are made to the rule.

III. Applicability to Contracts At or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This DFARS rule implements section 2821 of the NDAA for FY 2020 (Pub. L. 116–92). Section 2821 prohibits use of energy sourced from inside the Russian Federation unless a waiver is approved by the head of the contracting activity. To implement section 2821, this rule creates a new solicitation provision and

EXHIBIT 2

Docket Number EPA-HQ-OPP-2008-0850
www.regulations.gov

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,

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[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]

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[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.

[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

<u>NON-SEED TREATMENT</u>

<u>Aerial and/or Chemigation applications</u>

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.

<u>Airblast applications</u>

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.

[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.

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[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]

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[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
Greenhouse nursery	Greenhouse nursery Irrigation handset	2.0	5.7	OR	56 at Day 1	460 at Day 2
Greenhouse nursery	Greenhouse nursery Irrigation handset	2.0	1.9	MN	59 at Day 1	90 at Day 2 140 at Day 3
Greenhouse nursery	Greenhouse nursery Hand harvest	2.0	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
Greenhouse nursery	Greenhouse nursery Hand harvest	2.0	2.2	OR	22 at Day 1	180 at Day 2
Greenhouse nursery	Greenhouse nursery Hand harvest	2.0	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) LC Irrigation	2.0	6.3	NY	N/A	Day 3: 71 Day 4: 130
			9	CA	N/A	N/A
			4.6	WA	N/A	Day 3: 94 Day 4: 160
Tree Nuts	Almonds (Dormant and Delayed Dormant) Harvesting Mechanical (Shaking)	4.0	37	CA	N/A	Day 1: 76 Day 2: 210
			45	CA	N/A	N/A
			1700	TX	N/A	N/A
			280	LA	N/A	N/A
			160	GA	N/A	N/A
	Almonds (Dormant and Delayed Dormant) Transplanting	4.0	31	CA	N/A	Day 2: 180
			38	CA	N/A	N/A
			1400	TX	N/A	N/A
			230	LA	N/A	N/A
			130	GA	N/A	N/A
	Almonds (Dormant and Delayed Dormant) Scouting	4.0	12	CA	N/A	Day 2: 70 Day 3: 120
			15	CA	N/A	N/A
			560	TX	N/A	N/A
			92	LA	N/A	N/A
			53	GA	N/A	N/A
Ornamental s/ Nurseries (Outdoor Only)	Non-bearing Fruit Trees (Peach, Nectarine) Container moving, hand pruning, tying/training, 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
Field and Row Crops	Alfalfa (LC, WDG), Soybean (LC, WDG) Scouting	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
	Alfalfa LC, WDG Irrigation		15	CA	N/A	Day 2: 160
			6.9	TX	N/A	N/A
			6	MS	N/A	N/A
			17	CA	N/A	N/A
			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	Ornament als- 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 3

of Environmental Conservation (DEC) of the following:

Date of Receipt of the Certification Request: November 30, 2022.

Reasonable Period of Time to Act on the Certification Request: One year (November 30, 2023).

If the New York DEC fails or refuses to act on the water quality certification request on or before the above date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: December 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–27127 Filed 12–13–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Denial of Water Quality Certification

	Project No.
Eagle Creek Hydro Power, LLC	9690–115
Eagle Creek Water Resources, LLC.	
Eagle Creek Land Resources, LLC.	
Eagle Creek Hydro Power, LLC	10481–069
Eagle Creek Water Resources, LLC.	
Eagle Creek Land Resources, LLC.	
Eagle Creek Hydro Power, LLC	10482–122
Eagle Creek Water Resources, LLC.	
Eagle Creek Land Resources, LLC.	

On March 31, 2020, Eagle Creek Hydro Power, LLC, Eagle Creek Water Resources, LLC, and Eagle Creek Land Resources, LLC (co-licensees collectively referred to as Eagle Creek) jointly filed an application for a new license for each of the ''Mongaup River Projects'' consisting of the Swinging Bridge Hydroelectric Project (P–10482), Mongaup Falls Hydroelectric Project (P–10481), and the Rio Hydroelectric Project (P–9690). Eagle Creek filed with the New York Department of Environmental Conservation (New York DEC) a request for water quality certification for the Mongaup River Projects under section 401(a)(1) of the Clean Water Act on March 30, 2021. On March 24, 2022, the New York DEC denied certification for the project. Eagle Creek filed a copy of New York DEC's denial of certification on November 14, 2022. Pursuant to 40 CFR 121.8, we are providing notice that New York DEC's denial satisfies the requirements of 40 CFR 121.7(e).

Dated: December 8, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–27121 Filed 12–13–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0417; FRL–10108–01–OCSPP]

Chlorpyrifos; Notice of Intent To Cancel Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) hereby announces its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the Agency's revocation of all tolerances for chlorpyrifos. This document identifies the products at issue, summarizes EPA's basis for this Notice of Intent to Cancel (NOIC), and explains how adversely affected persons may request a hearing and the consequences of requesting or failing to request such a hearing.

DATES: The affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before January 13, 2023, whichever occurs later. Other adversely affected parties must request a hearing on or before January 13, 2023. Please see unit VII. for specific instructions.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2022–0417, is available online at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.* For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Requests for hearing must be filed with the Hearing Clerk in EPA's Office of Administrative Law Judges (OALJ), in conformance with the requirements of 40 CFR part 164. The OALJ uses different addresses depending on the delivery method. Please see unit VII. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the revocation of all chlorpyrifos tolerances. Specifically, EPA intends to cancel each of the following pesticide products, which allow for use on food crops, listed in sequence by EPA registration number.

- EPA Reg. No. 93182–3 Chlorpyrifos Technical.
- EPA Reg. No. 93182–7 Pilot 4E Chlorpyrifos Agricultural Insecticide.
- EPA Reg. No. 93182–8 Pilot 15G Chlorpyrifos Agricultural Insecticide.

The following information is the address on record for Gharda, the registrant of the products listed in this unit and subject to this notice, and includes the company number which corresponds to the first part of the EPA registration number of the products:

- EPA Co. No. 93182—Gharda Chemicals International, Inc., 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238.

In addition, this document summarizes EPA's legal authority for the proposed cancellation (see unit II.); the revocation of tolerances for residues of chlorpyrifos on food commodities (see unit III.); the Agency's rationale for issuance of this NOIC (see unit IV.); the timing of the proposed cancellations, EPA's existing stocks determination, and the potential scope of any final cancellation order (see unit V.); the results of the Agency's coordination with the U.S. Department of Agriculture (USDA) and the FIFRA Science Advisory Panel (SAP) (see unit VI.); and how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (unit VII.).

B. What is the Agency's authority for this action?

The Agency's authority to cancel a pesticide that does not comply with the provisions of FIFRA is contained in FIFRA section 6(b), 7 U.S.C. 136d(b).

C. Who may be affected by this action?

This announcement will directly affect the pesticide registrant listed in unit I.A., supplemental distributors, and others who may distribute, sell, or use the products listed in unit I.A. This announcement may also be of particular interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. EPA believes the stakeholders described above encompass those likely to be affected; however, more remote interests may also be affected, and the Agency has not attempted to describe all specific entities that may be affected by this action.

II. Legal Authority

With minor exceptions not at issue here, as provided in FIFRA section 3(a), a pesticide product may not be lawfully sold or distributed in the United States unless and until the product is registered by EPA. 7 U.S.C. 136a(a). A pesticide registration is a license allowing a pesticide product to be sold and distributed and includes a label with use instructions that delineates the specific uses for which the pesticide may be used, including precautions and other terms and conditions established by EPA when it grants the registration.

As a general matter, in order to obtain or maintain a registration for a pesticide under FIFRA, an applicant or registrant must demonstrate that the pesticide satisfies the statutory standard for registration. 7 U.S.C. 136a(c)(5). That standard requires, among other things, that the pesticide perform its intended function without causing ''unreasonable adverse effects on the environment.'' *Id.* The term ''unreasonable adverse effects on the environment'' is defined under FIFRA section 2(bb) as including two parts: (1) ''[A]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide'' and (2) ''[A] human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.'' 7 U.S.C. 136(bb). It is under the second part of the definition that the FIFRA registration standard incorporates the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, safety standard.

EPA establishes, modifies, or revokes tolerances for pesticide residues under FFDCA section 408. 21 U.S.C. 346a. A ''tolerance'' represents the maximum level for residues of a pesticide legally allowed in or on raw agricultural commodities and processed food. Under the FFDCA, ''any pesticide chemical residues in or on a food shall be deemed unsafe,'' unless a tolerance or exemption for such residues ''is in effect''. 21 U.S.C. 346a(a)(1). In other words, without a tolerance or an exemption from the requirement of a tolerance, pesticide residues in or on food are considered unsafe, as a matter of law. The consequence of having pesticide residues in or on food that are not covered by a tolerance, or an exemption is that the food containing such residues is rendered adulterated under the FFDCA. 21 U.S.C. 342(a)(2)(B). It is a violation of the FFDCA to introduce adulterated food into interstate commerce. 21 U.S.C. 331(a).

Because the FIFRA registration standard incorporates the FFDCA safety standard, a pesticide that results in residues in or on food that are unsafe, which includes residues not covered by a tolerance or tolerance exemption, does not meet the FIFRA registration standard. EPA will not approve any application to register a pesticide with food uses that may reasonably be expected to result in pesticide residues on food without appropriate tolerances or exemptions in place, *see* 40 CFR 152.112(g), and registrations bearing labeling for food use must be modified or cancelled, pursuant to FIFRA section 6(b).

The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration and continues as long as the registration is in effect. 40 CFR 164.80(b); *see also Industrial Union Dept.* v. *American Petroleum Institute,* 448 U.S. 607, 653 n.61 (1980); *Stearns Electric Paste* v. *EPA,* 461 F.2d 293 (7th Cir. 1972); *Environmental Defense Fund* v. *EPA,* 510 F.2d 1292, 1297 (D.C. Cir. 1975).

Under FIFRA section 6(b), the Agency may issue a notice of its intent to cancel a registration of a pesticide product whenever it appears either that ''a pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.'' 7 U.S.C. 136d(b). The cancellation proposed in the notice shall become final 30 days after publication of the notice, or the date the registrant receives the notice, whichever is later, unless the registrant makes the necessary corrections to the registrations, or a hearing is requested by a person adversely affected by the notice. If a hearing is requested by an adversely affected person, the final order concerning cancellation of the product is not issued until after an administrative hearing.

A cancellation hearing shall be conducted in accordance with the regulations establishing the procedures for hearings under FIFRA set forth at 40 CFR part 164. Under those regulations, the Agency has the burden of presenting an affirmative case for cancellation. 40 CFR 164.80(a). However, the ultimate burden of proof is on the proponent of the registration. 40 CFR 164.80(b); *Industrial Union Dept.,* 448 U.S. at 653, n. 61; *Stearns Electric Paste* v. *EPA,* 461 F.2d 293 (7th Cir. 1972). Once the Agency makes its *prima facie* case that a product's continued use fails to meet the FIFRA standard for registration, the responsibility to demonstrate that the product meets the FIFRA standard is upon the proponents of continued registration. 40 CFR 164.80(b); *Dow* v. *Ruckelshaus,* 477 F.2d 1317, 1324 (8th Cir. 1973).

III. Revocation of Chlorpyrifos Tolerances

Chlorpyrifos is a broad-spectrum, chlorinated organophosphate insecticide that is registered for a wide variety of food and non-food uses. In September 2007, Pesticide Action Network North America and Natural Resources Defense Council filed a petition with EPA requesting revocation of all chlorpyrifos tolerances alleging that, among other things, the pesticide caused adverse neurodevelopmental effects in children at exposure levels below the Agency's regulatory standard (*i.e.,* 10% acetylcholinesterase inhibition). See Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos, available at *https://www.regulations.gov,* using document identification number EPA–HQ–OPP–2007–1005–0005. Following several years of proposed responses and litigation, EPA issued a final response to the petition on March 29, 2017. *See* 82 FR 16581, April 5, 2017 (FRL–9960–77). That response denied the many claims of the petition, including by concluding that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. *See id.* at 16590. As permitted under the FFDCA, objections to EPA's denial were filed, and EPA responded to those objections on July 18, 2019. *See* 84 FR 35555, July 18, 2019 (FRL–9997–06). In its denial of those objections, rather than issuing a determination concerning the safety of chlorpyrifos, EPA denied the objections in part on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the petitioners' burden. *See id.* at 35562. EPA's denial of the petition and denial of objections were subsequently challenged by several advocacy groups and states in the Ninth Circuit.

On April 29, 2021, the Ninth Circuit Court of Appeals ruled against EPA in litigation involving the question of whether the chlorpyrifos tolerances should be revoked. *See League of United Latin American Citizens et al.,* v. *Regan,* 996 F.3d 673 (9th Cir. 2021) (''*LULAC*''). In that case, the Court concluded that EPA violated the FFDCA by not making a safety determination to support the retention of the chlorpyrifos tolerances, as required under the FFDCA. Consequently, the Court ordered EPA to issue a final rule in which the Agency would either revoke the tolerances (if it could not make the requisite safety finding to leave tolerances in place) or modify the existing chlorpyrifos tolerances, provided that the Agency concurrently issued a safety determination supporting the modified tolerances. The Court imposed a tight deadline for EPA to issue the final rule and told EPA not to engage in further fact-finding or delay. Specifically, the court said: ''To be clear, however, this is not an open-ended remand or a remand for further factfinding. The EPA must act based upon the evidence and must immediately revoke or modify chlorpyrifos tolerances. For these reasons, the Court remands this matter to the EPA with instructions to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate.''

In implementing the Court's order within the mandated timeframe, EPA found that it could not make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA section 408(b)(2). 21 U.S.C. 346a(b)(2). Under the FFDCA, a tolerance may be left in place only if the Agency determines that the tolerances are safe, *i.e.,* that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' Id. Because EPA found that at the time it could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to chlorpyrifos residues, including all anticipated dietary (food and drinking water) exposures and all other exposures, EPA published the final rule revoking all tolerances for chlorpyrifos in the **Federal Register** on August 30, 2021. 86 FR 48315, August 30, 2021 (FRL–5993–04–OCSPP) (the Final Rule). As described in greater detail in the Final Rule, the Agency's analysis indicated that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from then-currently registered uses, exceeded safe levels. Id. at 48317. That analysis relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition level as an endpoint for risk assessment and included the FFDCA default tenfold (10X) margin of safety to account for uncertainties related to the potential for adverse neurodevelopmental effects to infants, children, and pregnant women. Id. The Final Rule revoked the chlorpyrifos tolerances but provided a transition period of six months, until February 28, 2022. *Id.* at 48334.

Pursuant to FFDCA section 408(g)(2), EPA provided an opportunity to file objections to the Final Rule and seek an evidentiary hearing on those objections. See also 21 U.S.C. 346a(g)(2); 40 CFR 178.32(b). In response to the Final Rule, several objections, hearing requests, and requests to stay the Final Rule were filed by parties representing a wide variety of growers and pesticide users. On February 28, 2022, EPA published its order denying all objections, hearing requests, and requests to stay the Final Rule in the **Federal Register** (87 FR 11222, February 28, 2022) (FRL–5993–05–OCSPP) (the Denial Order). EPA's publication of the Denial Order completed the Agency's administrative process for the Final Rule. Pursuant to the terms of the Final Rule, all chlorpyrifos tolerances expired on February 28, 2022. EPA notes that EPA's Final Rule revoking chlorpyrifos tolerances is a separate final agency action, and as such, comments challenging EPA's action in that Final Rule are outside the scope of this Notice. Gharda and several other grower groups have challenged that rule in the U.S. Court of Appeals for the Eighth Circuit, *see Red River Valley Sugarbeet Growers Ass'n et al.,* v. *Regan* (9th Cir. No. 22–1422).

Because at this time there are no tolerances or exemptions from the requirement of a tolerance for chlorpyrifos residues in or on food, there is no basis for allowing food uses to remain on chlorpyrifos registered products. See 21 U.S.C. 346a(a)(1). Therefore, between March 1 and March 9 of 2022, after EPA's publication of the Denial Order, EPA issued letters to all registrants of chlorpyrifos products with food uses confirming revocation of the tolerances and recommending that such registrants consider various cancellation and label amendment options. EPA requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food uses from product labels or to submit a voluntary cancellation for products where all uses are subject to the tolerance revocation by March 30, 2022. All chlorpyrifos registrants to whom that letter was sent have submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels, with the exception of Gharda, the registrant of products listed in this Notice. While Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, Gharda's products identified in unit I.A. are subject to this Notice.

IV. Basis for Issuance of Notice of Intent To Cancel

EPA has determined that the chlorpyrifos registrations listed in unit I.A. must be cancelled because they each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products, bearing labeling for use on food crops, (i) pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the FFDCA and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

As noted in unit II., tolerances establish the maximum amount of pesticide residues that are allowed in or on a food. In situations where no tolerance exists to cover residues of a particular pesticide in or on food, those residues are ''deemed unsafe,'' as a matter of law under the FFDCA. 21 U.S.C. 346a(a)(1). As a consequence, a pesticide resulting in residues in or on food for which there is no tolerance does not meet the FIFRA standard for registration. See 7 U.S.C. 136(bb). Moreover, any food containing ''unsafe'' pesticide chemical residues is ''deemed to be adulterated,'' and introduction of that food into interstate commerce is a violation of the FFDCA. 21 U.S.C. 342(a)(2)(B), 331(a).

A. The Pesticide Generally Causes Unreasonable Adverse Effects on the Environment Because It Is Unsafe as a Matter of Law

As discussed in unit II., in order to maintain a registration for a pesticide under FIFRA, a registrant has the burden to demonstrate that the pesticide satisfies the statutory standard for registration. 40 CFR 164.80(b); see also 7 U.S.C. 136a(c)(5). One element of that standard is that the pesticide performs its intended function without unreasonable adverse effects on the environment, which is defined under FIFRA section 2(bb) to include ''a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.'' 7 U.S.C. 136(bb). The standard referenced in the FIFRA definition is the FFDCA safety standard, *i.e.,* that tolerances, which cover the amount of pesticide residues in or on food, must be safe. See 21 U.S.C. 346a(b)(2).

Also noted in unit II., it is a matter of law that pesticide chemical residues in or on food are ''deemed unsafe,'' unless covered by a tolerance or exemption. 21 U.S.C. 346a(a)(1). Any residues from pesticides used on food where no tolerances exist for those residues are, therefore, unsafe. Unsafe residues are not consistent with the FFDCA safety standard. Thus, any pesticide resulting in such residues, causes, as a legal matter, unreasonable adverse effects on the environment. Such pesticide is subject to cancellation under FIFRA section 6(b).

Because all tolerances for chlorpyrifos have been revoked, chlorpyrifos residues in or on food are unsafe as a matter of law. Because the chlorpyrifos registrations listed in unit I.A. bear labeling for use on food, use of which would result in unsafe pesticide residues on food, these products pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2). 7 U.S.C. 136(bb)(2).

B. The Pesticide and Its Labeling Do Not Comply With FIFRA

Additionally, because the chlorpyrifos products in unit I.A. bear labeling for use on food, for which the registrant did not submit the necessary label amendments and/or cancellations to remove all food uses, and because all tolerances for chlorpyrifos have been revoked, these products are misbranded and thus not in compliance with FIFRA. It is a violation of FIFRA to sell and distribute pesticides that are misbranded. 7 U.S.C. 136j(a)(1)(E). FIFRA's definition of ''misbranded'' provides many ways in which a pesticide may be misbranded, including if its labeling ''bears any statement . . . that is false or misleading.'' 7 U.S.C. 136(q)(1)(A). Pesticide labeling bearing directions for use on food crops that results in adulterated food is misleading because it is illegal to distribute that food in commerce. A commercial farmer complying with approved use directions would apply the pesticide to crops but then, in the absence of necessary tolerances or an exemption, would be producing adulterated food, which cannot be delivered into interstate commerce without violating the FFDCA. Thus, the label misleads the consumer into believing a pesticide can be applied to food crops, but ultimately results in adulterated food or feed crops that cannot be sold. To avoid this conflict, EPA's regulations prevent EPA from issuing a registration for a pesticide that ''bears labeling with directions for use on food, animal feed, or food or feed crops, or may reasonable be expected to result, directly or indirectly, in pesticide residues (or results of any active or inert ingredient of the product, or of any metabolite or degradate thereof) in or on food or animal feed,'' unless tolerances or exemptions covering such residues have been issued. 40 CFR 152.112(g).

In summary, because the aforementioned products would result in pesticide residues in or on food that are, as a matter of law, unsafe, the products pose unreasonable adverse effects on the environment. Moreover, EPA has determined that because the aforementioned products are misbranded, continued sale and distribution would not comply with the provisions of FIFRA. Consequently, EPA has determined that these products must be cancelled.

V. Status of Products That Become Cancelled

A. Timing of Cancellation

The cancellation of registration for the specific products identified in unit I.A. of this document will be final and effective 30 days after the affected registrant receives notice of EPA's intent to cancel the pesticide registrations listed in unit I.A., or on January 13, 2023, unless within that time the registrant makes the necessary corrections (see unit V.C.) or a hearing is requested by an adversely affected person regarding such product. 7 U.S.C. 136d(b).

In the event a hearing is held concerning a particular product, the cancellation of the registration for that product will not become effective except pursuant to (i) an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b) or (ii) if the Administrative Law Judge's initial decision is appealed or subject to Administrator review pursuant to 40 CFR 164.101, a final order issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator. Final cancellation orders following a public hearing are subject to judicial review within 60 days of the entry of the order. 7 U.S.C. 136d(h).

B. Existing Stocks Issues

FIFRA section 6(a)(1) allows the Agency to permit the continued sale and use of existing stocks of pesticides whose use has been cancelled, to the extent the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). EPA has defined ''existing stocks'' as ''those stocks of a registered pesticide which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action.'' 56 FR 29362, June 26, 1991 (FRL–3846–4). This section addresses how the Agency intends to treat existing stocks when and if pesticide registrations are cancelled pursuant to this Notice.

The Agency does not believe that continued sale or use of existing stocks of any chlorpyrifos registrations identified in this Notice following cancellation would be consistent with FIFRA. The continued sale and distribution of products cancelled in a proceeding pursuant to this Notice would be the sale and distribution of misbranded products, which, if used in accordance with the labeling, would lead to the production of adulterated food and the use of products that would pose unreasonable adverse effects on human health due to residues in or on food that are inconsistent with the FFDCA safety standard. Accordingly, EPA has determined that the continued sale and distribution of existing stocks of pesticide products cancelled pursuant to this Notice should not be permitted, with the exception of movement of existing stocks for the sole purposes of lawful export consistent with FIFRA; disposal consistent with applicable state disposal requirements; or return to the registrant consistent with the terms of a return program agreement with EPA, if any. Moreover, EPA does not intend to allow existing stocks in the hands of end-users to continue to be used, unless they are being used for non-food uses. Any use of chlorpyrifos on food would result in adulterated food, which is illegal to deliver into interstate commerce; therefore, use of existing stocks for use on food cannot be permitted.

It is settled law that existing stocks issues are not required to be a part of a cancellation proceeding, and that the treatment of existing stocks issues is only included as an issue in a cancellation proceeding when the Notice giving rise to the right to a hearing voluntarily identifies and includes existing stocks as an issue for examination. See *In the Matter of Cedar Chemical Co., et al.,* 2 E.A.D. 584, nn. 7, 9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator). The Administrator's decision in *Cedar Chemical* on whether existing stocks had to be included as an issue in the hearing was affirmed by the United States Court of Appeals for the Ninth Circuit in *Northwest Food Processors Association* v. *Reilly,* 886 F. 2d 1075, 1078 (9th Cir. 1989). In the case of this Notice, EPA has determined not to include existing stocks as an issue in any hearing arising from this Notice, since the lack of tolerances means that any continued sale, distribution, or use of the pesticide would be inconsistent with the purposes of FIFRA. Instead, the only issue for hearing under this Notice is whether the subject products should be cancelled.

C. Potential Scope of Final Action

FIFRA section 6(b) allows the registrant, within the 30 days following publication or receipt of EPA's notice, to ''make the necessary corrections, if possible''. 7 U.S.C. 136d(b). As noted in unit IV., the chlorpyrifos products listed in unit I.A. must be cancelled because they bear labeling for use on food although no tolerances exist to cover chlorpyrifos residues in or on food for those uses. Terminating food uses and removing those uses from labels would resolve the violations EPA has identified in this Notice. Therefore, EPA recognizes that the registrant has an opportunity to make corrections by requesting cancellation of these uses and amending labels.

FIFRA section 6(b) also states ''in taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the **Federal Register** an analysis of such impact.'' Id.

Accordingly, in any final action on this Notice, EPA may consider, as an alternative to cancellation of the whole registrations, cancelling only those uses that result in residues in or on food. As part of its registration review of chlorpyrifos, EPA considered the potential economic impacts on growers if chlorpyrifos use was eliminated for various registered food crops. *See* Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (November 18, 2020), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969;* Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031.* Although EPA may consider benefits for certain uses under FIFRA, economic impacts to growers is not a consideration for EPA in making a safety determination under the FFDCA. Because EPA determined that the tolerances did not meet the safety standard under the FFDCA, EPA revoked all chlorpyrifos tolerances. See 86 FR 48315. As a result, chlorpyrifos may not be used in or on food without resulting in adulterated food, which cannot be distributed in interstate commerce. Restricting the chlorpyrifos products listed in unit I.A. to only those uses that do not result in residues in or on food would have no economic impact, beyond the impact already resulting from the revocation of the chlorpyrifos tolerances, since these products already cannot be used on food due to the lack of tolerances.

VI. Mandated FIFRA Reviews

A. What is required?

When EPA intends to issue a NOIC, it must furnish a draft of that Notice and an analysis of the impact of the proposed action on the agricultural economy to the Secretary of the USDA for comment at least 60 days prior to sending such Notice to the registrant or making such Notice public. 7 U.S.C. 136d(b). When a public health use is affected, FIFRA section 6(b) also directs the Secretary of the Department of Health and Human Services (HHS) to provide available benefits and use information, or an analysis thereof. Within the same time period, the Agency must also submit the proposed cancellation action to the FIFRA Scientific Advisory Panel (SAP) for comment concerning the impact of the proposed action on health and the environment, unless the SAP agrees to waive its review. 7 U.S.C. 136w(d).

In the event that written comments are received from the USDA, HHS, or the SAP within 30 days of such referral, the Agency must publish those comments and the Agency's response to the comments.

B. What are the results of this review?

Because all tolerances for chlorpyrifos have already been revoked for the reasons set forth in the Final Rule and Denial Order, this proposed cancellation action itself is not anticipated to have any impacts on the agricultural economy. This NOIC is purely an administrative action to address three registrations that the registrant is unable or unwilling to cancel or modify to comply with the Agency's tolerance revocation. EPA provided a draft of this NOIC to the SAP requesting a waiver due to the lack of scientific issues for consideration by the SAP. The SAP waived its review of this NOIC on August 19, 2022.

This NOIC is not subject to review by HHS because there are no public health uses affected by this NOIC.

On August 11, 2022, EPA provided a draft of this NOIC to USDA for review and received a response from USDA on September 11, 2022. USDA expressed three major concerns in its comments: (1) that an economic analysis was not provided for review in conjunction with the draft NOIC; (2) USDA's opinion that historical precedent and procedures was not followed; and (3) USDA's opinion that EPA could have retained some tolerances consistent with the proposal in the Proposed Interim Registration Review Decision for Chlorpyrifos (2020 PID) instead of revoking all tolerances and should initiate action to reestablish tolerances consistent with the conclusions of the 2020 PID. USDA's comments are available at *https://www.regulations.gov* in the docket for this action, docket ID EPA–HQ–OPP–2022–0417.

The Agency has considered each of these comments prior to finalizing this Notice. Below is a summary of these comments and the Agency's detailed responses to these comments.

Comment: USDA notes that FIFRA requires EPA to consider the impact of the action proposed in the NOIC on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and to provide that analysis to the USDA. USDA expressed concern with statements in EPA's draft NOIC that the cancellation of the products would produce no negative effects beyond those that were already imposed when EPA revoked the chlorpyrifos tolerances. Since, as USDA notes in their comments, the FFDCA does not provide for consideration of economic impacts in a determination of whether to retain tolerances, the USDA had concerns about the lack of consideration to the economy.

EPA Response: As noted in unit III, EPA revoked the chlorpyrifos tolerances in a final rule issued in August 2021, as a result of concluding that the chlorpyrifos tolerances were not safe. As USDA recognizes, the FFDCA does not authorize EPA to consider economic impacts to farmers when determining whether to retain tolerances. As noted in the Final Rule and the Denial Order, the FFDCA permits EPA to leave a tolerance in place only if it is safe; whether a tolerance is important to the agricultural economy is not a permissible consideration for EPA in determining whether to leave a tolerance in place.

When the tolerances were revoked, chlorpyrifos was no longer permitted to be used on food crops. Although not a consideration under the FFDCA, as part of its assessment of chlorpyrifos in registration review, EPA prepared a benefits assessment and a small business analysis of the economic benefits of chlorpyrifos for a variety of crops as well as the potential economic impact if chlorpyrifos were not available. *See* Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (November 18, 2020), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969;* Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021), available at *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031.*

Although the benefits assessment and small business analysis did indicate some economic impacts as a result of chlorpyrifos not being available for growers, those impacts have already occurred as a result of the revocation of the tolerances and would not be attributable to the cancellation of these products. Even if these products were not cancelled, the products could still not be used as a result of the tolerance revocation; thus, the same economic impact would result with or without this cancellation action. To the extent the products being cancelled are registered for non-food uses, these are not the only chlorpyrifos products registered for these non-food uses. Consequently, EPA concluded that the cancellation action being proposed in this NOIC itself does not actually result in any impact on agricultural commodities, retail food prices, or the agricultural economy.

Comment: USDA notes that it considers EPA's process for revoking tolerances as ''harmful precedent'' that has created confusion and concern among agricultural stakeholders and international trading partners. USDA asserts that the lack of a phase-out period has caused a widespread disposal problem for existing stocks of chlorpyrifos, and that the ''divergence from normal procedures caused confusion and concerns'' and may ''harm the economic viability of U.S. producers in the long-term'' by undercutting U.S. credibility in future trade negotiations.

EPA Response: As an initial matter, EPA notes that this comment does not appear to be directly relevant to the cancellation of the particular products identified in this NOIC, but rather a commentary on EPA's issuance and implementation of the final rule revoking tolerances. Prior to the issuance of the final rule, EPA coordinated with FDA and USDA to ensure they could develop any necessary enforcement guidance, such as how long legally treated food and feed commodities may be in the channels of trade, and FDA released a document entitled *Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities,* in order to provide guidance to stakeholders in the food industry. In addition, in the Final Rule itself and contrary to the USDA's assertion, EPA did provide a six-month transition period between the publication of the final revoking tolerances and the effective date of the revocation consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures. Although EPA recognizes that there has been confusion in the regulated community on what to do with registered chlorpyrifos products that can no longer be used on food, EPA is, and has been, working with registrants to provide for an appropriate transition. Specifically, the Agency continues to work with the registrants in the development of their return programs and update stakeholders and the Agency's website with the latest information regarding chlorpyrifos.

To the extent this comment expressed a concern about the process EPA used for terminating use of chlorpyrifos on food, EPA fully addressed this comment in its Denial Order. *See* 87 FR at 11247–49. Objectors to EPA's Final Rule alleged that EPA was required to negotiate with chlorpyrifos registrants and cancel food uses under FIFRA before revoking tolerances under the FFDCA. Consistent with EPA's position in the Denial Order, neither FIFRA nor the FFDCA direct that the Agency proceed with cancellation under FIFRA prior to revoking tolerances under the FFDCA. *Id.* Where EPA determines that tolerances are not safe, the FFDCA requires that tolerances be revoked, regardless of the economic impact of that revocation. In addition, in this particular instance, the Ninth Circuit prioritized the Agency taking action under the FFDCA over taking action under FIFRA, by ordering EPA to take action on the tolerances within 60 days of the issuance of the mandate in that case, *i.e.,* August 20, 2021, and to take action to cancel food uses ''in a timely fashion''. *LULAC,* 996 F.3d. at 703–04.

Nonetheless, even with the restricted timeframe imposed by the Ninth Circuit and the need to prioritize tolerance actions under the FFDCA over cancellations under FIFRA, EPA did attempt to coordinate the tolerance revocations with cancellation actions. While EPA was unable to complete the necessary steps for that process to impact the tolerance revocation rule for chlorpyrifos by the Court's deadline, EPA recognizes that coordinating tolerance revocations and FIFRA cancellations can be helpful since product cancellation orders can provide clarity around existing stocks and disposal procedures.

Comment: USDA's comments outline its opinion that the Agency could have pursued a pathway on the 11 high benefit uses outlined in the 2020 PID instead of revoking all tolerances. USDA also requests Agency-initiated action to reestablish tolerances consistent with the conclusions of the 2020 PID.

EPA Response: EPA notes that this comment appears to be more appropriately directed towards the Final Rule itself rather than the cancellation action that is the subject of this NOIC. Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of the 2021 final tolerance rule and may also request a hearing on those objections. USDA did not file any such objection, although several other parties did, asserting that EPA should have left tolerances in place associated with 11 uses as described in the 2020 PID rather than revoking all the tolerances. EPA denied that objection in its Denial Order. See 87 FR at 11244–47. The Denial Order fully explained the rationale for not adopting the proposal presented in the 2020 PID. Briefly, in the December 2020 PID, EPA proposed that all chlorpyrifos uses contributing aggregate exposures be cancelled except for 11 specific uses in specific geographic areas. Those 11 uses were identified by registrants and EPA as having high benefits, although the Agency recognized that it was just one possible subset of uses that might be retainable. The Agency's proposed safety determination for those uses was contingent on other uses being cancelled and additional use restrictions being in effect. It is also important to note that the findings in the PID were simply proposals, and those proposals, and the underlying risk assessments on which those proposals were based, were subject to public comment and did not represent a final safety determination. Despite the potential for supporting a safety finding consistent with the PID, at the time that EPA was required to expeditiously issue a rule by the Ninth Circuit, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: no uses had been cancelled, no labels had been revised to geographically limit applications or limit maximum application rates, nor had any applications to initiate such actions been filed with the Agency. Therefore, at the time of the Final Rule, the option to leave certain tolerances in place was not available. Thus, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance, finding that it could not determine that there was a reasonable certainty of no harm from aggregate exposure. As a result, chlorpyrifos tolerances were revoked and expired as of February 28, 2022.

A challenge to the Final Rule is outside the scope of this NOIC. All the chlorpyrifos tolerances have been revoked, so the products identified in this document must be cancelled because they bear labeling for use on food. As noted above, the Agency views this NOIC as an administrative action, as once tolerances were revoked, chlorpyrifos products cannot bear labeling for use on food, since the products could no longer be used without rendering food and feed crops adulterated.

The request to reestablish tolerances associated with those 11 uses is also outside the scope of this NOIC. At this time, the Agency does not intend to initiate a rulemaking to re-establish those tolerances. Initiating tolerance rulemaking under section 408(e) of the FFDCA is a discretionary action, 21 U.S.C. 346a(e), and at this time, no petition has been submitted requesting specific tolerances to be established under section 408(d) of the FFDCA, 21 U.S.C. 346a(d). Even if EPA initiated such a rulemaking, or if a petition were submitted, EPA would need to follow the statutory process and make a determination that the tolerances were safe in order to establish them. It is important to note that the proposal in the 2020 PID was only a proposed safety finding based on a subset of uses; it was not a final determination of safety. Any final safety determination supporting the re-establishment of the tolerances would need to take into consideration aggregate exposures to chlorpyrifos.

VII. Requesting a Hearing

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Who can request a hearing?

A registrant or any other person who is adversely affected by a cancellation of registration as described in this Notice may request a hearing.

B. When must a hearing be requested?

A request for a hearing by a registrant must be submitted in writing within 30 days after the date of receipt of the NOIC, or within 30 days after publication of this announcement in the **Federal Register**, whichever occurs later. A request for a hearing by any other person adversely affected by the Agency's proposed action must be submitted within 30 days after the date of publication of this Notice in the **Federal Register**. See the **DATES** section of this document.

C. How must a hearing be requested?

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Among other requirements, these rules include the following requirements:

- Each hearing request must specifically identify by registration or accession number each individual pesticide product for which a hearing is requested, 40 CFR 164.22(a);
- Each hearing request must be accompanied by a document setting forth specific objections that respond to the Agency's reasons for proposing cancellation as set forth in this Notice, and stating the factual basis for each such objection, 40 CFR 164.22(a); and
- Each hearing request must be received by the OALJ within the applicable 30-day period, 40 CFR 164.5(a).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation for the products in question by operation of law.

D. Where does a person submit a hearing request?

Requests for hearing must be submitted to the OALJ. The OALJ strongly encourages electronic filing due to the coronavirus pandemic. *See* Order Urging Electronic Service and Filing, issued by Chief ALJ Biro (April 10, 2020), available at *https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.*

1. *Submitting the hearing request electronically.* To file a document electronically, a party shall use a web-based tool known as the OALJ E-Filing System by visiting the OALJ's website at *https://www.epa.gov/alj.* Documents filed electronically are deemed to constitute both the original and one copy of the document.

Any party choosing to file electronically must first register with the OALJ E-Filing System at *https://yosemite.epa.gov/oa/eab/EAB-ALJ_Upload.nsf.* There may be a delay of one to two business days between the time a party applies for registration and the time at which the party is able to upload documents into the system.

A document submitted to the OALJ E-Filing System is considered ''filed'' at the time and date of electronic reception, as recorded by the OALJ E-Filing System immediately upon reception. To be considered timely, documents submitted through the OALJ E-Filing System must be received by 11:59 p.m. Eastern Time on the date the document is due, unless another time is specified by the Judge. Within an hour of a document being electronically filed, the OALJ E-Filing System will generate an electronic receipt of the submission that will be sent by email to both the party submitting the document and the Headquarters Hearing Clerk. This emailed electronic receipt will be the filing party's only proof that the OALJ received the submitted document. The absence or presence of a document on the OALJ's E-Docket Database web page, available at *https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf,* or on the Agency's Administrative Enforcement Dockets web page, available at *https://yosemite.epa.gov/oa/rhc/epaadmin.nsf,* is not proof that the document was or was not received. If the filing party does not receive an electronic receipt within one hour after submitting the document through the OALJ E-Filing System, the

Headquarters Hearing Clerk may be able to confirm receipt of the document but not earlier than one hour after the document was submitted.

The OALJ E-Filing System will accept any type of digital file, but the file size is limited to 70 megabytes. Electronically filed textual documents must be in Portable Document Format (''PDF''). If a party's multimedia file exceeds 70 megabytes, the party may save the file on a compact disc and send it by U.S. mail to the Hearing Clerk mailing address identified in unit VII.D.2. of this Notice, or the party may contact the Headquarters Hearing Clerk at (202) 564–6281 for instructions on alternative electronic filing methods.

A motion and any associated brief may be filed together through the OALJ E-Filing System. However, any documents filed in support of a brief, motion, or other filing, such as copies of proposed exhibits submitted as part of party's prehearing exchange, should be filed separately as an attachment. Where a party wishes to file multiple documents in support of a brief, motion, or other filing, rather than filing a separate attachment for each such document, the documents should be compiled into a single electronic file and filed as a single attachment, to the extent technically practicable.

2. *Submitting the hearing request by non-electronic means.* Alternatively, if a party is unable to file a document utilizing the OALJ E-Filing System, *e.g.,* the party lacks access to a computer, the party may file the document by U.S. mail or facsimile, although the OALJ's ability to receive filings via those methods is limited. U.S. mail is currently being delivered to the OALJ at an offsite location on a weekly basis only, and documents sent by facsimile will also be received offsite. If a party must file documents by U.S. mail or facsimile, the party shall notify the Headquarters Hearing Clerk each time it files a document in such a manner by calling (202) 564–6281.

To file a document using U.S. mail, the document shall be sent to the following mailing address: Mary Angeles, Headquarters Hearing Clerk, Office of Administrative Law Judges (Mail Code 1900R), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Please note that mail deliveries to federal agencies are screened off-site, and this security procedure can delay delivery.

Facsimile may be used to file a document if it is fewer than 20 pages in length. To file a document using facsimile, the document shall be sent to OALJ's offsite location at (916) 550–9639.

A document submitted by U.S. mail or facsimile is considered ''filed'' when the Headquarters Hearing Clerk physically receives it, as reflected by the inked date stamp physically applied by the Headquarters Hearing Clerk to the paper copy of the document.

At this time, the OALJ is not able to accept filings or correspondence by courier or commercial delivery service, such as UPS, FedEx, and DHL. Likewise, the physical office of the OALJ is not currently accessible to the public, and the OALJ is not able to receive documents by personal delivery. For further information on filings with the OALJ, please see *https://www.epa.gov/alj.*

3. *Important reminders.* Regardless of the method of filing, all filed documents must be signed in accordance with 40 CFR part 164 and must contain the contact name, telephone number, mailing address, and email address of the filing party or its authorize representative. A copy of each document filed in this proceeding shall also be ''served'' by the filing party on the presiding judge and on all other parties.

E. The Hearing

If a hearing concerning any product affected by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings, 40 CFR part 164, and the procedures set forth in this unit. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

F. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. 40 CFR 164.7. To facilitate compliance with the *ex parte* rule, the following are designated as adjudicatory personnel for purposes of this proceeding: the Administrative Law Judges and their staff and the Environmental Appeals Board and its staff. None of the persons identified as adjudicatory personnel may discuss the merits of the proceeding with any person with an interest in the proceeding, or representative of such person, except in compliance with 40 CFR 164.7.

List of Subjects

Environmental protection, Pesticides and pests, Cancellation.

Dated: December 9, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–27130 Filed 12–13–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0732; FRL–9942–02–OCSPP]

Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final revision to the risk determination for the perchloroethylene (PCE) risk evaluation issued under the Toxic Substances Control Act (TSCA). The revision to the PCE risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that PCE, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. This revision supersedes the condition of use-specific no unreasonable risk determinations in the December 2020

EXHIBIT 4

33658-17 11|28|2011 1of5

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

November 28, 2011

Frank E. Sobotka
IPM Resources LLC
4032 Crockers Lake Blvd., Suite 818
Sarasota, FL 34238

Dear Dr. Sobotka:

Subject: Amended labeling to modify the directions for use
Product Name: Chlorpyrifos Technical
EPA Reg. No.: 33658-17
EPA Decision No.: 456408
Your submission dated 10/3/11; resubmission dated 11/21/11

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

- On page 3, in the third paragraph, delete the phrase "post-bloom spray" in the statement: "Any use to formulate…products intended for use on tomatoes…is strictly prohibited." This phrase appears to have been inadvertently retained.

Please submit two copies of your final printed labeling before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at: (703) 308-8735, or by email at: chao.julie@epa.gov.

Regards,

Venus Eagle

Venus Eagle, Product Manger (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Gharda Chemicals Limited

CHLORPYRIFOS TECHNICAL

ACCEPTED
With COMMENTS
In EPA Letter Dated:
NOV 28 2011
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No: 33658-17

AN INSECTICIDE FOR FORMULATING USE ONLY

Active Ingredient:
Chlorpyrifos
O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate…………………. 98.00 %
Other Ingredients:………………………………………………………………. 2.00 %
100.00 %

READ ALL DIRECTIONS BEFORE USING
KEEP OUT OF REACH OF CHILDREN
WARNING

FIRST AID
(Organophosphate Insecticide)

If swallowed:	▪ Call poison control center or doctor immediately for treatment advice. ▪ Have person sip a glass of water if able to swallow. ▪ Do not induce vomiting unless told to do so by the poison control center or doctor. ▪ Do not give anything by mouth to an unconscious person.
If inhaled:	▪ Remove person to fresh air. ▪ If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. ▪ Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	▪ Take off contaminated clothing. ▪ Rinse skin immediately with plenty of water for 15-20 minutes. ▪ Call a poison control center or doctor for treatment advice.
If in eyes:	▪ Hold eye open and rinse slowly and gently with water for 15-20 minutes. ▪ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. ▪ Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER
(Organophosphate Insecticide)

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information call: 1-(866)-359-5660

NOTE TO PHYSICIAN

Chlorpyrifos is a cholinesterase inhibitor. Initial treatment measures include removal of secretions, maintenance of a patent airway and, if necessary, artificial respiration. When cyanosis is relieved, atropine may be administered in large therapeutic doses, repeated as necessary to the point of tolerance. If symptoms warrant further treatment, protopam chloride (pralidoxime chloride, 2-PAM chloride) has shown utility as adjunctive therapy. Never use morphine. Continued absorption of the poison may occur, resulting in a fatal relapse after initial improvement in condition. Close supervision of the patient is indicated for at least 48 to 72 hours.

See additional precautionary statements on side panel.

Gharda Chemicals Limited
660 Newtown-Yardley Road
Newtown, PA 18940

EPA Reg. No. 33658-17
EPA Est. No. 33658-IND-3

Net Wt. 625 lbs. (283.5 KGS)

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

WARNING

May be fatal if swallowed. May be fatal if inhaled. Do not breathe dust. Remove contaminated clothing and wash clothing before reuse. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Environmental Hazards

This pesticide is toxic to birds and wildlife, and extremely toxic to fish, aquatic organisms and bees. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR MANUFACTURING USE ONLY

CHLORPYRIFOS TECHNICAL may be used only for formulation into other manufacturing-use products or end-use products for uses accepted by the United States Environmental Protection Agency. Because of their properties and intended uses, insecticidal formulations containing CHLORPYRIFOS TECHNICAL will require precautionary labeling different from that given. Formulators should develop their own use and precautionary labeling based on the properties and intended use of their own finished formulations, and are responsible for obtaining EPA registrations of these products.

CHLORPYRIFOS TECHNICAL MAY BE FORMULATED ONLY INTO END-USE PRODUCTS WITH THE FOLLOWING USES ON THE LABEL:

This product may only be formulated for the agricultural uses listed below if the EPA-approved labeling of the formulated product bears revised worker reentry intervals (REIs) of a duration no less than the following:

For all crops: 24 hours, unless specifically noted otherwise below

- Cauliflower: 3 days
- Fruit trees (dormant/delayed dormant: trunk spray or preplant dip): 4 days
- Citrus trees: 5 days
- Citrus orchard floors: 5 days
- Fig: 4days

The end-use product labeling may include the following statement: "Certified crop advisors or persons entering under their direct supervision under certain circumstances may be exempt from the early reentry requirement pursuant to 40 CFR Part 170."

Agricultural Uses - Alfalfa, Asparagus, Christmas Tree Plantations, Banana, Blueberry, Caneberry, Cherimoya, Citrus Fruits, Corn (maximum of 3 lb ai/acre/season and no application to popcorn), Cotton, Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, Soybeans, Sunflowers, Sugar Beets, Sugarcane, Strawberries, Sweet Potatoes, Tobacco, Tree Fruit, [apples (Only one application of any chlorpyrifos containing product can be made per year. The application can be either a pre-bloom dormant/delayed dormant to the canopy or the trunk, or a post bloom application to the lower 4 feet of the trunk)], pears, cherries, plums/prunes, peaches and nectarines), Tree Nuts (almonds, filberts, pecans, and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and Wheat.

Non-Agricultural Uses - Non-Residential Outdoor Pest Control (golf courses, road medians, and industrial plant sites); and, Non-Residential Ornamentals (flowers, shrubs, vines, shade & flowering trees, non-bearing fruit, nut, and citrus trees, and evergreens), Sod Farms, Perennial Grass Seed Crops, Annual and Perennial Plants, Road Medians, and Industrial Plant Sites.

ANY USE TO FORMULATE MANUFACTURING-USE OR END-USE PRODUCTS INTENDED FOR POST-BLOOM SPRAY USE ON TOMATOES, INDOOR, GREENHOUSE, NURSERY GROWN ORNAMENTALS, PAINT ADDITIVE, PET CARE, ANIMAL HEALTH, OR FOR MOSQUITO CONTROL IS STRICTLY PROHIBITED.

ALL MANUFACTURING-USE PRODUCTS PRODUCED FROM THIS PRODUCT MUST BEAR A STATEMENT PROHIBITING FORMULATION OF SUCH PRODUCTS FOR USES OTHER THAN IDENTIFIED ABOVE.

Any manufacturing-use product formulated from this product must bear EPA-approved labeling that is consistent with the terms of the June 7, 2000 memorandum of agreement between EPA and registrants of pesticide products containing chlorpyrifos.

This product may only be used to formulate an end-use pesticide product labeled for non-agricultural, non-termite control uses in accordance with the following conditions:

Any emulsifiable concentrate (EC) end-use product formulated from this product must be labeled as a restricted use product. All end-use products formulated from this product must be labeled as restricted use or packaged in containers no smaller than 50 pounds for granular formulations. All other end-use products formulated from the product must either be labeled as restricted use or packaged in containers no smaller than 15 gallons of a liquid formulation or 25 pounds of a dry formulation.

The product may not bear use directions for any residential outdoor use.

The product may not bear use instructions for any non-residential outdoor use other than one or more of the following uses:

(a) golf courses, road medians, and industrial plant sites, provided that the maximum label application rate is no greater than 1 lb./ai per acre;

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.
Pesticide Storage: Store in a cool, dry area away from heat or open flame. Protect from moisture. Avoid contamination with water, acids, or alkalis. Keep container closed. Store in original container in locked storage area.
In Case of Spill: Isolate the spill. Hold this package, other cargo and vehicles involved. For Emergency spill assistance call CHEMTREC (24-hour service): 1-800-424-9300.
Pesticide Disposal: Rinse spray equipment. Any pesticide, spray mixture, or rinse water that cannot be used according to label instructions or chemically reprocessed should be disposed of in a landfill approved for pesticides.
Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.
Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse** as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse** as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.
General: Consult Federal, State or local disposal authorities for approved alternative procedures.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose under normal conditions of use. This is the only warranty made on this product. To the fullest extent permitted by law seller expressly disclaims any implied warranties of merchantability or fitness for any particular purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of the Seller. To the fullest extent permitted by law, in no event shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. To the fullest extent permitted by law ll such risks shall be assumed by the Buyer. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Registered with comments: 12/22/03
Amended: 08/08/06 (Deleted Termiticide Use/Amended Active Ingredients Statement)
Amended: TBA (Amended per RED)

EXHIBIT 5

33658-26 12/20/2012 1/53

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 20, 2012

Gharda Chemicals, Ltd.
c/o Dr. Frank E. Sobotka
IPM Resources LLC
4032 Crockers Lake Blvd., Suite 818
Sarasota, FL 34238

Subject: Amended labeling to implement required spray drift mitigation measures
Product Name: Pilot 4E Chlorpyrifos Agricultural Insecticide
EPA Registration Number: 33658-26
Submission dated August 28, 2012; resubmission dated December 18, 2012

Dear Dr. Sobotka:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy of the label is enclosed for your records. Please submit one copy of your final printed labeling before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at 703-308-8735, or by email at chao.julie@epa.gov.

Regards,

for Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

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[Front Cover (Page 1) of Directions for Use Label Booklet]

RESTRICTED USE PESTICIDE
For retail sale to and use only by certified Applicators or persons under their direct supervision and only for those uses covered by the certified Applicator's certification.

Pull to Open ▶

Group	1B	Insecticide

Pilot® 4E

Chlorpyrifos Agricultural Insecticide

For control of listed insects infesting certain field, fruit, nut, and vegetable crops and wheat.

Active Ingredient:
Chlorpyrifos: O,O-diethyl-O-(3,5,6-trichloro-2-pyridinyl)
phosphorothioate 45.0%
Other Ingredients:..55.0%
Total 100.0%
Contains petroleum distillate
Contains 4 pounds of Chlorpyrifos per gallon.

KEEP OUT OF REACH OF CHILDREN
WARNING AVISO
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Refer to inside Label Booklet for additional Precautionary information including Directions for Use.

EPA Registration No.: 33658-26

FIRST LETTERS IN BATCH CODE INDICATES PRODUCING ESTABLISHMENT:
EPA Est. No.: 5905–GA–01=CG
5905–IA–01=DI
44616–MO–1=SJ

ACCEPTED
DEC 20 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No: 33658-26

Manufactured for:
Gharda Chemicals Limited
660 Newtown-Yardley Rd., Suite 106
Newtown, PA 18940
1-(215)-968-9474

Net Contents: [1.0, 2.5, Bulk] gal

[Inside (Page 2) Directions for Use Label Booklet]

RESTRICTED USE PESTICIDE
For retail sale to and use only by certified Applicators or persons under their direct supervision and only for those uses covered by the certified Applicator's certification.

PILOT ® 4E Chlorpyrifos Agricultural Insecticide

For control of listed insects infesting certain field, fruit, nut, and vegetable crops and wheat.

Group	1B	Insecticide

Active Ingredient:
Chlorpyrifos: O,O-diethyl O-(3,5,6-trichloro-2-pyridinyl) phosphorothioate 45.0%
Other Ingredients: 55.0%
Total: 100.0%
Contains petroleum distillate
Contains 4 pounds of Chlorpyrifos per gallon.

KEEP OUT OF REACH OF CHILDREN

WARNING AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Agricultural Use Requirements
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Agricultural Chemical: Do not ship or store with food, feeds, drugs or clothing.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING. May Be Fatal If Swallowed. Harmful If Absorbed Through The Skin. Causes Moderate Eye Irritation. Avoid contact with skin, eyes or clothing.

Personal Protective Equipment (PPE)

Materials that are chemical-resistant to this product are Barrier Laminate and Viton ≥ 14 mils. If you want more options, follow the instructions for category G on an EPA chemical resistance category selections chart.

Mixers and loaders using a mechanical transfer loading system and applicators using aerial application equipment must wear:
- Long-sleeved shirt and long pants
- Shoes and socks

In addition to the above, mixers and loaders using a mechanical transfer loading system must wear:
- Chemical-resistant gloves
- Chemical-resistant apron
- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approved number prefix TC-21C or

a NIOSH-approved respirator with any R, P, or HE filter

See Engineering Controls for additional requirements.

All other mixers, loaders, applicators and other handlers must wear:
- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves
- Chemical-resistant apron when mixing or loading or exposed to the concentrate
- Chemical resistant footwear plus socks
- Chemical-resistant headgear for overhead exposure
- A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any R, P or HE filter.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls: Mixers and loaders supporting aerial applications must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal protection, and must:
- Wear the personal protective equipment required above for mixers/loaders
- Wear protective eyewear if the system operates under pressure, and
- Be provided and have immediately available for use in an emergency, such as broken package, spill, or equipment breakdown: coveralls, chemical resistant footwear and chemical-resistant headgear if overhead exposure

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6)].

Use of human flaggers is prohibited. Mechanical flagging equipment must be used.

When handlers use closed cab motorized ground application equipment in a manner that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:
- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing and/or PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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FIRST AID (Organophosphate Insecticide)	
If swallowed:	• Call poison control center or doctor immediately for treatment advice. • Do not give any liquid to the person. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled:	• Remove person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER (Organophosphate Insecticide)	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information call: 1-(866)-359-5660	
NOTE TO PHYSICIAN	
Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as 2- PAM/protopam, may be therapeutic if used early; however, use only in conjunction with atropine. In case of severe acute poisoning, use antidote immediately after establishing an open airway and respiration. **Note**: Contains Petroleum Distillate - vomiting may cause aspiration pneumonia.	

Environmental Hazards: This pesticide is toxic to fish, aquatic in- vertebrates, small mammals and birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Cover or incorporate spills. Do not contaminate water when disposing of equipment wash water or rinsate. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Physical or Chemical Hazards: Notice: Read the entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer at the end of this label.

Combustible. Do not use or store near heat or open flame.

Directions for Use

RESTRICTED USE PESTICIDE

For retail sale to and use only by certified Applicators or persons under their direct supervision and only for those uses covered by the certified Applicator's certification.

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read all Directions for Use carefully before applying.

This product cannot be reformulated or repackaged into other end- use products.
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the required restricted entry interval (REI). The REI for each crop is listed in the directions for use associated with each crop.

Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Certified crop advisors or persons entering under their direct supervision under certain circumstances may be exempt from the early entry requirements pursuant to 40 CFR Part 170.

Certified crop advisors or persons entering under their direct supervision under certain circumstances may be exempt from the early reentry requirements pursuant to 40 CFR Part 170.
PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:
- Coveralls over short-sleeved shirt and short pants;
- Chemical-resistant gloves made out of any water proof material;
- Chemical-resistant footwear plus socks;
- Chemical-resistant headgear for overhead exposure.

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

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Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in original container in secured dry storage area. Prevent cross-contamination with other pesticides and fertilizers. Do not store above 100°F for extended periods of time. Storage below 20°F may result in formation of crystals. If product crystallizes, store at 50°F to 70°F and agitate to redisolve crystals. If container is damaged or spill occurs, use product immediately or dispose of product and damaged container as indicated below.

Pesticide Disposal: Open dumping is prohibited. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Handling and Disposal

Nonrefillable containers 5 gallons or less: Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Offer for recycling, if available.

Nonrefillable containers 5 gallons or less: Triple rinse or pressure rinse container (or equivalent) promptly after emptying. <u>Triple rinse as follows</u>: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1⁄4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. <u>Pressure rinse as follows</u>: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow be- gins to drip. Hold container upside down over application equip- ment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.
Refillable containers 5 gallons or larger: Refillable containers. Refill this container with pesticide only. Do not reuse this container for any other purpose.

Refillable containers 5 gallons or larger: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water and, if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

SPILLS: For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away. **You may contact the CHEMTREC Emergency Response for decontamination procedures.**

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300

Use Precautions and Restrictions

Insect control may be reduced at low spray volumes under high temperature and wind conditions. Some reduction in insect control may occur under unusually cool conditions.
Flood Irrigation: To avoid contamination of irrigation tail waters, do not flood irrigate within 24 hours following a soil surface or foliar application of Pilot 4E. **Do not apply aerially in Mississippi.**

Insecticide Resistance Management (IRM)

Pilot 4E contains a Group 1B insecticide. Insect/mite biotypes with acquired resistance to Group 1B may eventually dominate the insect/mite population if Group 1 B insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by Pilot 4E or other Group 1B insecticides.
To delay development of insecticide resistance, the following practices are recommended:

- Avoid consecutive use of insecticides with the same mode of action (same insecticide group) on the same insect species.
- Use tank mixtures or premix products containing insecticides with different modes of action (different insecticide groups) provided the products are registered for the intended use.
- Base insecticide use on comprehensive integrated Pest Management (IPM) programs.
- Monitor treated insect populations in the field for loss of effectiveness.
- Contact your local extension specialist, or certified crop advisor for insecticide resistance management and/or IPM recommendations for the specific site and resistant pest problems.

Spray Drift Management

Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland sites, woodlands, pastures, rangelands, or animals. Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making decision to apply this product.

Observe the following precautions when spraying Pilot 4E adjacent to permanent bodies of water such as rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds

The following treatment setbacks or buffer zones must be utilized for applications around the above listed aquatic areas with the following application equipment:

Application Method	Required Setback (Buffer Zone) (feet)
ground boom	25
chemigation	25
orchard airblast	50
aerial (fixed wing or helicopter)	150

Making applications when wind is blowing away from sensitive areas is the most effective way to reduce the potential for adverse effects.

The following spray drift best management practices are recommended to avoid off-target drift movement from applications.

Spray Drift Mitigation Measures (SDMM)

The buffer distances specified in the below table are the distances in feet that must exist to separate sensitive sites from the targeted application site. Buffers are measured from the edge of the sensitive site to the edge of the application site. Sensitive sites are areas frequented by non-occupational bystanders (especially children). These include residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or commercial purposes. Sensitive sites include homes, farmworker housing, or other residential buildings, schools, daycare centers, nursing homes, and hospitals. Non-residential agricultural buildings, including barns, livestock facilities, sheds, and outhouses are not included in the prohibition.

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 Psylla control, up to 2.3 lb ai/A.
[2]NA is not allowed.

Only pesticide handlers are permitted in the setback area during application of this product. Do not apply this product if anyone other than a mixer, loader, or applicator, is in the setback area.
Exception: Vehicles and persons riding bicycles that are passing through the setback area on public or private roadways are permitted.

Specific Spray Drift Mitigation Use Directions
Spray Drift Mitigation Measures apply to all Agricultural Uses for chlorpyrifos products including Nurseries. These measures do not apply to Non-Agricultural uses, such as, golf-course turf, greenhouses, wood products or in applications where chlorpyrifos is applied as an adult mosquitoside.
Note: Spray Drift Mitigation Measures do not apply to Granular product applications made in-furrow, T-banded or banded post emergence. However, Spray Drift Mitigation Measures do apply to granular applications made by ground boom spreaders, or when chlorpyrifos granules are applied aerially.

Aerial Application

1. The boom width must not exceed 75% of the wingspan or 90% of the rotor blade.
2. Nozzles must always point backward, parallel with the air stream, and never be pointed downward more than 45 degrees.
3. Nozzles must produce a medium or coarser droplet size (255-340 microns volume median diameter) per ASE Standard 572 under application conditions. Airspeed, pressure, and nozzle angle can all effect droplet size. See manufacturer's catalog or USDA/NAAA Applicator's Guide for spray size quality ratings.
4. Applications must not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.
5. Use upwind swath displacement and apply only when wind speed is 3 to 10 mph as measured by an anemometer. Do not apply product when wind speed exceeds 10 mph.
6. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or crop canopy.

Where states have more stringent regulations, they must be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory.

Aerial Drift Reduction Advisory
This section is advisory in nature and does not supercede the mandatory label requirements.

Information on Droplet Size: The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent adverse effects from drift if applications are made improperly, or under unfavorable environmental conditions (**see Wind, Temperature and Humidity, and Temperature Inversions**).

Controlling Droplet Size:
- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- Nozzle orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
- Nozzle type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

Boom Length: For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

Application Height: Applications should not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making application at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

Swath Adjustment: When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator should compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

Wind: Drift potential is lowest between wind speeds of 2 to 10 mph. However, many factors, including droplet size and equipment type, determine drift potential at any given speed. Application should be avoided below 1.5 mph due to variable wind direction and high in- version potential. **Note:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Temperature and Humidity: When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions: Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by in- creasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas: The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas).

Ground Boom Application
The following mandatory spray drift best management practices are required to reduce the likelihood of off-target drift movement from ground applications.

1. Choose only nozzles and pressures that produce a medium or coarse droplet size (255-400 microns volume median diameter), per ASAE Standard 572. See manufacturer's catalog or USDA/NAAA Applicator's Guide for spray size quality ratings.
2. Apply with nozzle height no more than 4 feet above the ground or crop canopy.
3. Do not apply product when wind speed exceeds 10 mph as measured by an anemometer.

Orchard Airblast Application
The following mandatory spray drift best management practices are required to reduce the likelihood of off-target drift movement from airblast applications.

1. Nozzles must be directed so spray is not projected above the canopies.
2. Apply only when wind speed is 3 to 10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side.
3. Outward pointing nozzles must be shut off when turning corners at row ends.

The applicator should take into account the following best management practices to reduce off-site spray drift. This section is advisory and does not supercede mandatory label requirements.

1. Number of nozzles, nozzle orientation and spray volume, air speed and wind direction are key factors in adjusting airblast spray delivery to match the height and density of the crop canopy. Airblast equipment should be adjusted to provide uniform cover- age while minimizing the amount of spray movement over-the-top or completely through the crop canopy.
   - High air volumes deliver spray more efficiently than air at high speed. Reducing forward travel speed decreases the air speed necessary to deliver the spray to the top of the crop canopy.
   - Use air guides along with the number and orientation of spray nozzles to achieve the desired spray coverage and directional control.
2. The following steps should be taken to minimize drift and the amount of non-target spray:
   - Orient nozzles and adjust air speed/volume/direction to force the spray through the crop canopy but not allow drift past the canopy.
   - Shut off spray delivery when passing gaps in crop canopy within rows.
   - Spray the outside rows of orchards from outside in, directing the spray into the orchard and shutting off nozzles on the side of the sprayer away from the orchard.
   - When treating smaller trees, vines or bushes, shut off top nozzles to minimize over-the-top spray movement.

Application Directions

Broadcast Foliar Application
Apply with conventional power-operated spray equipment using nozzles and spray pressures recommended for insecticides. Apply Pilot 4E in a spray volume of not less than 2 gallons per acre for aerial application equipment (fixed wing or helicopter) or not less than 10 gallons per acre for ground equipment, unless otherwise specified. Increase spray volume to ensure adequate coverage with increased density and height of crop canopy. See Spray Drift Precautions section for recommendations on droplet size.

Ground Application
Orient the boom and nozzles so that uniform coverage is obtained. The swath width should not be wider than the boom. Follow nozzle manufacturer's recommendations for insecticide nozzles with respect to nozzle type, pressure, and spacing.

Broadcast Soil Application
Apply with conventional power-operated spray equipment that will apply the product uniformly to the soil surface. Use nozzles that produce medium or coarse droplets (235-400 microns). Unless otherwise indicated, a spray volume of 10 gallons or more per acre is recommended. For band application, use proportionally less spray volume.

Aerial Application
Use a minimum spray volume of 2 gallons per acre and follow recommendations for best management practices for aerial application, above. Marking of swaths by flagging, permanent markers, or use of GPS equipment is recommended.

Chemigation (Sprinkler Irrigation)
Pilot 4E may be applied to the following crops through properly equipped chemigation systems: alfalfa, citrus (orchard floors only), corn (field and sweet), cotton, cranberry, peppermint, spearmint, tree nut orchard floors (almond, pecan, and walnut), sorghum, soybeans, sugarbeet, and wheat. Do not apply this product by chemigation unless specified in crop-specific directions in this label. Do not apply to labeled crops through any other type of irrigation system.

Note: Unless otherwise indicated in specific use directions, the application rates for chemigation are the same as those recommended for broadcast application.

- **Use Directions for Chemigation (Sprinkler Irrigation)**
  The following use directions must be followed when Pilot 4E is applied by chemigation systems. Thoroughly clean the injection system and tank of any fertilizer or chemical residues, and dispose of the residues according to state and federal laws. Flush the injector with soap and water. Determine the amount of Pilot 4E needed to cover the desired acreage. Mix according to instructions in the Mixing Directions section and bring mixture to desired volume. Do not add crop oil when Pilot 4E is applied by chemigation. Maintain continuous agitation during mixing and throughout the application period. Set the sprinkler system to deliver the desired inches of water per acre. Start the water pump and sprinkler, and let the system achieve the desired pressure and speed before starting the injector. Start the injector and calibrate the injector system according to Calibration instructions in the following Special Use Precautions section. The mixture containing Pilot 4E must be injected continuously and uniformly into the irrigation water line as the sprinkler is moving to ensure uniform application at the correct rate. When the application is finished, flush and clean the entire irrigation and injector system prior to shutting down the system.

- **Use Precautions and Restrictions for Chemigation (Sprinkler Irrigation)**
  Following the below listed use precautions and restrictions will result in a safe and successful application of mixtures containing Pilot 4E:

1. Apply this product only through the following sprinkler irrigation systems: center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, micro sprinkler, or hand move. Do not apply this product through any other type of irrigation system. Do not apply through sprinkler systems that deliver a low coefficient of uniformity such as certain water drive units.
2. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
3. If you have questions about calibration, you should contact state extension service specialists, equipment manufacturers, or other experts.
4. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system.
5. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.
6. The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow. Refer to the American Society of Agricultural Engineer's Engineering Practice 409 for more information.

7. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
8. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
9. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
10. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
11. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. The metering pump must provide a greater pressure than that of the irrigation system at the point of injection.
12. To insure uniform mixing of the insecticide into the water line, inject the mixture through a nozzle placed in the fertilizer injection port or just ahead of an elbow or tee in the irrigation line so that the turbulence will assist in mixing. It is suggested that the injection point be higher than the insecticide tank to prevent siphoning.
13. The tank holding the insecticide mixture should be large enough to allow the system to complete the application with 1 filling. It must be free of rust, fertilizer, sediment, and foreign material, and equipped with an in-line strainer situated between the tank and the injector pump.
14. Calibration: In order to calibrate the irrigation system and injector to apply the mixture of Pilot 4E, determine the following: 1) Calculate the number of acres irrigated by the system; 2) Set the irrigation rate and determine the number of minutes for the system to cover the intended treatment area; 3) Calculate the total gallons of insecticide mixture needed to cover the desired acreage. Divide the total gallons of insecticide mixture needed by the number of minutes to cover the treatment area. This value equals the gallons per minute output that the injector must deliver. Convert the gallons per minute to milliliters or ounces per minute. Calibrate the injector pump with the system in operation at the desired irrigation rate. It is suggested that the timed output of the injector pump be checked at least twice before operation, and the system monitored during operation.
15. Do not apply when wind speed favors drift beyond the area intended for treatment. End guns must be turned off during the application if they irrigate non-target areas.
16. Do not allow irrigation water to collect or run off and pose a hazard to livestock, wells, or adjoining crops.
17. Reentry: Follow requirements in the Agricultural Use Requirements section or crop-specific sections of this label.
18. Do not apply through sprinkler systems that deliver a low coefficient of uniformity such as certain water drive units.

Mixing Directions

Pilot 4E insecticide forms an emulsion when diluted with water and is suitable for use in all conventional spray equipment.

To prepare the spray, add a portion of the required amount of water to the spray tank and with the spray tank agitator operating add the Pilot 4E. Complete filling the tank with the balance of water needed. Maintain sufficient agitation during both mixing and application to ensure uniformity of the spray mixture.

Tank Mixing: Pilot 4E may also be used in tank mixtures with certain herbicides and/or with non-pressure fertilizer solutions as recommended under specific crop use directions. Prepare tank mixtures in the same manner as recommended above for use of Pilot 4E alone. When tank mixtures of Pilot 4E and herbicides are involved, add wettable powders first, flowables second, and emulsifiable concentrates last. Where a fertilizer solution is involved, it is strongly recommended that a fertilizer pesticide compatibility agent such as Unite or Compex be used. Maintain constant agitation during both mixing and application to ensure uniformity of the spray mixture. Do not allow spray mixtures to stand overnight.

Tank Mix Compatibility Test: Test compatibility of the intended tank mixture before adding Pilot 4E to the spray or mix tank. Add proportionate amounts of each ingredient to a pint or quart jar, cap, shake, and invert the jar several times. Observe the mixture for approximately ½ hour. If the mixture balls-up, forms flakes, sludge's, jells, forms oily films or layers, or other precipitates that do not readily redispense, it is an incompatible mixture that should not be used.

Applications

Alfalfa

(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a broadcast foliar spray using aircraft or ground spray equipment. Use a higher rate in the rate range for increased pest pressure. Use a minimum spray volume of 2 gallons per acre (gpa) for aerial application (fixed wing or helicopter) or 10 gpa for ground equipment. Use a spray volume of 5 gpa or more by air or up to 20 gpa by ground when foliage is dense and/or pest population is high and/or under high temperature and wind conditions. Some reduction in insect control may occur under unusually cool conditions.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems to control listed foliar pests. Use listed broadcast application rates. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E
corn rootworm adults (spotted cucumber beetle) grasshoppers leafhoppers	0.5 - 1 pt/acre
alfalfa blotch leafminer alfalfa caterpillar alfalfa weevil larvae and adults armyworms blue alfalfa aphid cowpea aphid cutworms egyptian alfalfa weevil larvae and adults (1) pea aphid plant bugs spittlebugs spotted alfalfa aphid (suppression) (not for use in California)	1 - 2 pt/acre
alfalfa webworm	1.5 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **In California:** For **Egyptian alfalfa weevil** control, apply the specified dosage in a minimum of 5 gpa of water when larvae are actively feeding.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Pilot 4E should not be tank mixed with other pesticides, surfactants, or fertilizer formulations unless prior use has shown the combination to be non-injurious to alfalfa under current conditions of use. Some phytotoxic symptoms may be observed on young, tender, rapidly growing alfalfa treated with Pilot 4E. Alfalfa will outgrow these symptoms and no yield loss should be expected.

- This product is highly toxic to bees exposed to direct treatment on alfalfa. Do not apply if nearby bees are clustered outside of hives and bees are actively foraging in the treated area. Protective information may be obtained from your Agricultural Extension Service.
- To avoid contamination of irrigation tail waters, do not flood irrigate within 24 hours following an application of Pilot 4E.

Specific Use Restrictions:
- **Preharvest Interval**: Do not cut or graze treated alfalfa within 7 days after application of 1/2 pint per acre of Pilot 4E, within 14 days after application of 1 pint per acre, or within 21 days after application of rates above 1 pint per acre.
- Do not make more than four applications per season of Pilot 4E or other product containing chlorpyrifos or apply any product containing chlorpyrifos more than once per alfalfa cutting.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.

Apple Tree Trunk
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 days unless PPE required for early entry is worn.

Apply as a post-bloom application to the lower 4 feet of the apple tree trunk for borer control in states east of the Rockies only (except Mississippi). Mix with water and apply directly to trunk from a distance of no more than 4 feet using low volume handgun or shielded spray equipment. Do not allow spray to contact foliage or fruit.

Target Pests	Pilot 4E
American plum borer apple bark borer broad necked root borer dogwood borer flatheaded apple tree borer roundheaded apple tree borer tilehomed prionus	1.5 quart/100gal

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:
- **Preharvest Interval:** Do not apply within 28 days before harvest.
- Do not make more than one application of Pilot 4E to the apple tree trunk per year as either a prebloom or post-bloom application.
- This product may not be used if a prebloom application of any other product containing chlorpyrifos has been made during the year.
- Do not allow meat or dairy animals to graze in treated orchards.
- Treat only the lower 4 feet of the apple tree trunk.
- Do not apply when wind speed is greater than 10 mph.

Asparagus

(For use only in Arizona, California, Idaho, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Oregon, South Dakota, Washington, and Wisconsin)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a ground broadcast foliar spray. Use sufficient volume of finished spray to ensure thorough coverage of crop foliage. **Note:** Pilot 4E may be applied aerially or with ground equipment for control of armyworms and grasshoppers.

Pest	Pilot 4E
armyworms (1) asparagus aphids (1) asparagus beetles (1) cutworms (2) grasshoppers (1) symphylans (3)	2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. For **armyworms**, **asparagus beetles**, **asparagus aphids**, and **grasshoppers**, apply during the fern stage when field counts or crop injury indicates that damaging pest populations are developing or present.
2. For **cutworms**, it is preferable to apply when the soil is moist and worms are active on or near the soil surface.
3. For **symphylans**, apply at least two weeks before harvest for optimum control.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval:** Do not make more than one preharvest application per season or apply within 1 day of harvest.
- Do not make more than two postharvest applications during the fern stage.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- For use only in the Midwest and Pacific northwest states.
- Maximum single application rate preharvest or postharvest is 1 lb ai chlorpyrifos per acre.

Brassica (Cole) Leafy Vegetables[1] and Radish, Rutabaga, and Turnip

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours (3 days for cauliflower) unless PPE required for early entry is worn.

[1] *Brassica* (cole) leafy vegetables including broccoli, broccoli raab. Brussels sprouts, cabbage, cauliflower, cavalo broccoli, Chinese broccoli, Chinese cabbage, collards, kale, kohnlrabi, mizuna, mustard greens, mustard spinach, rape greens

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- If a preplant incorporation application for direct seeded or transplanted crops is made, **do not** apply this product as an at-plant or post plant soil application. If an at-plant or post plant soil application is made, **do not** apply this product as a preplant incorporation application for direct seeded or transplanted crops.

Preplant Incorporation Application for Direct Seeded or Transplanted Crops

Apply Pilot 4E as a broadcast spray to the soil surface using power-operated ground spray equipment. Use a total spray volume of 10 gpa or more. On the day of treatment, incorporate Pilot 4E into the top 2 to 4 inches of soil using a disc, field cultivator, or equivalent equipment.

Crop	Pest	Pilot 4E
cauliflower	Billbugs Cutworms Grubs Root maggot Symphylans wireworms	4.0 pt/acre
broccoli broccoli raab Brussels sprout cabbage Cavalo broccoli Chinese broccoli Chinese cabbage collards kale kohlrabi mizuna mustard greens mustard spinach rape greens turnip		4.5 pt/acre
radish		5.5 pt/acre
rutabaga		4.5 pt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Insecticides, including Pilot 4E, may contribute to the stress of plants under certain environmental conditions. This stress may reduce plant stand or interfere with normal plant development. Herbicides used preplant incorporated may interact with insecticides and enhance this stress.

At-plant or Post Plant Soil Application

- Apply as indicated in Pest Specific Use Directions. Use a higher rate in the rate range when there is increased pest pressure.

Crop	Pest	Pilot 4E (fl oz/1000 ft of row)

cauliflower	root maggot (1)	1.6 – 2.4
broccoli broccoli raab Brussels sprout cabbage Cavalo broccoli Chinese broccoli Chinese cabbage collards kale kohlrabi mizuna mustard greens mustard spinach rape greens turnip		1.6 – 2.75
broccoli cabbage	root aphid (2)	1.2 (2.4 for double row plantings)
radish	root maggot (3)	1
rutabaga	root maggot (1)	1.6 – 3.2

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. Root maggot:

- **Direct seeded crops (broccoli , broccoli raab, Brussels sprout, cabbage, cauliflower, Cavalo broccoli, Chinese broccoli, Chinese cabbage, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens, rutabaga, turnip):** Apply the specified dosage in a water-based spray as a 4-inch wide band over the row at planting time. Band placement should be behind the planter shoe and in front of the press wheel to achieve shallow incorporation. Use a minimum of 40 gpa total spray volume.
- **Transplanted crops (broccoli , broccoli raab, Brussels sprout, cabbage, cauliflower, Cavalo broccoli, Chinese broccoli, Chinese cabbage, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens, rape greens, turnip):** Apply Pilot 4E as a water-based spray directed to the base of the plants immediately after setting. Use a minimum of 40 gpa total spray. Do not add any additional adjuvants, surfactants or spreader stickers. Do not apply as a foliage application.

2. **Root aphid (broccoli, cabbage):** Apply Pilot 4E in water or with liquid fertilizer injected as a side dress on each side of the row after plants are established. See Mixing Directions section for Mixing instructions for Liquid Fertilizer. Avoid mechanical damage to crop roots. Use a minimum of 15 gpa of total spray volume.

3. **Root maggot (radish):** Apply the specific dosage as a water based drench in the seed furrows with the seed at planting time. Use a minimum of 40 gpa of total drench.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions for Preplant Incorporation and At-Plant or Post Plant Soil Applications:

Post Plant Soil Applications:

- **Soil applications (all labeled crops):**
  - **Preharvest Interval:** Do not apply within 30 days before harvest.
  - Do not foliar apply any other chlorpyrifos product labeled for foliar applications within 10 days of a soil application of Pilot 4E.
  - **Do not aerially apply this product in Mississippi.**
- **Cauliflower:** Do not apply more than 2 pints of Pilot 4E to cauliflower planted in 40-inch rows. Use proportional amounts for other row spacing, but do not exceed 4 pints per acre of Pilot 4E. Do not make more than 1 soil application per crop. The maximum application rate for cauliflower is 1.2 oz ai chlorpyrifos per 1000 ft of row.
- **Broccoli , broccoli raab, Brussels sprout, cabbage, cauliflower, Cavalo broccoli, Chinese broccoli, Chinese cabbage, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens, rape greens, turnip:** Do not apply more than 2.6 pints of Pilot 4E per acre when planted in 40- inch rows. Do not apply more than 4.5 pints of Pilot 4E per acre to these crops when in 20-inch rows (or 2 rows per bed). Use proportional amounts for other row spacing, but do not exceed 4.5 pints per acre of Pilot 4E.
- **Radish:** Do not apply more than 5.5 pints of Pilot 4E per acre. The maximum single application rate for radish is 0.5 oz ai chlorpyrifos (1 fl oz of Pilot 4E) per 1000 ft of row.
- **Rutabaga:** Do not apply more than 4.5 pints of Pilot 4E per acre. The maximum application rate for rutabaga is 1.6 oz ai chlorpyrifos (3.2 fl oz of Pilot 4E) per 1000 ft of row. Do not use rutabaga tops for food or feed purposes.

Foliar Application [*Brassica* (Cole) Leafy Vegetables Only]

Apply with conventional power-operated spray equipment in 20 to 150 gpa of water. Use a higher rate in the rate range when there is in- creased pest pressure. Consult your state agricultural experiment station extension service specialist, or integrated pest control advisor for proper time to treat in your area.

Pest	Pilot 4E
armyworms cabbage aphid cutworms imported cabbage worm striped flea beetle (adult)	1 – 2 pt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 21 days before harvest.
- Do not make more than three applications of products containing chlorpyrifos per crop.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- **Do not aerially apply this product in Mississippi.**

Christmas Trees (Nurseries and Plantations)
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Unless otherwise indicated, apply as a foliar spray using power operated ground equipment. Thorough coverage of foliage is essential. Use a minimum 10 gpa of finished spray with ground equipment. Use higher volume of finished spray, 20 gpa or more, when foliage is dense and/or pest density is high and/or under high temperature and wind conditions.

Nurseries and Plantation Crops

Tree Variety	Insects Controlled	Pilot 4E
balsam fir blue spruce concolor fir douglas fir eastern white pine fraser fir grand fir noble fir scotch pine white spruce	ants (4) aphids adelgids (cooley, eastern spruce gall) Douglas fir needle midge European pine sawfly European pine shoot moth grasshoppers gypsy moth mites (1) (european red spider, two spotted spider) pales weevil (adult) pine needle midge pine spittlebug plant bugs scale (2) (black pine) (pine needle) (pine tortoise) (spruce bud) (striped pine) spittlebugs spruce budworm spruce needleminer	1 qt/acre
	pales weevil (3)	3 qt/100 gal

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Specific Use Directions:
For nurseries, apply only in wholesale nursery operations. Wholesale nursery operations are commercial agricultural operations which do not sell or distribute directly to consumers or the general public through retail sales. Plants, trees, or any parts of the plants or trees treated with this product cannot be sold or distributed directly to consumers or the general public through retail sales.

Pest Specific Use Directions:
1. When large numbers of spider mite eggs are present at the first application, a second application after 7 to 10 days may be required to control newly hatched nymphs and maintain effective control. **Not for control of mites in Washington and Oregon.**
2. For **scale** control apply when scale crawlers are active.
3. Apply as a cut stump drench.
4. Excludes ants of significant public health importance, such as fire ants, harvester ants, carpenter ants, and pharaoh ants.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- **Phytotoxicity:** Do not apply under conditions of extreme heat or drought stress. Environmental factors and varietal differences significantly influence potential phytotoxic expression. **Testing has shown that Pilot 4E *may be used at recommended rates on the following conifer species without serious* phytotoxicity: balsam fir, concolor fir, Douglas fir, eastern white pine, Fraser fir, grand fir, noble fir, Scotch pine, white spruce.** Before treating large numbers of other conifer species, it is recommended that a small block of plants be treated and observed 7 to 10 days for symptoms of phytotoxicity. **Note**: The user assumes responsibility for determining if it is safe to treat other conifer species with Pilot 4E under commercial growing conditions.

Specific Use Restrictions:

- Do not make more than three applications of Pilot 4E or other product containing chlorpyrifos per season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 7 days of the first application.
- Do not allow meat or dairy animals to graze in treated areas.

Citrus Fruits[1]
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 5 days unless PPE required for early entry is worn.

[1]Including calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin (tangerine), pummelo, satsuma mandarin, sour orange, sweet orange, tangelo, tangor

Apply as a concentrate or dilute spray using conventional, power operated spray equipment. Use a higher rate in rate range when there is increased pest pressure. Use sufficient water to ensure thorough and complete coverage of the foliage and fruit. For dilute sprays (greater than 200 gpa), use a spray concentration of at least 0.5 pints of Pilot 4E per 100 gallons of finished spray. Complete coverage is not necessary for outside canopy sprays targeting certain pests such as *lepidoptera* insects and katydids. Treat when pests become a problem or in accordance with the local spray schedule as recommended by your State Agricultural Experiment Station, certified Pest Control Advisor, or Extension Service Specialist. To avoid excessive ridging, do not apply Pilot 4E to citrus from December up to the initiation of bloom.

Use of Spray Oils: To improve control of aphids, **mealybugs, scale insects, and thrips,** a petroleum spray oil approved for use on citrus trees may be added to spray mixtures at up to 1.8 gallons per 100 gallons of spray.

Pest	Pilot 4E
aphids (including brown citrus aphids) glassywinged sharpshooter grasshoppers (1) katydids *Lepidopterous* larvae (such as avocado leafroller, cutworms, fruit tree leafroller, orange dogs, orange tortrix, western tussock moth) mealybugs (see below for California and Arizona) scale insects (such as: black scale, brown soft scale, chaff scale, California red scale (see below for California and Arizona), Florida red scale, long scale, purple scale and snow scale) thrips (see below for California and Arizona)	2 – 7 pt/acre

citrus rust mites (2) (3)	4 – 7 pt/acre
citrus psylla (4)	5 pt/acre
thrips suppression and mealybugs (California and Arizona, see restrictions)	6 – 12 pt/acre
california red scale (California and Arizona, see restrictions)	8 - 12 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Lubber grasshoppers**: Effective control requires direct contact with spray when grasshoppers are small (less than 1 inch in length).
2. For control of **citrus rust mites**, use a spray concentration of at least 1 pint per 100 gallons.
3. In Los Angeles, Monterey, Orange, San Diego, San Luis Obispo, Santa Barbara, and Ventura Counties *in California, Pilot 4E may be tank mixed with petroleum spray oils registered for control of* **mites** *in* citrus. Follow all label directions and precautions for Pilot 4E and tank mix partners. Do not exceed 1.8% oil v/v or 1.8 gallons of oil per 100 gallons of spray. Use only on citrus species and varieties for which Pilot 4E is registered.
4. For control of **citrus psylla** add citrus oil at 2% v/v in a tank mix with Pilot 4E.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Observe local recommendations for tank mix combinations especially with regard to use of Pilot 4E with spray oil. Consult with a county farm advisor, county agency, extension service personnel, agricultural commissioner or pest control advisor, for local recommendations.
- Do not apply when trees are stressed by drought or high temperatures.
- Pilot 4E is highly toxic to bees exposed to direct treatment and should not be applied when bees are actively visiting the area. During the citrus bloom period in California, apply from 1 hour after sunset until 2 hours before sunrise.
- Additional Precautions for California and Arizona: Pilot 4E should not be used in combination with spray oil when temperatures are expected to exceed 95°F the day of application or for several consecutive days thereafter.

Specific Use Restrictions:

- **Preharvest Interval**: Do not treat within 21 days of harvest for applications of up to 7 pints of Pilot 4E per acre or within 35 days for application of rates above 7 pints per acre.
- The use of application rates greater than 8 pints of Pilot 4E (4 lb ai chlorpyrifos) per acre are allowed only in the following counties in California: Fresno, Tulare, Kern, Kings, and Madera.
- Do not apply more than 15 pints of Pilot 4E (7.5 lb ai chlorpyrifos) per acre per year.
- Do not make more than two applications of Pilot 4E or other products containing chlorpyrifos per year (does not include citrus orchard floors).
- Do not make second foliar application of Pilot 4E or other product containing chlorpyrifos within 30 days of the first application.
- Do not allow meat or dairy animals to graze in treated areas.

Citrus Orchard Floors[1]
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 5 days unless PPE required for early entry is worn.

[1]Including calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin (tangerine), pummelo, satsuma mandarin, sour orange, sweet orange, tangelo, tangor

Apply as a ground broadcast spray directed to the orchard floor to control foraging ants and suppress mounds. Do not apply spray to contact foliage or fruit. Apply in a total spray volume of 25 gpa or more using equipment that will apply the spray uniformly to the soil surface. Use a higher rate in the rate range for increased pest pressure. For best results, remove weed growth or other obstructions that might prevent the spray from reaching the soil surface. Foliar applications of Pilot 4E or other products containing chlorpyrifos may be made in addition to the orchard floor treatments but must comply with the 10 day re-treatment interval (see Specific Use Restrictions).

Chemigation: Pilot 4E may be applied to citrus orchard floors through sprinkler irrigation systems only if the system uniformly covers the soil surface at the base of the tree. Apply at listed broadcast application rates to control listed pests. **See Chemigation (Sprinkler Irrigation) section** for application instructions.

Note: Do not apply in tank mixture with Evik herbicide.

Pest	Pilot 4E
Ants(1)	1.5 - 2 pt/acre

Pest specific Use Directions:

1. Excludes ants of significant public health importance, such as fire ants, harvester ants, carpenter ants, and pharaoh ants.

Application with Dry Bulk Fertilizer: Most dry fertilizers can be used for impregnation with Pilot 4E. Apply Pilot 4E at the equivalent broad- cast rate using a minimum of 200 lb per acre of dry bulk fertilizer.

Impregnation of Dry Bulk Fertilizer: Use a closed rotary drum mixer suitable for blending of dry bulk fertilizer equipped with an internal spray nozzle. Add the dry fertilizer to the mixer followed by the ap- propriate amount of Pilot 4E. After mixing the dry ingredients to en- sure uniformity, add water through the spray nozzle in an amount sufficient to just dampen the mixture (4 to 8 pints of water per ton of fertilizer). The spray nozzle should be positioned within the mixer to provide uniform coverage of the tumbling mixture of fertilizer and Pilot 4E. Addition of water will cause Pilot 4E to uniformly adhere to the dry bulk fertilizer. Bulk fertilizers impregnated with Pilot 4E should be applied immediately, not stored. Foliar applications of Pilot 4E may be made in addition to the orchard floor treatments.
Compliance with any and all federal and state laws and regulations relating to the Pilot 4E and fertilizer mixture is the responsibility of the person offering such mixture for sale or distribution.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply last treatment within 28 days before harvest.
- Do not apply more than 3 quarts of Pilot 4E (3 lb ai chlorpyrifos) per acre per year.
- Do not make more than three applications of Pilot 4E or other products containing chlorpyrifos per year (does not include foliar applications to citrus trees).
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not allow meat or dairy animals to graze in treated areas.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.

Corn (Field Corn and Sweet Corn, Including Corn Grown for Seed)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Conservation Tillage: Preplant, At-Plant, or Preemergence Applications

Apply as a broadcast spray to surface trash and exposed soil surface using power-operated ground spray equipment. Use a total spray volume of 20 gpa or more.

Use a higher use rate of Pilot 4E in the rate range when there is increased pest pressure.

Tank Mixing and Mixing with Liquid Fertilizer: Pilot 4E may be applied in tank mixture with liquid fertilizer solutions. **See Mixing Directions section** for tank mixing instructions. Read and carefully follow all applicable directions, restrictions, and precautions on labeling for each product used in combination with Pilot 4E.

Pest	Pilot 4E
armyworms cutworms	1 - 2 pt/acre

Postemergence Application

Apply as a postemergence broadcast spray using sufficient spray volume to ensure thorough coverage of treated plants, but no less than 15 gpa for ground spray equipment or 2 to 5 gpa for aircraft equipment. Control may be reduced at low spray volumes under high temperature and wind conditions. **Note: Do not apply aerially in Mississippi. Tank Mix with Glyphosate:** Pilot 4E may be tank mixed with glyphosate products when application is to be made to glyphosate-tolerant corn.

Chemigation: Pilot 4E may be broadcast applied postemergence through sprinkler irrigation systems at listed application rates to control listed foliar pests. For best results, tank mix Pilot 4E with 2 pints of non-emulsifiable oil. **See Chemigation (Sprinkler Irrigation) section for application instructions**.

Pest	Pilot 4E
grasshoppers	0.5 – 1 pt/acre
aphids armyworms chinch bugs (1) corn rootworm adults (2) cutworms (3) European corn borer (5) flea beetle adults (1) southern corn leaf beetle webworms (4) western bean cutworm	1 – 2 pt/acre
corn earworm Southwestern corn borer (6)	1.5 – 2 pt/acre
billbugs (1) common stalk borer (9) corn rootworm larvae (7), (8) lesser cornstalk borer	2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. For best **billbug, chinch bug, or flea beetle** control, ground apply in a minimum spray volume of 20 to

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40 gpa at 40 psi. If corn is less than 6 inches tall, apply in a 9- to 12-inch wide band over the row. For corn greater than 6 inches tall, apply using drop nozzles directed to the base of the plant. Do not reduce the application rate for banded or directed applications. Concentrate the full labeled dosage rate in the treated zone. When chinch bugs continue to immigrate to corn over a prolonged period or under extreme pest pressure, a second application may be needed.

2. The recommended dosage will control silk clipping by **corn rootworm** adults.
3. For **cutworms**, it is preferable to apply Pilot 4E when soil is moist and worms are active on or near the soil surface. If ground is dry, cloddy, or crusted at time of treatment, worms may be protected from the spray and effectiveness will be reduced. Shallow incorporation using a rotary hoe or other suitable equipment immediately before or soon after treatment may improve control. A second application may be required if damage or density levels exceed economic thresholds established for your area.
4. For **webworm** control, shallow incorporation using a rotary hoe or other suitable equipment immediately before or soon after treatment is necessary.
5. For **European corn borer** control, use 1 1/2 to 2 pints per acre when application is made with power-operated ground or aerial equipment or 1 to 2 pints per acre when application is made through a sprinkler irrigation system. University research indicates that achieving greater than 50% control of first-generation **European borer** with a single liquid insecticide treatment is highly de- pendent on timing, insecticide placement, and weather conditions.
6. For **southwestern corn borer**, a second application may be applied 21 days later if needed due to re-infestation.
7. For postemergence control of **corn rootworm larvae** apply at cultivation. Direct the spray to both sides of the row at the base of the plants just ahead of the cultivator shovels. Cover the insecticide with soil around the brace roots. A cultivation application of Pilot 4E may be made in addition to an at-planting application of Pilot 15G insecticide.
8. Pilot 4E may also be applied through sprinkler irrigation systems at the rate of 2 pints per acre to control **corn rootworm larvae**. Time application to coincide with the appearance of the second instar larvae. Apply with enough water to wet the root zone to the depth control needed. If soils are wet, allow enough soil drying to occur such that an application using a minimum amount of water will not produce surface runoff. **See Chemigation (Sprinkler Irrigation) section for application instructions**.
9. Do not use Pilot 4E in combination with a burn down herbicide for control of **common stalk borer**. For **common stalk borer** control, treat approximately 11 days after application of Roundup herbicide or after burn down with paraquat herbicide is complete (3 to 5 days).

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 21 days before harvest of grain, ears, forage, fodder.
- Do not apply more than 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make more than three applications of any product containing chlorpyrifos per season including the maximum allowed of two granular applications, at the 1 lb ai chlorpyrifos rate.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- If more than 1 lb ai granular chlorpyrifos per acre is applied at-plant (for a maximum of 1.3 lb ai per acre per season), only one additional application of liquid product containing chlorpyrifos at 1 lb ai per acre is allowed per season, for a total of 2.3 lb ai chlorpyrifos per acre per season.
- The maximum single application rate is 2 pints of Pilot 4E (1 lb ai chlorpyrifos) per acre.
- Do not apply in tank mixes with Steadfast and Lightning herbicides.
- **Do not aerially apply this product in Mississippi.**

Cotton
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a broadcast foliar spray using aircraft or ground spray equipment in all states except Arizona and California. Use a higher rate in the rate range when there is increased pest pressure. Use sufficient spray volume to ensure thorough coverage of treated plants, but no less than 10 gpa for ground spray equipment or 2 gpa for aircraft equipment. Increase spray volume when foliage is dense and/or pest population is high and/or under high temperature and wind conditions. Treat when field counts indicate damaging insect populations are developing or present.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems at listed broadcast application rates to control listed foliar pests. **See Chemigation (Sprinkler Irrigation) section for application instructions**.

Proper application methods are necessary to ensure thorough spray coverage and correct rate, and minimize off-target drift. Follow Application Guidelines for ground and aerial application and Spray Drift Management recommendations in General Information section of this label.

All States except Arizona and California

Pest	Pilot 4E
cotton fleahopper (1) plant bugs (1) (*Lygus, Mirids*)	0.37 – 1 pt/acre
grasshoppers thrips	0.5 – 1 pt/acre
cotton aphid fall armyworm yellowstriped armyworm	0.5 – 2 pt/acre
spider mites (2)	1 pt/acre
beet armyworm cotton bollworm (3) cutworms pink bollworm salt marsh caterpillar tobacco budworm (3)	1.5 – 2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:
1. The 3/8 pint per acre rate will not provide a high degree of control but, compared to the 1 pint per acre rate, will minimize the damage from **plant bugs** and **cotton fleahoppers** and allow in- creased survival and build-up of beneficial insects to aid in the control of bollworms infesting cotton.
2. **Spider mites:** When large numbers of eggs are present, scout the treated area in 3 to 5 days. If newly hatched nymphs are present, make a follow-up application of a non-chlorpyrifos product that is effective against mites.
3. **Bollworms and budworms:** For best results, it is suggested that fields be scouted twice per week and applications made when worms are 1/4-inch or less in length.

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Arizona and California

Pest	Pilot 4E
armyworms cotton aphid cotton fleahopper *Lygus* salt marsh caterpillar silverleaf whitefly (1) thrips	1 – 2 pt/acre
boll weevil cotton bollworm (2) cotton leaf perforator (suppression) cutworms pink bollworm spider mites (suppression) tobacco budworm (2)	2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Silverleaf whitefly:** Apply in tank mix combination with the recommended rate of a pyrethroid insecticide labeled for control or suppression.
2. **Bollworms and budworms:** For best results, it is suggested that fields be scouted twice per week and applications made when worms are 1/4-inch or less in length.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply within 14 days before harvest.
- Do not apply more than 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make more than three applications of Pilot 4E or other products containing chlorpyrifos per crop season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not allow meat or dairy animals to graze in treated areas.
- Do not feed gin trash or treated forage to meat or dairy animals.
- Maximum single application rate is 1 lb ai (2 pints) chlorpyrifos per acre.

Cranberries
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a broadcast foliar spray. Use sufficient spray volume to ensure thorough coverage, but no less than 15 gpa. Except for control of cranberry weevil, treat when field counts indicate damaging insect populations are developing or present.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems to control listed pests. Apply at listed broadcast application rates. **See Chemigation (Sprinkler Irrigation) section for application instructions**.

Pest	Pilot 4E
brown spanworm cranberry fruitworm cranberry weevil (1) cutworms fireworms sparganothis fruitworms	3 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. For weevil control, apply once at flower bud development (late May, early June) and, if weevils are present, once after 100% bloom (early to mid-July).

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Apply only after the winter flood water has been removed. To avoid pesticide contamination of flood waters, do not apply when bogs are flooded.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply within 60 days before harvest.
- Do not make more than two applications of Pilot 4E or other products containing chlorpyrifos per season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Maximum single application rate is 1.5 lb ai chlorpyrifos per acre.

Figs
(Not for Use in California)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 days unless PPE required for early entry is worn.

Apply Pilot 4E as a dormant application in late winter prior to beetle emergence and prior to leaf formation. Use a spray volume of 10 gpa or more and apply as a broadcast spray to the soil surface using power operated ground spray equipment. On the day of treatment, incorporate Pilot 4E into the top 3 inches of soil using suitable equipment.

Pest	Pilot 4E
dried fruit beetle	2 qt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply within 7 months (217 days) of harvest.
- Make only one application per year of Pilot 4E or other product containing chlorpyrifos.
- Maximum single application rate is 2 lb ai chlorpyrifos (2 quarts Pilot 4E) per acre.

Grape (Areas East of the Continental Divide Only) (Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Soil Surface Application

Apply Pilot 4E just before the pest emerges from the soil. Apply 2 quarts of the diluted spray mixture to the soil surface on a 15-square foot area (4.4 ft circle) around the base of each vine.

Pest	Pilot 4E (pint/100 gal)
grape borer	4.5

Specific Use Precautions for Soil Surface Applications:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions for Soil Surface Applications:

- Do not allow spray to contact fruit or foliage.
- Maximum single application rate for soil surface application is 2.25 lb ai chlorpyrifos per 100 gallons.

Prebloom Application

Apply as a spray drench ground application using a minimum spray volume of 25 gpa.

Pest	Pilot 4E
climbing cutworm (1) grape mealybugs (2)	1 qt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Cutworm:** For control, apply 1 quart of Pilot 4E per acre as a broadcast spray in a minimum spray volume of at least 50 gallons of water using power-operated ground spray equipment. Treat when cutworms first become active and when field counts indicate damaging insect population are developing or present. Do not apply after bloom stage of growth. Consult your state agricultural experiment station or extension service specialist concerning cutworm control practices in your area.
2. **Grape mealybug:** For control, apply 1 quart of Pilot 4E per acre in a minimum spray volume of at least 50 gallons of water per acre using power-operated ground spray equipment only prior to late budbreak. Applications after budbreak may result in transient yellowing (Concords).

Specific Use Precautions for Prebloom Applications:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions for Prebloom Applications:

- Do not use in conjunction with soil surface application for grape borer control.
- Maximum single application rate for prebloom application to minimize phytotoxicity is 1 lb ai chlorpyrifos (1 quart of Pilot 4E) per acre.

Specific Use Restrictions for Soil Surface Application and Prebloom Application:

- **Preharvest Interval:** Do not apply within 35 days before harvest.
- Do not make more than one application of Pilot 4E or other products containing chlorpyrifos per season.
- Based upon available residue data, the use of Pilot 4E in grapes is restricted to areas east of the Continental Divide only.
- **Do not use in the state of Mississippi.**

Legume Vegetables[1] (Succulent or Dried) Except Soybean
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

[1]Including: but not limited to: adzuki bean, asparagus bean, bean, blackeyed pea, broad bean (dry and succulent), catjang, chickpea, Chinese longbean, cowpea, crowder pea, dwarf bean, edible pod pea, English pea, fava bean, field bean, field pea, garbanzo bean, garden pea, grain lupin, green pea, guar, hyacinth bean, jackbean, kidney bean, lablab bean, lentil, lima bean (dry and green), moth bean, mung bean, navy bean, pea, pidgeon pea, pinto bean, rice bean, runner bean, snap bean, snow pea, southern pea, sugar snap pea, sweet lupin, tepary bean, urd bean, white lupin, white sweet lupin, yardlong bean.

Preplant Broadcast Application
Apply Pilot 4E at a rate of 2 pints per acre to control seed maggots. Make a preplant broadcast application in a minimum of 10 gpa of spray to the soil surface using suitable ground equipment. To improve the activity against seed maggots, Pilot 4E must be incorporated into the top 1 to 3 inches of soil using suitable tillage equipment.

At Plant T-Band Application
Apply 1.8 fl oz of Pilot 4E per 1000 feet of row at 30-inch row spacing. Apply the spray in a 3-to5-inch wide band over the row behind the planter shoe and in front of the press wheel to achieve shallow incorporation. Mix the specified dosage in a minimum of 10 gpa of spray and apply to the soil surface using suitable ground spray equipment. Equivalent rates of insecticide spray required per 100 feet of row for various row spacing are given in the accompanying table. To improve the activity of Pilot 4E against seed maggots, incorporate the Pilot 4E into the top 1/2 to 1-inch of soil using tines or chains or other suitable equipment.

Spray volume Per Acre (Gallons)	Fl oz of Spray Volume per 100 feet of Row			
	30-inch	28-inch	24-inch	22-inch
10	7.3	6.9	5.9	5.4
15	11	10.3	8.8	8.1
20	14.7	13.7	11.8	10.8

Specific Use Precaution:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section).**
- Insecticides, including Pilot 4E, may contribute to the stress of the bean plant under certain environmental conditions. This stress may reduce plant stand or interfere with normal plant development. Herbicides used preplant incorporated may interact with insecticides and enhance this stress.

Specific Use Restrictions:
- Do not make more than one application per year.
- Do not apply more than 2 pints of Pilot 4E per acre.
- Do not apply Pilot 4E at-plant if the field was treated with a preplant incorporated treatment of Pilot 4E.

Onions (Dry Bulb)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

At-Plant Soil Drench Application

For direct seeded onions to control onion maggot, apply Pilot 4E in a water based spray as a 2- to 4-inch wide band over the row at planting time in a minimum of 40 gpa. Equivalent rates of insecticide spray required per 1000 feet of row for various row spacings are given in the accompanying table. Shallow incorporation is necessary. Placement behind the planter shoe and in front of the press wheel is recommended. Phytotoxicity may occur if Pilot 4E is sprayed directly onto onion seeds. Do not mix Pilot 4E with other pesticide products. **Note**: The user should exercise reasonable judgment and caution with this product. Until familiar with results under user planting and growing conditions, limit application of this product to a small area to determine plant tolerance and extent of injury if such occurs prior to initiating large scale applications.

Row Spacing	Pilot 4E (fl oz/1000 ft of row)			
	6-inch	10-inch	12-inch	18-inch
32 fl oz/acre	0.37	0.61	0.73	1.1

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- Do not make more than 1 application per year.
- Maximum single application rate is 0.03 lb ai chlorpyrifos per 1000 feet of row.
- **Do not aerially apply this product in Mississippi.**

Postplant Soil Drench Application

Apply as an early season directed spray to the base of onion seedlings or transplants during peak egg lying. Use a minimum of 100 gpa for thorough wetting.

Pest	Pilot 4E
onion maggot seedcorn maggot	1 qt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval**: Do not harvest within 60 days of application.
- Do not make more than two applications (at plant plus postplant) per year.
- Maximum single application rate is 1 lb ai (1 quart of Pilot 4E) chlorpyrifos per acre.
- **Do not aerially apply this product in Mississippi.**

Peanut

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply to the soil surface as a preplant broadcast spray followed by immediate soil incorporation to a depth of 3 to 4 inches. Use a minimum of 10 gpa total spray.

Pest	Pilot 4E
wireworms (suppression)	4 pt/acre

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:
- **Preharvest Interval**: Do not harvest within 21 days after treatment.
- The combined total of preplant and postplant applications of Pilot 4E, Pilot 15G or other products containing chlorpyrifos must not exceed 4 lb ai chlorpyrifos per acre per season.
- Do not make more than one preplant application of Pilot 4E per season.
- Do not feed treated peanut forage or hay to meat or dairy animals.
- Maximum single application rate is 2 quarts Pilot 4E (2 lb ai chlorpyrifos) per acre.
- **Do not aerially apply this product in Mississippi.**

Pear
(For Use in California, Oregon and Washington)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Postharvest Application
Mix the specified dosage in 100 to 400 gpa of spray and apply using an airblast speed sprayer or other suitable ground equipment.

Pest	Pilot 4E
codling moth	4 pt/acre

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:
- Do not make more than one postharvest application (prior to dormancy) per year.
- Maximum single application rate is 2 quarts Pilot 4E (2 lb ai chlorpyrifos) per acre.
- Do not harvest or use treated fruit for food or feed.
- Do not allow meat or dairy animals to graze in treated orchards.
- If unauthorized entry into a treated orchard cannot be prevented, then the orchard must be posted with the appropriate signs according to the Worker Protection Standard while treated, unharvested fruit remains on the tree.

Peppermint and Spearmint
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a broadcast spray using a total spray volume of 10 gpa or more using ground equipment.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems at listed broadcast application rates to control listed foliar pests. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E
cutworm (1)	2 – 4 pt/acre
garden symphylans(2) mint root borer (3)	4 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:
1. <u>**Cutworms:**</u> Apply during May and June when field counts indicate damaging insect populations are developing or present. When larvae are less than 3/4 inch in length, use the 2 pint rate; otherwise, use the higher rate.
2. <u>**Garden symphylans:**</u> Apply preplant to the soil surface. On the same day of treatment, incorporate the insecticide into the top 2 to 4 inches of soil using a disc, field cultivator, or equivalent equipment.
3. <u>**Mint borer:**</u> Apply postharvest when field counts indicate damaging insect populations are developing or present. If ground applied, follow with approximately 1 acre inch of sprinkler irrigation immediately after application to incorporate the insecticide into the soil or apply by chemigation.

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:
- **Preharvest Interval**: Do not apply within 90 days before harvest.
- Make only one application of Pilot 4E or other product containing chlorpyrifos during the growing season.
- Do not make more than one preplant incorporated application in the spring.
- Do not use in conjunction with a broadcast foliar application of Pilot 4E for cutworm control.
- Make only one postharvest application per season of Pilot 4E or other products containing chlorpyrifos.
- Maximum single application rate is 2 quarts Pilot 4E (2 lb ai chlorpyrifos) per acre.
- Do not use in conjunction with a broadcast foliar application of Pilot 4E for cutworm control.

Sorghum - Grain Sorghum (Milo)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a postemergence broadcast spray using sufficient spray volume to ensure thorough coverage of treated plants, but no less than 15 gpa for ground spray equipment or 2 to 5 gpa for aircraft equipment. **Note: Do not aerially apply in Mississippi**. Control may be reduced at low spray volumes under high temperature and wind conditions.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems at listed broadcast application rates to control listed foliar pests. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E
sorghum midge (1)	0.5 pt/acre
grasshoppers yellow sugar cane aphid and other aphids	0.5 – 1 pt/acre
greenbug (2)	0.5 – 2 pt/acre
armyworms chinch bugs (3) cutworms lesser cornstalk borer (3)	1 – 2 pt/acre
webworms	1 pt/acre
European and Southwestern corn borer	1.5 – 2 pt/acre
corn earworm	2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Sorghum midge:** Apply when 30% to 50% of the seed heads are in bloom
2. **Greenbug:** Use a higher rate within the indicated rate range when pest populations are high.
3. **Chinch bugs and lesser cornstalk borer:** Apply as a directed spray toward the base of the plant using power-operated ground spray equipment with sufficient water to ensure coverage of an 8- to 12-inch band centered in the row. For plants less than 6 inches high, apply an 8- to 12-inch band centered over the row. Do not reduce the dosage for banded or directed applications. Concentrate the full labeled dosage rate in the treated zone.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- To minimize the potential for chemical injury, do not apply Pilot 4E to drought stressed grain sorghum within 3 days following irrigation or rain except where the product is applied in irrigation water.
- Be aware that sorghum lines used in seed production fields may be more susceptible to chemical injury. Susceptible inbred lines or hybrids are likely to be at greater risk of yield-reducing chemical injury when treated at the higher application rates. Do not apply more than 1 pint of Pilot 4E per acre to seed sorghum if the additional risk of crop injury is unacceptable.

Specific Use Restrictions:

- **Preharvest Interval**: Do not harvest for grain, forage, fodder, hay, or silage within 30 days after application of 1 pint of Pilot 4E per acre or within 60 days after application of rates above 1 pint per acre.
- Do not apply more than 3 pints of Pilot 4E (1.5 lb ai chlorpyrifos) per acre per season.
- Do not make more than three applications of Pilot 4E or other products containing chlorpyrifos for a total of 1.5 lb ai chlorpyrifos per use season. If application rate of 2 pints Pilot 4E (1 lb ai chlorpyrifos) is used, then only one additional application of no more than 1 pint Pilot 4E (0.5 lb ai chlorpyrifos) may be made.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not treat sweet varieties of sorghum.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.

Soybean
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Soil Application

Apply as a broadcast treatment to soil surface in a minimum spray volume of 10 gpa using suitable ground spray equipment or as a band application. Use a higher rate in the rate range when there is increased pest pressure. For band application, equivalent rates of insecticide spray required per 100 feet of row for various row spacing are given in the accompanying table. For at-plant treatments, apply in a 4- to 6-inch band centered over the row. Position the spray nozzle in front of the planter shoe or press wheel or after the press wheel followed by a drag chain for light incorporation. **Do not apply as an in-furrow treatment.** For a postemergence rescue treatment, apply as a directed spray in a 9- to 12-inch band at the base of the plant. For plants less than 6 inches tall, apply over-the-top in a 6- to 12-inch band.

Pest	At-Plant Treatment (Broadcast, T-band or band)	Postemergence Rescue Treatment (band only)
cutworms lesser cornstalk borer	1 - 2 pt/acre	1 - 2 pt/acre

Fluid Ounces of Spray Required Per Various Row Spacings			100 Feet of Row for Volumes	
Volume of Per Acre	36"	32"	28"	24"
10 gallons	8.8	7.9	6.9	5.9
15 gallons	13.2	11.8	10.3	8.8
20 gallons	17.6	15.7	13.7	11.8

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section).**

Foliar Application

Apply as a postemergence broadcast spray using sufficient spray volume to ensure thorough coverage of treated plants, but no less than 15 gpa for ground spray equipment or 2 to 5 gpa for aircraft equipment. Apply when field counts indicate damaging pest populations are developing or present. Use a higher rate in the rate range when there is increased pest pressure.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems at listed broadcast application rates to control listed foliar pests. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E
grasshoppers green cloverworm spider mites (1) velvetbean caterpillar	0.5 - 1 pt/acre

armyworms bean leaf beetle corn earworm cutworms Mexican bean beetle potato leaf hopper saltmarsh caterpillar and other woolly bears soybean aphid thistle caterpillar (painted lady butterfly)	1 - 2 pt/acre
European corn borer southern green stink bug	2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Spider mites:** When large numbers of eggs are present, scout the treated area in 3 to 5 days. If newly hatched nymphs are present, make a follow-up application of a non-chlorpyrifos product that is effective against mites.

Specific Use Precaution:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- On determinate soybeans, do not make more than 1 application after pod set.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply last treatment within 28 days before harvest.
- Do not apply more than 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not make more than three applications per year of Pilot 4E or other products containing chlorpyrifos.
- Do not allow meat or dairy animals to graze in treated areas or otherwise feed treated soybean forage, hay, and straw to meat or dairy animals.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.

Strawberry
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Preplant IncorporationTreatment

Apply Pilot 4E in sufficient water to ensure uniform soil coverage and incorporate into the soil in the spring for protection of straw- berries during the following year.

Pest	Pilot 4E
garden symphylans grub	2 qt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Foliar Application

Apply as a broadcast foliar spray when buds first appear and repeat application 10 to 14 days later. Use a minimum spray volume of 40 gpa.

Pest	Pilot 4E
strawberry bud weevil	1 qt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Postharvest Application

Apply as a directed spray to crown of strawberry plants immediately after harvest and after plants are topped. Repeat application, if required, 14 to 18 days later. Use a minimum spray volume of 100 gpa.

Pest	Pilot 4E
strawberry crown moth	1 qt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Pilot 4E should not be tank mixed with pesticides, surfactants, or fertilizer formulations unless prior use has shown the combination non-injurious under your current conditions of use.
- Phytotoxicity may occur when Pilot 4E is applied to strawberries under conditions of high temperature and drought stress.

Specific Use Restrictions:

- For pre-bloom use only. Do not apply after berries start to form or when berries are present.
- **Preharvest Interval**: Do not apply within 21 days before harvest.
- Preplant Application: Do not make more than one application per year of Pilot 4E or other products containing chlorpyrifos for a total of 4 pints (2 lb ai chlorpyrifos) per acre per season.
- Foliar and Postharvest Applications: Do not make more than two applications per year of Pilot 4E or other products containing chlorpyrifos for a total of 4 pints (2lb ai chlorpyrifos) per acre per season.
- Postharvest Application: Do not sprinkle irrigate for 1 week following application.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first foliar application and within 14 days for postharvest application.
- Maximum single application rate is 2 lb ai chlorpyrifos per acre for preplant incorporation and 1 lb ai chlorpyrifos per acre for foliar and postharvest application.

Sugarbeet

(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Soil Application (At Planting or Preplant Incorporated)

To reduce feeding damage from early season insects such as cut- worms, apply at planting or as a preplant treatment and incorporate to a depth of 1 to 2 inches. Do not apply as an in-furrow treatment. Apply 1 pint of Pilot 4E per planted acre to a 10-inch wide band centered over the row for furrows 30 inches apart. (For rows 30 inches apart, this is equivalent to 9.2 fl oz of Pilot 4E per 10,000 feet of row). For other row widths, adjust the spray volume per planted acre in proportion to the length of row actually treated.

Postemergence Treatment

Apply specified rate as a broadcast or banded foliar spray. Treat when field counts indicate that damaging insect populations are developing or present.

Broadcast Application: Apply the specified dosage in water using 2 to 5 gpa of finished spray when using aerial spray equipment or 10 to 30 gpa when using ground spray equipment.

Banded Foliar Spray: Apply the specified rate within the band using a minimum of 7 gallons of spray volume in a 5- to 7-inch wide band centered over the row. Do not reduce the rate for band applications. Concentrate the full labeled dosage rate (see band rates in table below) in the treated zone. For best results, band-applied treatments should be lightly incorporated, either mechanically or with irrigation.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems to control listed pests. Apply at listed broadcast application rates. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E	
	Broadcast	**Band**
grasshoppers (1)	0.5 – 1 pt/acre	–
leafminers spider mites	1 pt/acre	0.67 pt/acre
tarnished plant bug (Lygus)	1 pt/acre	–
aphids fall armyworm yellowstriped armyworm webworms	1 – 2 pt/acre	0.67 – 1.33 pt/acre
beet armyworm	0.5 – 2 pt/acre	1 – 1.33 pt/acre
cutworms flea beetle adults	2 pt/acre	1.33 pt/acre
sugarbeet root maggot adults (2), (5)	0.5 – 1 pt/acre	–
sugarbeet root maggot larvae (3), (5)	-	1.33 – 2 pt/acre
sugarbeet root maggot larvae (4), (5)	2 pt/acre	1.33 – 2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Grasshoppers:** The low rate will control small nymphs (1st through 3rd instar).
2. **Sugarbeet root maggot adults:** Apply anytime from 7 days before until 3 days after peak adult emergence in order to target adults present at time of application based on local field trap monitoring.
3. **Sugarbeet root maggot larvae:** Use as primary treatment to control root maggot larvae. Base application timing on local field trap monitoring. Apply anytime from 7 days before until 3 days after peak adult emergence.
4. **Sugarbeet root maggot larvae:** Use as supplemental postemergence treatment following an at-plant insecticide application for control of root maggot larvae. Base application timing on local field trap monitoring. Apply anytime from 7 days before until 3 days after peak adult emergence.
5. To prevent potential development of insecticide resistance in sugarbeet root maggot, producers are encouraged to take the following steps: (1) avoid making more than two applications of Pilot 4E per season when adults are active; (2) if an organophosphate insecticide was applied at planting, make no more than one postemergence application of Pilot 4E when adults are active.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply within 30 days of harvest of beet roots and tops.
- Do not apply more than 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make more than three applications of Pilot 4E or other products containing chlorpyrifos per season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of

the first application.

- Do not allow meat or dairy animals to graze in treated areas or harvest treated beet tops as feed for meat or dairy animals within 30 days of last treatment.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.

Sunflower
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Preplant IncorporationTreatment

Broadcast apply to soil surface in a minimum spray volume of 10 gpa using suitable ground spray equipment. On the same day of treatment, incorporate the insecticide into the top 2 to 4 inches of soil using a disc, field cultivator, or equivalent equipment. Use a higher rate in the rate range when there is increased pest pressure.

Pest	Pilot 4E
cutworms	2 – 4 pt/acre

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Postemergence Broadcast Treatment

Apply as a postemergence broadcast spray using sufficient spray volume to ensure thorough coverage of treated plants, but no less than 15 gpa for ground spray equipment or 2 to 5 gpa for aircraft equipment. Use a higher rate in the rate range when there is increased pest pressure.

Pest	Pilot 4E
grasshoppers	1 pt/acre
banded sunflower moth seed weevil (4) stem weevil (2) sunflower beetle larvae and adults (1) sunflower moth (3) woolly bears	1- 1.5 pt/acre
cutworms	2 pt/acre
tarnished plant bug (*Lygus*) (5)	1 – 2 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Sunflower beetle:** For control of larvae or adults, treat when field counts indicate 10 larvae or 1 to 2 adults per seedling.
2. **Stem weevil:** Optimal treatment time is within 5 to 7 days after adult weevils begin to appear.
3. **Sunflower moth:** To control, make first application during early 1% to 5% bloom stage.
4. **Seed weevil:** To control, apply when field counts indicate 10 to 12 adults per plant for oil crop varieties and 1 to 3 adults per plant on confectionery crop varieties.
5. **Tarnished plant bug (*Lygus*):** Use a higher rate in the rate range where populations are heavy. Apply at the onset of pollen spread or approximately 10% bloom (R-5 growth stage). For best protection, make a second application 10 days later. Use sufficient water to ensure thorough coverage of treated plants.

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:
- **Preharvest Interval**: Do not apply within 42 days before harvest.
- Do not apply more than 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make more than three applications per season of Pilot 4E or other products containing chlorpyrifos for a total of 6 pints of Pilot 4E (3 lb ai chlorpyrifos) per acre per season.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not allow meat or dairy animals to graze in treated areas. Maximum single application rate is 2 lb ai chlorpyrifos per acre for preplant incorporation and 1.5 lb ai chlorpyrifos per acre for postemergence broadcast treatment.

Sweet Potato

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply to the soil surface as a preplant broadcast spray to reduce the feeding damage caused by listed pests. Use a spray volume of 10 gpa or more. Incorporate immediately after application to a depth of 4 to 6 inches using a rotary hoe, disc cultivator, or other suitable incorporation equipment. Plant sweet potatoes in the usual manner no more than 14 days after treatment. Delaying planting more than 14 days after application will reduce the time interval of protection against feeding damage.

Pest	Pilot 4E
conderus (wireworm) sweet potato flea beetle systeria (flea beetle)	4 pt/acre

Specific Use Precaution:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Pilot 4E will not control false wireworms, white fringe beetle or other grubs that attack sweet potatoes.

Specific Use Restrictions:
- **Preharvest Interval**: Do not apply within 125 days before harvest.
- Do not make more than one application of Pilot 4E or other product containing chlorpyrifos per season.
- Maximum single application rate is 2 quarts Pilot 4E (2 lb ai chlorpyrifos) per acre.
- **Do not apply aerially in Mississippi**.

Tobacco

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply as a preplant broadcast spray to reduce the feeding damage caused by listed pests. Apply 24 to 48 hours before bedding and transplanting using a spray volume of 10 gpa or more. Incorporate immediately after application to a depth of 2 to 4 inches using suit- able incorporation equipment.
Before broadcast application of Pilot 4E onto existing beds, knock down beds to final shape for transplanting. Use of PTO-driven implements that will incorporate Pilot 4E to a depth of 4 inches is recommended.

Pest	Pilot 4E
cutworms flea beetles mole crickets root maggots wireworms	2 pt/acre

To control the above listed pests and suppress populations of root- knot nematodes in all tobacco growing regions, use Pilot 4E in a tank mix with Nemacur 3 at the rate of 2 quarts of Pilot 4E plus 4 quarts of Nemacur 3 nematicide per acre. Read and carefully follow all applicable directions, restrictions, and precautions on labeling for Nemacur 3 used in combination with Pilot 4E. Apply the specified rate(s) to the soil surface in a spray volume of 10 gpa or more 24 to 48 hours before bedding and transplanting. Immediately following application, incorporate into the soil to a depth of at least 4 inches using suitable equipment. Where the nematode species *Meloidogyne arenaria or M. javanica* are present or high populations of *M. incognita*, apply Telone II soil fumigant at the listed label rate.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- Do not make more than one application of Pilot 4E or other product containing chlorpyrifos per season.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre per season.
- Do not aerially apply this product in Mississippi.

Tree Fruit[1], Almond and Walnut
(Dormant/Delayed Dormant Sprays)
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 days for tree fruits and 24 hours for almond and walnut unless PPE required for early entry is worn.

[1] **Apple, cherry, nectarine, peach, pear, plum, prune**

Apply as a dormant or delayed dormant spray. While Pilot 4E may be used without oil, oil is recommended to control additional pests such as European red mite. See precautions for use of oil below. Apply as a concentrate or dilute spray using conventional, power operated spray equipment. For dilute sprays (greater than 200 gpa), use sufficient spray volume to completely wet tree foliage, but not to point of runoff. For concentrate sprays (less than 200 gpa), uniformly apply an equivalent amount of Pilot 4E per acre.

Use a higher rate in the rate range when there is increased pest pressure.

Specific Use Precautions for Tree Fruits, Almond and Walnut:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Cold or dry conditions may cause Pilot 4E plus oil sprays to infuse into trees, resulting in bud damage or bud drop. Do not apply until winter rains or irrigation has replenished soil moisture such that bark and twigs are not desiccated.
- To avoid contamination of irrigation tall waters, do not flood irrigate within 24 hours of application of Pilot 4E.

Specific Use Restrictions for Tree Fruits, Almond and Walnut:

- Do not use more than 4 pints of Pilot 4E (2 lb ai chlorpyrifos) per acre per season as a dormant/delayed dormant application.

- For apple, do not make more than one application of Pilot 4E to the apple tree trunk per year as either a prebloom or post-bloom application.
- Make only one application of chlorpyrifos during the dormant season.
- Do not allow meat or dairy animals to graze in treated orchards.

Additional Restrictions Specific to California:

- Use a minimum of 250 gpa of total spray volume.
- Do not use any adjuvants or surfactants in addition to, or as a substitute for, a petroleum spray oil in a tank mix with Pilot 4E.
- Do not use any adjuvants or surfactants in addition to, or as a substitute for, a petroleum spray oil in a tank mix with Pilot 4E.
- Refer to the University of California pest management guide for apples.

Almond, Cherry, Nectarine, Peach, Pear, Plum, Prune

Pest	Pilot 4E
American plum borer brown almond mite climbing cutworms European red mite greater peach tree borer lesser peach tree borer mealy plum aphid peach twig borer pear psylla adults San Jose scale	1.5 - 4 pt/acre

Specific Use Precautions for Almond, Cherry, Nectarine, Peach, Pear, Plum, Prune, Walnut:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Avoid contact with foliage in sweet cherries as premature leaf drop my result.

Specific Use Restrictions for Almond, Cherry, Nectarine, Peach, Pear, Plum, Prune, Walnut:

- Do not make a soil or foliar application of Pilot 4E or products containing chlorpyrifos within 10 days of a dormant/delayed dormant application of chlorpyrifos to the orchard.

Additional Restrictions Specific to California for Almond, Cherry, Nectarine, Peach, Pear, Plum, Prune, Walnut:

- Do not use more than 1% dormant oil and/or penetrating surfactants in almond orchards less than 4 years old.
- Use a minimum of 100 gpa of total spray volume.
- Use up to 2% Supreme oil with no more than 4 gpa on almonds.
- Use up to 2% supreme oil with no more than 6 gpa on peaches and nectarines.
- Refer to the University of California pest management guide for pears, plums, and prunes.
- In orchards with high overwintering populations of European red mite or brown almond mite, use higher spray volumes that allow for the use of higher per acre rates of oil.
- Do not use any adjuvants or surfactants in addition to, or as a substitute for, a petroleum spray oil in a tank mix with Pilot 4E.
- Do not apply on almonds in the following counties in California: Butte, Colusa, Glenn, Solano, Sutter, Tehama, Yolo, and Yuba.

Apple

Pest	Pilot 4E
climbing cutworm *Lygus* obliquebanded leafroller pandermis leafroller rosy apple aphid san Jose scale	1.5 - 4 pt/acre

Specific Use Restrictions for Apple:

- Only one application of any chlorpyrifos containing product can be made per year. The application can be either a prebloom dormant/delayed dormant spray to the canopy or the trunk, or a post-bloom application to the lower 4 feet of trunk **[for post-bloom application instructions and restrictions on apple, refer to Apple Tree Trunk section of the label].**

Additional Restrictions Specific to California for Apple:

- Use a minimum of 100 gpa of total spray volume.
- Refer to the University of California pest management guide for apples.
- In orchards with high overwintering populations of European red mite or brown almond mite, use higher spray volumes that allow for the use of higher per acre rates of oil.
- Do not use any adjuvants or surfactants in addition to, or as a substitute for, petroleum spray oil in a tank mix with Pilot 4E.

Tree Fruits[1] and Almond (Trunk Spray or Preplant Dip)
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 days for tree fruits and 24 hours for almond and walnut unless PPE required for early entry is worn.

[1] **Cherry, Nectarine, Peach and Plum**

Apply Pilot 4E to tree trunks and lower branches using a coarse, low-pressure spray to control pests listed in the following table. Use a higher rate in the rate range when there is increased pest pressure. Unless otherwise specified, a second application may be made after two weeks and a third application may be made after harvest. Avoid spray contact with foliage in sweet cherries as premature leaf drop may result. Consult your state agricultural experiment station or extension service specialist for proper application timing for your area.

Crop	Pest	Pilot 4E (quart/100 gal)
cherry	American plum borer greater peach tree borer lesser peach tree borer	1.5 - 3
almond nectarine peach plum	peach tree borers (1) (2)	3

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. **Preplant Dip Application (Peaches and Nectarines Only):** For preplant control of **peachtree borer**,

use Pilot 4E at the equivalent application rate of 3 quarts per 100 gallons of water. Dip trees several inches above the grafting bud scar and plant immediately or allow them to dry before returning to storage. Do not allow peach trees to remain in contact with the dip solution.

2. **Peach tree borer:** For control in established trees, apply before newly hatched borers enter the tree. Use as a coarse, low-pressure trunk spray and thoroughly wet all bark areas from ground level to scaffold limbs. Do not allow spray to contact fruit. Consult written recommendations provided by your state agricultural experiment station or extension service specialist for proper time to treat in your area.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 14 days before harvest of almonds, nectarines, peaches and plums or within 21 days before harvest of cherries.
- Do not make more than one chlorpyrifos application per year in peaches and nectarines and no more than three chlorpyrifos applications per year in cherries.
- Do not allow meat or dairy animals to graze in treated orchards.

Tree Nuts[1] (Foliar Sprays)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

[1] Almond, filbert, pecan, walnut

Apply Pilot 4E as a foliar spray at the dosages indicated to control pests listed in the following table. Mix the required dosage in sufficient water to ensure thorough and complete coverage of the foliage and crop and apply as a concentrate or dilute spray using conventional, power-operated spray equipment. For dilute sprays applied to tree nut crops, mix the required dosage in sufficient water to allow for spray to runoff. For concentrate sprays, apply an equivalent amount of Pilot 4E per acre. Treat when pests appear or in accordance with local conditions. Aerial application may result in less effective insect control because of reduced coverage. Consult your State agricultural experiment station, certified pest control advisor, or extension service specialist for specific use information in your area.

Crop	Pest	Pilot 4E
almond	leaf footed plant bug navel orangeworm peach twig borer San Jose scale	4 pt/acre
filbert	eye-spotted bud moth filbert aphid filbert leafroller filbert worm obliquebanded leafroller omnivorous leaftier winter moth	3 – 4 pt/acre
pecan	blackmargined aphid (1) spittlebugs (2) yellow pecan aphid (1)	1 – 4 pt/acre
	fall webworm pecan nut casebearer	1.5 – 4 pt/acre

	black pecan aphid hickory shuckworm (3) *Phylloxera spp.*(4) pecan leaf scorch mite (suppression) (5)	2 – 4 pt/acre
walnut	codling moth walnut husk fly walnut scale	4 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:

1. For control of **yellow pecan aphid** and **blackmargined aphid**, apply in tank mix combination with the recommended rate of a pyrethroid insecticide labeled for control or suppression of these aphids.
2. For control of **spittlebug**, use a dosage of 2 to 4 pint per acre for concentrate sprays.
3. For best results against **hickory shuckworm**, make 2 applications, 10 to 14 days apart.
4. For best control of ***Phylloxera spp.,*** make 2 applications at a 10- day interval using a minimum of 1 pint of Pilot 4E per acre starting at bud swell.
5. For suppression of **pecan leaf scorch mite**, use a preventative program.

Specific Use Precautions:

- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- Pilot 4E is highly toxic to bees exposed to direct treatment and should not be applied when bees are actively foraging in the treated area.
- To avoid contamination of irrigation tail waters, do not flood irrigate within 24 hours of application of Pilot 4E.

Specific Use Restrictions:

- **Preharvest Interval**: Do not apply within 14 days of harvest of almonds, filberts and walnuts, or 28 days of harvest of pecans.
- Do not apply more than 8 pints of Pilot 4E (4 lb ai chlorpyrifos) per acre per season as a foliar spray.
- Do not make more than three total applications per season of Pilot 4E or other products containing chlorpyrifos to almonds, pecans and filberts and no more than one application per season on walnuts.
- Do not apply more than 8 pints (4 lb ai chlorpyrifos) per acre per season as a foliar spray.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not allow meat or dairy animals to graze in treated orchards.
- **Do not use on almond, filbert or walnut in Mississippi.**
- **Do not aerially apply this product in Mississippi.**

Tree Nut[1] Orchard Floors
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

[1] Almond, Pecan, Walnut

Apply as a ground broadcast spray directed to the orchard floor using ground application equipment that will apply the spray uniformly. Do not allow spray to contact foliage or fruit. Treat when ant activity (excluding fire, harvester, carpenter, and pharaoh ants) becomes evident in the orchard. Since worker ants (excluding fire, harvester, carpenter, and pharaoh ants) cease most of their foraging activity at temperatures above 90°F, best results will be achieved if applied at a time of day when temperatures are below 90°F.

Chemigation: Pilot 4E may be applied to almond, pecan and walnut orchard floors through sprinkler irrigation systems only if the system uniformly covers the soil surface at the base of the tree. Use specified broadcast application rates to control listed pests. **See Chemigation Application section.**

Orchard floor	Pest	Pilot 4-E
pecan	ants (1)	4 pt/acre
almond walnut		4 – 8 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:
1. Excludes ants of significant public health importance, such as fire ants, harvester ants, carpenter ants, and pharaoh ants.

Eliminate weed growth that would prevent uniform coverage of the orchard floor by mowing or herbicide treatment. Foliar applications of Pilot 4E may be made in addition to the orchard floor treatment.

Pest Specific Use Precautions
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section)**.
- To avoid contamination of irrigation tail waters, do not flood irrigate within 24 hours of application of Pilot 4E.

Specific Use Restrictions:
- **Preharvest Interval:** Do not apply within 14 days before harvest.
- Do not make more than two applications of Pilot 4E or other product containing chlorpyrifos per season to the orchard floor. If the 8 pint per acre rate is used, a second application is not allowed.
- Do not apply more than a total of 8 pints Pilot 4E (4 lbs ai) chlorpyrifos per acre per season to the orchard floor.
- Do not make a second application of Pilot 4E or other product containing chlorpyrifos within 10 days of the first application.
- Do not allow meat or dairy animals to graze in treated orchards.
- **Do not apply this product in Mississippi.**

Turfgrass
(Not for Use in Mississippi)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply to turfgrass grown for sod. Dilute Pilot 4E in water and apply using suitable application equipment. For best results, turf should be moist at time of treatment.

Pest	Amount of Pilot 4E per	
	Fl oz/1000 sq ft	Qt/acre

ants (1) armyworms (such as: beet, fall, yellowstriped) centipedes chiggers chinch bugs crickets cutworms deer ticks earwigs European crane fly larvae *fiery skipper* fleas gnats grasshoppers greenbug aphids green June beetle grubs leafhoppers Lucerne moth millipedes mites (such as: clover, Bermudagrass stunt, winter grain) mosquitoes pillbugs springtails sod webworms (lawn moths) (2) sowbugs ticks	0.75	1
billbug adults (such as bluegrass, Denver, hunting) (3)	0.75 – 1.5	1 - 2
annual bluegrass weevil (*Hyperodes*) (4) black turfgrass ataenius adults (5) mole crickets (6)	1.5	2
white grubs (such as: black turfgrass ataenius, European chafer, Japanese beetle larvae, and northern and southern masked chafers) (7)	1.5 - 3	2 - 4

Numbers in parentheses (-) refer to Specific Use Directions below.

Pest Specific Use Direction:

1. Excludes ants of significant public health importance, such as fire ants, harvester ants, carpenter ants, and pharaoh ants.
2. For **sod webworms**, watering or mowing of the treated area should be delayed for 12 to 24 hours after treatment.
3. For **billbugs,** spray early in the season just prior to or coinciding with first appearance of adults as recommended by you local agricultural extension service specialist.
4. To control **annual bluegrass weevil**, spray suspected problem areas in mid-April and again in mid-May, or as recommended by your local agricultural extension service specialist.
5. For black **turfgrass ataenius** adults, spray early in the season as recommended by you local agricultural extension service specialist. A repeat application may be needed 1 to 2 weeks later.
6. To control **mole crickets** in turfgrass, apply Pilot 4E through high pressure injection or other suitable subsurface placement application equipment. Depending on the application equipment used, follow the manufacturer's recommendation for calibration and the volume of spray per acre needed to provide control or as recommended by your local agricultural extension service specialist. For best results, apply when young nymphs are active.
7. For **white grubs**, spray when grubs are young and actively feeding near the soil surface, usually during late July and August or as recommended by your local agricultural extension service specialist. For best results, soil should be moist prior to treatment. **For best results, immediately after spraying, irrigate the treated area with 1/2 to 1 inch of water to wash the insecticide into the thatch and**

underlying soil.

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section).**

Wheat
(For use only in Arizona, California, Colorado, Idaho, Kansas, Minnesota, Montana, Nebraska, New Mexico, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington and Wyoming)

Worker Restricted Entry Interval: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Foliar Application:
Mix the required dosage with water and apply in a minimum of 2 to 5 gpa finished spray volume for aerial equipment, or 15 gpa for ground equipment. Apply using aerial (fixed wing or helicopter) or power-operated ground spray equipment. Apply when field counts indicate damaging pest populations are developing or present.

Chemigation: Pilot 4E may be applied through sprinkler irrigation systems at listed broadcast application rates to control listed foliar pests. **See Chemigation (Sprinkler Irrigation) section for application instructions.**

Pest	Pilot 4E
Aphids (1) (such as Russian wheat aphid, greenbug, English grain aphid) brown wheat mite grasshoppers	0.5 – 1 pt/acre
army cutworms (2) armyworms (3) cereal leaf beetle (4) cutworms (suppression) (2) wheat midge (5)	1 pt/acre

Numbers in parentheses (-) refer to Pest Specific Use Directions.

Pest Specific Use Directions:
1. Consult university extension bulletins for local treatment recommendations.
2. Control may be reduced under high temperature conditions (greater than 80°F), under dry soil conditions, or if larvae are more than 1/2 inch long.
3. Expect suppression under conditions of heavy pest populations or large worms.
4. Target application when eggs are near hatching and larvae is emerging as monitored by plant inspection.
5. **Wheat midge:** For control, treatment is recommended when 75% of the wheat heads have emerged from the boot and when midge adults are found in the crop (1 midge per 4-5 heads). If possible, apply in the late afternoon or early evening when temperatures exceed 50°F and wind speed is less than 7 mph.

Specific Use Precautions:
- Read and follow all Spray Drift Mitigation Measures **(See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:
- **Preharvest Interval**: Do not apply within 14 days of harvest for forage and hay and within 28 days of

harvest for grain and straw.

- Do not make more than two applications of Pilot 4E or products containing chlorpyrifos per season.
- Maximum single application rate is 0.5 lb ai chlorpyrifos per acre.
- Do not allow meat or dairy animals to graze or otherwise feed on treated forage within 14 days of application.
- Do not feed straw from treated wheat within 28 days of application.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Crop injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to label instructions (including conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Gharda Chemicals Limited or the seller. To the extent permitted by applicable law, all such risks shall be assumed by buyer.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose under normal conditions of use. This is the only warranty made on this product. To the extent permitted by applicable law, Seller expressly disclaims any implied warranties of merchantability or fitness for any particular purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other un- intended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of the Seller. To the extent permitted by applicable law Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

EPA Registered: February 17, 2004 (Chlorpyrifos MOA)
Amended: December, 2004 (EPA Reg. No. Change)
Revised by Notification: July, 2005
Amended: January 15, 2008

Revised by Notification July 13, 2011
Amended: (EPA Spray Mitigation Measures/Label Use Directions Update)

EPA Registration No.: 33658-26

First letters in batch code indicate producing Establishment:
EPA Establishment No.: 5905–GA–01=CG
5905–IA–01=DI
44616–MO–1=SJ
Net Contents: [1.0, 2.5, Bulk] gal

Pilot® is a registered trademark of Gharda Chemicals Limited
Roundup is a trademark of Monsanto Company.
Nemacur 3 is a trademark of Bayer CropScience.
Evik is a trademark of Syngenta Group Company.

Manufactured for:
Gharda Chemicals Limited
660 Newtown-Yardley Rd., Suite 106
Newtown, PA 18940
1-(215)-968-9474

[Container Label – Remains on Container when Label Booklet is Removed]

RESTRICTED USE PESTICIDE
For retail sale to and use only by certified Applicators or persons under their direct supervision and only for those uses covered by the certified Applicator's certification.

For control of listed insects infesting certain field, fruit, nut, and vegetable crops and wheat.

Group	1B	Insecticide

Active Ingredient:
Chlorpyrifos: O,O-diethyl-O-(3,5,6-trichloro-2-pyridinyl)
phosphorothioate 45.0%
Other Ingredients: 55.0%
Total 100.0%
Contains petroleum distillate
Contains 4 pounds of Chlorpyrifos per gallon.

KEEP OUT OF REACH OF CHILDREN
WARNING AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Agricultural Use Requirements
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Refer to inside Label Booklet for additional Precautionary information including Directions for Use.

Agricultural Chemical: Do not ship or store with food, feeds, drugs or clothing.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

WARNING. May Be Fatal If Swallowed. Harmful If Absorbed Through The Skin. Causes Moderate Eye Irritation. Avoid contact with skin, eyes or clothing.

Personal Protective Equipment (PPE)

Materials that are chemical-resistant to this product are Barrier Laminate and Viton ≥ 14 mils. If you want more options, follow the instructions for category G on an EPA chemical resistance category selections chart.

Mixers and loaders using a mechanical transfer loading system and applicators using aerial application equipment must wear:
- Long-sleeved shirt and long pants
- Shoes and socks

In addition to the above, mixers and loaders using a mechanical transfer loading system must wear:
- Chemical-resistant gloves
- Chemical-resistant apron
- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approved number prefix TC-21C or a NIOSH-approved respirator with any R, P, or HE filter

See Engineering Controls for additional requirements.

All other mixers, loaders, applicators and other handlers must wear:
- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves
- Chemical-resistant apron when mixing or loading or exposed to the concentrate
- Chemical resistant footwear plus socks
- Chemical-resistant headgear for overhead exposure
- A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any R, P or HE filter.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls: Mixers and loaders supporting aerial applications must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal protection, and must:
- Wear the personal protective equipment required above for mixers/loaders
- Wear protective eyewear if the system operates under pressure, and
- Be provided and have immediately available for use in an emergency, such as broken package, spill, or equipment breakdown: coveralls, chemical resistant footwear and chemical-resistant headgear if overhead exposure

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6)].

Use of human flaggers is prohibited. Mechanical flagging equipment must be used.

When handlers use closed cab motorized ground application equipment in a manner that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:
- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing and/or PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

EPA Registration No.: 33658-26
First letters in batch code indicate producing Establishment:
EPA Est. No.: 5905–GA–01=CG
5905–IA–01=DI
44616–MO–1=SJ

Manufactured for:
Gharda Chemicals Limited
660 Newtown-Yardley Rd., Suite 106
Newtown, PA 18940
1-(215)-968-9474

Pilot® is a registered trademark of Gharda Chemicals Limited

Net Contents: [1.0, 2.5, Bulk] gal

EXHIBIT 6

33658-27 12/20/2012 1/12

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 20, 2012

Gharda Chemicals, Ltd.
c/o Dr. Frank E. Sobotka
IPM Resources LLC
4032 Crockers Lake Blvd., Suite 818
Sarasota, FL 34238

Subject: Amended labeling to implement required spray drift mitigation measures
Product Name: Pilot 15G Chlorpyrifos Agricultural Insecticide
EPA Registration Number: 33658-27
Submission dated August 28, 2012; resubmission dated December 18, 2012

Dear Dr. Sobotka:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy of the label is enclosed for your records. Please submit one copy of your final printed labeling before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at 703-308-8735, or by email at chao.julie@epa.gov.

Regards,

for Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

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[50lb Pilot 15G Bag Label]

Gharda Chemicals Limited

PILOT™ 15G

Chlorpyrifos Agricultural Insecticide

For control of listed insects infesting certain field and vegetable crops.

Group	1B	Insecticide

Active Ingredient:
Chlorpyrifos: O,O-diethyl
O-(3,5,6-trichloro-2-pyridinyl)
phosphorothioate 15.0%
Other Ingredients: 85.0%
Total: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque a aiguien para que se la explique a usted en detaile. (If you do not understand the label, find someone to explain it to you in detail.)

Manufactured for:
Gharda Chemicals Limited
660 Newtown-Yardley Rd., Suite 106
1-(215)-968-9474

EPA Reg. No.: 33658-27
First Letters in Batch Code Indicate
Producing Establishment:
EPA Est. No.: 5905-GA-01=CG
5905-IA-01=DI
44616-MO-1=SJ

Net Contents: 50 pounds

Pilot is a registered trademark of Gharda Chemicals Limited
Newtown, PA 18940

ACCEPTED
DEC 2 0 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No: 33658-27

FIRST AID
(Organophosphate Insecticide)

If swallowed:	▪ Call poison control center or doctor immediately for treatment advice. ▪ Have person sip a glass of water if able to swallow. ▪ Do not induce vomiting unless told to do so by the poison control center or doctor. ▪ Do not give anything by mouth to an unconscious person.
If in eyes:	▪ Hold eye open and rinse slowly and gently with water for15-20 minutes. ▪ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. ▪ Call a poison control center or doctor for treatment advice.
If on skin or clothing:	▪ Take off contaminated clothing. ▪ Rinse skin immediately with plenty of water for 15-20 minutes. ▪ Call a poison control center or doctor for treatment advice.
If inhaled:	▪ Remove person to fresh air. ▪ If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. ▪ Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER
(Organophosphate Insecticide)
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **For emergency medical treatment information call: 1-(866)-359-5660**

NOTE TO PHYSICIAN
Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as 2-PAM/protopam, may be therapeutic if used early; however, use only in conjunction with atropine. In case of severe acute poisoning, use antidote immediately after establishing an open airway and respiration.

Precautionary Statements
Hazards To Humans And Domestic Animals

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling.

Personal Protective Equipment (PPE)
Some materials that are chemical-resistant to this product are barrier laminate or viton. If you want more instructions, follow the instructions for category H on an EPA chemical resistance category selections chart.

All mixers, loaders, other applicators and other handlers must wear:
- coveralls over long-sleeved shirt and long pants;
- chemical-resistant gloves;
- chemical resistant footwear plus socks;
- a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N,R,P or HE filter.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- *Remove clothing and/or PPE immediately if pesticide gets inside.* Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Engineering Controls

Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

When applicators use closed cab equipment in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

Environmental Hazards

This pesticide is toxic to fish, aquatic invertebrates, small mammals and birds. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Cover or incorporate spills. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

This product is not registered in California and Arizona. California and Arizona law prohibits sale, distribution, and use within the State of any products not registered by the State.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read all Directions for Use before applying.

Do not apply this product in a way that will contact workers or other persons either directly or through drift. **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).** Only protected handlers may be in the area during application. Do not apply by aircraft at a rate greater than 6.5 pounds of formulated product (1 pound of active ingredient) per acre. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Spray Drift Mitigation Measures (SDMM)

The buffer distances specified in the below table are the distances in feet that must exist to separate sensitive sites from the targeted application site. Buffers are measured from the edge of the sensitive site to the edge of the application site. Sensitive sites are areas frequented by non-occupational bystanders (especially children). These include residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or commercial purposes. Sensitive sites include homes, farmworker housing, or other residential buildings, schools, daycare centers, nursing homes, and hospitals. Non-residential agricultural buildings, including barns, livestock facilities, sheds, and outhouses are not included in the prohibition.

Application rate Lb ai/A	Required Setback (Buffer Zones)	
	Aerial	Ground**
>0.5 - 1	25	10
>1 - 2	NA	10
>2 - 3	Not Allowed	10
>3 - 4	Not Allowed	10
>4	Not Allowed	10

**The required buffer zones for ground applications apply to applications made via spreaders.

Only pesticide handlers are permitted in the setback area during application of this product. Do not apply this product if anyone other than a mixer, loader, or applicator, is in the setback area.
Exception: Vehicles and persons riding bicycles that are passing through the setback area on public or private roadways are permitted.

Specific Spray Drift Mitigation Use Directions
Spray Drift Mitigation Measures apply to all Agricultural Uses for chlorpyrifos products including Nurseries. These measures do not apply to Non-Agricultural uses, such as, golf-course turf, greenhouses, wood products or in applications where chlorpyrifos is applied as an adult mosquitoside. **Note**: Spray Drift Mitigation Measures do not apply to Granular product applications made in-furrow, T-banded or banded post emergence. However, Spray Drift Mitigation Measures do apply to granular applications made by ground boom spreaders, or when chlorpyrifos granules are applied aerially.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow entry into treated areas during the restricted entry interval (REI). The REI for each crop is listed in the directions for use associated with each crop.

Also see specific Use Directions under **Approved Crops** Section of this label

Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

Certified crop advisors or persons entering under their supervision , under certain circumstances, may be exempt from the early reenter requirement pursuant to 40 CFR Part 170.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- coveralls over short-sleeved shirt and short pants;
- chemical-resistant gloves made out of water proof material;
- chemical-resistant footwear plus socks;
- chemical-resistant headgear for overhead exposure.

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Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a secured dry storage area. Prevent cross contamination with other pesticides and fertilizers. If container is damaged or spill occurs, use product immediately or dispose of product and damaged container as indicated below.

In Case of Spill: Isolate the spill. Hold this package, other cargo and vehicles involved. For Emergency spill assistance Call CHEMTREC (24-hour service): 1-800-535-5053.

Pesticide Disposal: Open dumping is prohibited. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty bag into application equipment. Offer for recycling if available, or, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPROVED USES

Alfalfa (Missouri only)

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply Pilot 15E at planting as an in-furrow treatment for suppression of the target pests during establishment. Direct the granules into the planter shoe with the seed, place the applicator tube directly behind the planter shoe so that the granules drop into the seed furrow, or place the granular band applicator behind the planter shoe so that the granules fall on the soil surface and the open seed furrow and are covered with soil.

Pests Controlled	Pilot 15G lb/acre
cutworms grubs wireworms	6.6

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not cut or graze treated alfalfa within 21 days after application.
- Do not make more than 1 application of Pilot 15G per year.
- Maximum single application rate is 1 lb ai chlorpyrifos per acre.
- **For use only in Missouri.**

Asparagus (California only)

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Apply Pilot 15G as a postharvest ground application for suppression of the target pest. Apply as a band over the entire crown area when the asparagus beds have been split (i.e., remove most of the soil from above the asparagus crowns). Cover the area with soil the day of application. **Note:** Control may be reduced in soils with high organic matter content.

Pests Controlled	Pilot 15G lb/acre
symphylans	10

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 180 days before harvest.
- Do not apply more than a total of 3 lb ai chlorpyrifos per acre between harvests.
- **For use only in California.**

Citrus Orchard Floors

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 5 days unless PPE required for early entry is worn.

Pests Controlled	Application Rate Lb/acre
ants (1)	6.6

Numbers in parentheses (-) refer to Pest-Specific Use Directions

Pest-Specific Use Directions:
1. Excludes ants of significant public health importance such as fire ants, harvester ants, carpenter ants, and pharaoh ants.

Postplant Broadcast Treatment: To control foraging ants and suppress mounds, apply Pilot 15G with ground application equipment. Use a suitable granular applicator, such as a cyclone fertilizer spreader, that will uniformly broadcast the granules over the grove floor. Pilot 15G may be custom blended with granular fertilizers provided that application of the blended Pilot 15G plus fertilizer mixture can be applied uniformly to the grove floor. Do not apply where weed growth or other obstructions would impede uniform coverage of the grove floor.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 28 days before harvest.
- Do not make more than 3 applications of Pilot 15G or other products containing chlorpyrifos per year (does not include foliar applications to citrus trees).
- Do not apply more than 20 lbs. of Pilot 15G per year (3 lb. ai per acre per season).
- Do not allow livestock to graze in treated areas.
- Do not make a second application within 10 days of any application of chlorpyrifos to the orchard.
- Do not apply more than 1 lb. ai chlorpyrifos per application.

Cole Crops (Brassica) Leafy Vegetables

(Bok Choy, Broccoli, Broccoli Raab, Brussels Sprout, Cabbage, Cauliflower, Chinese Broccoli, Chinese Cabbage, Collards, Kale, Kohlrabi, and Turnip)

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours (3 days for cauliflower) unless PPE required for early entry is worn.

Pests Controlled	Application Rate Ounces per 1,000 feet of row
root maggot	4.6 to 9.2

At Plant T-Band Treatment: For direct seeded and transplanted crops, apply Pilot 15G as a 4-inch wide band centered over the row. This application requires a spreader or splitter on the end of the applicator drop tube. Shallow incorporation is necessary. Placement behind the planter shoe and in front of the press wheel is recommended.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply to cauliflower within 21 days before harvest: to broccoli, Brussels sprout, cabbage, Chinese cabbage, collard, kale, kohlrabi and turnip within 30 days before harvest.
- The maximum single application rate is 1.4 oz ai chlorpyrifos per 1,000 ft. of row, except for cauliflower. For cauliflower, the maximum application rate is 1.2 oz ai/1,000 ft. of row.
- Do not make a foliar application of any other product containing chlorpyrifos within 10 days of an at-plant application of Pilot 15G.
- Do not apply more than 7 1/2 pounds of Pilot 15G per acre to crops planted in 40 inch rows or more than 15 pounds of Pilot 15G per acre to crops planted in 20 inch rows (or two rows per bed). Use proportional amounts for other row spacing not to exceed 15 pounds of Pilot 15G per acre.
- Do not make more than one application per season.

Corn (Field Corn, Sweet Corn, and Corn Grown for Seed)*

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Application Rates and Pests Controlled

Pests Controlled	Banded/In furrow Applications (Ounces per 1,000 Feet of Row) 40-inch Row Spacing*			Aerial Broadcast Application (lb/Acre)
	At Plant Applications		Postplant Treatment	
	T-Band	In-Furrow		
ants (4)	8	8	-	-
armyworms	-	-	6 - 8	-
billbugs	8	-	-	-
Chinch bug (1)	8	8	-	-
Cutworms (1)	8	8	-	-
European and southwestern corn borer(3) 1st Generation 2nd Generation	 - -	 - -	 3.5 to 8 6 to 8	 5.0 to 6.5 6.5
grubs	8	8	-	-
lesser cornstalk borer	8	-	-	-
Northern, Western and Southern corn rootworm larvae	8	8	8	-
seed corn beetle	8	8	-	-
seed corn maggots	8	8	-	-
Southern corn Rootworm larvae	8	8	8	-
symphylans	8	-	-	-
wireworms (2)	8	8	-	-

Numbers in parentheses (-) refer to Pest-Specific Use Directions.

NOTE: Pilot 15G insecticide is compatible with all ALS inhibitor herbicides, including Accent and Beacon herbicides, applied in accordance with label recommendations. Refer to product label for additional Precautionary Statements, Mixing and Application instructions.

Pest Specific Use Directions:

1. **Cutworms and chinch bugs:** The 8 oz rate provides suppression only for in-furrow treatments.
2. **Wireworms:** For best control, apply as an in-furrow treatment. Consider using a hopper box insecticidal seed treatment with T-band applications.
3. **European corn borer:** When using post plant banded applications, use rates of 3.5 to 4 oz of Pilot 15G per 1000 feet of row for low to moderate first generation infestations before larvae have entered corn stalks. Use application rates of 6 to 8 oz of Pilot 15G per 1000 feet of row for severe first generation infestations and all second generation infestations before larvae have entered corn stalks.
4. Ants: Excludes ants of significant public health importance such as fire ants, harvester ants, carpenter ants, and pharaoh ants. The 8 oz rate provides suppression only for in-furrow treatments.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

At Plant T-Band Application: Apply 8 oz of Pilot 15G per 1000 ft of row as a T-band over an open seed furrow over the row behind the planter shoe, in front of the press wheel. In conventional and minimum-till corn, incorporate into the top ½ to 1 inch of soil using suitable equipment. A soil applied T-band treatment may be followed by post-applied herbicides. Pilot 15G has demonstrated suppression of certain soil-borne pathogens that may result in physiological and agronomic advantages to corn under environmental stress conditions when compared to corn not treated with Pilot 15G.

At Plant In-Furrow Application: Apply 8 oz of Pilot 15G per 1000 ft of row at planting as an in-furrow treatment in conventional, minimum and no-till corn. Direct the granules into the planter shoe with the seed, or place the applicator tube directly behind the planter shoe so that the granules drop into the seed furrow, or place the granular band applicator behind the planter shoe so that the granules fall on the soil surface and into the open seed furrow and are covered with soil.

Postplant Application: To control corn rootworm larvae, apply 8 oz of Pilot 15G per 1000 ft of row at cultivation by placing the granules at the base of the plant on both sides of the row just ahead of the cultivation shovels and covering the granules with soil. To control European and southwestern corn borer larvae, apply Pilot 15G in a band over the row so that the granules are directed into the whorl or use a postplant broadcast treatment. Consult your state agricultural experiment station or extension service specialist for proper time to treat and local threshold information. Scouting for insect damage is strongly encouraged.

Postplant Broadcast Treatment: To control European and southwestern corn borers, apply Pilot 15G by uniformly broadcasting the granules over the corn plants by aerial application or by applying the granules into the corn whorls by ground application. For aerial applications, do not apply within 150 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fishponds. Apply at a rate of 5 lb per acre for low to moderate first generation infestations or at 6.5 lb per acre for severe first generation infestations and all second-generation infestations. Apply before larvae have entered corn stalks. Consult your state agricultural experiment station or extension service specialist for local threshold information. Scouting for insect damage is strongly encouraged.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 21 days before harvest of grain or ears.
- Do not apply by aircraft at a rate greater than 1 lb ai per acre.
- Do not make more than 1 at-plant application and 1 foliar application of Pilot 15G per season at the 1 lb ai chlorpyrifos rate.
- Do not make more than 3 applications of any product containing chlorpyrifos per season, including the maximum allowed of 2 granular applications, at the 1 lb ai chlorpyrifos rate. Re-treatment with a second soil application of Pilot 15G is allowed under replant situations due to loss of crop during establishment only when initially applied at the rate of 1 lb.
- Do not apply more than a total of 3 lb ai chlorpyrifos per acre per season.
- Do not make a second application of Pilot 15G or other product containing chlorpyrifos within 10 days of the first application.
- Maximum single application rate for at-plant applications is 8 oz of Pilot 15G per 1000 ft of row (1.3 lb ai chlorpyrifos per acre).
- Maximum single application rate for postplant applications is 6.5 lb of Pilot 15G (1 lb ai chlorpyrifos) per acre.
- If more than 1 lb ai granular chlorpyrifos per acre is applied at-plant (for a maximum of 1.3 lb ai per acre per season), only 1 additional application of a liquid product containing chlorpyrifos at 1 lb ai per acre is allowed per season, for a total of 2.3 lb ai chlorpyrifos per acre per season.

Onions (Dry Bulb)

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate Ounces per 1,000 feet of row (at 18-inch row spacing)
onion maggot	3.7

At Plant In-Furrow Treatment: Apply as an at-planting in-furrow treatment. In Colorado, Idaho, Washington, and Oregon, to control onion maggots in onions planted in double rows with rows spaced 2 to 4 inches apart, apply Pilot 15G at the rate of 3.7 oz per 1,000 feet of double row. Place the granules in a 5 to 7 inch wide band over both rows behind the planter shoe and in front of the press wheel to achieve shallow incorporation. Do not exceed 6.6 lb Pilot 15G per acre (1 lb.ai chlorpyrifos).

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply last treatment within 7 days before harvest.
- Do not apply more than 1 lb. ai chlorpyrifos per crop per season.
- Do not make more than 1 application of any product containing chlorpyrifos per year.

Peanuts

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Use Pilot 15G to control cutworms, lesser cornstalk borer, southern corn rootworm larvae, suppress wireworms, and inhibit the growth and development of white mold (southern blight) disease caused by *Sclerotium rolfsii*. Pilot 15G will control only those cutworms existing in the soil from the time of application up to 30 days following application.

Application Rates and Pests Controlled

	Banded Applications (Ounces/1,000 feet of row)	
Pests Controlled	At-Plant Treatment	Postplant Treatment
*Preventative Treatments: cutworms lesser cornstalk borer southern corn rootworm larvae wireworms white mold (Southern blight) (1)	7.5 to 15	7.5 to 15
potato leafhopper	-	15
**Rescue Treatments: lesser cornstalk borer (2)	-	7.5 to 15

***At Plant Preventive Treatment:** Apply Pilot 15G in a 6 to 12 inch band over the row behind the planter shoe and in front of the press wheel. Incorporate granules to a depth of 1-inch with tines or chains or other suitable equipment. If the 7.5 oz rate is used at planting time, then another application of 7.5 oz per 1,000 feet of row should be made postplant to extend control.

***Postplant Preventative Treatment:** Apply Pilot 15G to peanuts at early flowering to pegging stage of growth in a 6 to 8 inch band over the row. For extended insect control and continued suppression of white mold (southern blight), a second application of Pilot 15G may be made. Best suppression of white mold (southern blight) is obtained by applying the maximum rate of 15 oz per 1,000 ft of row for each postplant treatment. Irrigation or rain following application is needed to enhance treatment effectiveness for suppression of white mold. Under conditions of heavy white mold pressure, a suitable fungicide may also be required and must be applied separately.

****Band Rescue Treatment:** Use Pilot 15G for the control of lesser cornstalk borer when the insect first appears, usually just prior to or at pegging. Apply in a 10 to 18 inch band over the fruiting zone.

Pest Specific Use Precautions

1. **Suppression of white mold:** Best suppression of white mold (southern blight) is obtained by applying the maximum rate of 15 oz per 1000 ft of row. Irrigation or rain following application is needed to enhance treatment effectiveness for suppression of white mold. Under conditions of heavy white mold pressure, a suitable fungicide may also be required and must be applied separately.
2. **Lesser cornstock borer:** Use Pilot 15G for the control of lesser corstock borer as a rescue treatment when the insect first appears, usually just prior to or at pegging.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 21 days before harvest.
- Do not make more than 2 applications of Pilot 15G per year.
- Do not make a second application of Pilot 15G or any other product containing chlorpyrifos within 10 days of the first application.
- Do not apply more than 15 oz of Pilot 15G per 1000 feet of row per crop season or apply more than 4 lb ai chlorpyrifos per acre.
- Do not feed peanut forage or hay to meat or diary animals.
- The combined total of preplant and postplant applications of Pilot 4E and Pilot 15G must not exceed 4 pounds of active ingredient per acre per crop season.
- Aerial application of Pilot 15G to peanuts is prohibited.

Radishes

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate Ounces per 1,000 feet of row
root maggot	3.3

At Plant In-Furrow Treatment: Place the granules in the seed furrow with the seed at planting time.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 7 days before harvest.
- The maximum single application rate is 0.5 oz ai chlorpyrifos per 1,000 ft. of row (2.75 lb ai chlorpyrifos per acre).
- Do not apply more than 18.3 pounds of Pilot 15G per acre or make more than one application per season.

Rutabagas

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate Ounces per 1,000 feet of row
root maggot	4.6 to 9.2

At Plant T-Band Treatment: For direct seeded and transplanted rutabaga, apply Pilot 15G as a 4-inch wide band centered over the row. This application requires a spreader or splitter on the end of the applicator drop tube. Shallow incorporation is necessary. Placement behind the planter shoe and in front of the press wheel is recommended.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 7 days before harvest.
- Application rate is 10.56 oz Pilot 15G per 1,000 ft. of row.
- The maximum single application rate is 1.6 oz ai chlorpyrifos per 1,000 ft of row (8.8 lb ai chlorpyrifos per acre).
- Do not make more than one application per crop season.
- Do not use rutabaga tops for food or feed purposes.

Sorghum-Grain Sorghum (Milo)

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Application Rates and Pests Controlled

Pests Controlled	Banded Applications (Ounces per 1,000 feet of row) At Plant Treatments	
	T-Band	Band
lesser cornstalk borer	4 to 8	4 to 8
ants (2) corn rootworm and cutworms	8	8
chinch bug (1)	8	-

Numbers in parentheses (-) refer to Pest-Specific Use Directions.

Pest- Specific Use Directions:

1. **Chinch bugs:** 8 oz. rate suppression only.
2. **Ants:** Excludes ants of significant public health importance such as fire ants, harvester ants, carpenter ants, and pharaoh ants. 8 oz rate suppression only.

At Plant T-Band or Band Treatments: Apply in a 6 to 8 inch band over the row and incorporate into the top 1-inch of soil using suitable equipment. Equivalent rates of Pilot 15G per acre for various row spacing is given in Table 1. Use the lowest rate for lesser cornstalk borer control when protection is desired for 2 to 3 weeks and higher rates for longer residual activity. It is absolutely necessary to incorporate the granules, especially at lower rates.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply last treatment within 7 days before harvest.
- Do not make a foliar application of any other product containing chlorpyrifos within 10 days of an at-plant application of Chlorpyrifos 15G.
- Do not make more than 1 application of Pilot 15G per season.
- The maximum single application rate is 8 oz per 1000 feet of row (1.3 lb ai chlorpyrifos in 30-inch row spacing). Use proportional amounts for other row spacings not to exceed 1.5 lb ai chlorpyrifos per acre.

Soybeans

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

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Application Rates and Pests Controlled

Pests Controlled	Banded Applications (Ounces per 1,000 feet of row)		
	At Plant Treatments		
	T-Band	Band	Postplant Treatment
ants (1)	8	8	-
lesser cornstalk borer cutworms	8	8	8

Numbers in parentheses (-) refer to Pest-Specific Use Directions.

Pest-Specific Use Directions:

1. Excludes ants of significant public health importance such as fire ants, harvester ants, carpenter ants, and pharaoh ants.

At Plant and Postplant Treatments: Use Pilot 15G insecticide to control larvae of the lesser cornstalk borer and cutworms by application at planting time or postemergence as a band (row) treatment at the rate of 8 oz per 1,000 feet of row. In the southeast apply 4 to 8 oz per 1,000 feet of row as an at-plant treatment. Equivalent rates of Pilot 15G per acre for various row spacing are given in Table 1. When applied at planting time incorporate the granules into the top 1 inch of soil by placing in a 4 to 10 inch band over the row behind the planter shoe and ahead of the press wheel. A drag chain can also be used for incorporation. For postemergence treatment when insects first appear incorporate the granules in a 4 to 10 inch band to a depth of 1/2 to 1 inch using a suitable cultivator. Apply Pilot 15G with equipment that will provide uniform distribution of the granules. Do not apply as an in-furrow treatment. For suppression of fire ants, use Pilot 15G at 8 oz per 1,000 feet of row as an at-plant T-band treatment.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**
- Do not apply as an in-furrow treatment.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 28 days before harvest.
- The maximum single application rate is 8 oz. of Pilot 15G (1.2 oz ai chlorpyrifos) per 1000 feet of row.
- The maximum single application rate is 2 lb ai chlorpyrifos per acre for preplant/at-plant incorporation and 1 lb ai chlorpyrifos per acre for foliar and postharvest application.
- Do not make more than 3 applications of any product containing chlorpyrifos per season with a maximum of 1 granular application and 2 liquid applications.
- Do not make a foliar application of any other product containing chlorpyrifos within 10 days of an at-plant application of Pilot 15G.

Sugar Beets

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Application Rates and Pests Controlled

Pests Controlled	Banded Applications (Ounces per 1,000 feet of row)		
	At Plant Treatments		
	T-Band	Band	Postplant Treatment
Sugar beet root maggot (1)	-	4.5 to 9.0	6.5 to 9.0
cutworms	-	6.6 to 9.0	-
wireworms (suppression)	-	6.5 to 9.0	-

Numbers in parentheses (-) refer to Pest-Specific Use Directions.

Pest-Specific Use Directions:

1. When root maggot populations are expected to be low, apply Pilot 1G at a rate of 4.5 oz per 1000 feet of row (equivalent to 6.75 lb per acre based upon 22-inch row spacing). If initial adult fly activity indicates higher than anticipated populations, apply Pilot 15G at or near the time of peak adult emergence to augment control.

At Plant Band Treatment: To control sugar beet root maggot larvae and cutworms at planting time, place Pilot 15G in a band 4 to 5 inches wide behind the planter shoe, over the drill row, and in front of the press wheel. Do not apply granules in direct contact with seeds. Apply Pilot 15G at the rate of 4.5 to 9 ounces per 1,000 feet of row (equivalent to 6.7 to 13.5 lb per acre based on a 22 inch row spacing). When root maggot populations are expected to be low, apply Pilot 15G at a rate of 4.5 ounces per 1,000 feet of row (equivalent to 6.7 lb per acre based on 22 inch row spacing). If initial adult fly activity indicates higher than anticipated populations, apply Pilot 4E at or near the time of peak adult emergence to augment control. (Review label for Pilot 4E for recommended use rates, application timing, methods of application, and insecticide resistance management). Incorporate Pilot 15G into the top 1/2 to 1 inch of soil using suitable equipment.

Postemergence Band Treatment: For postemergence control of sugar beet maggot larvae, place Pilot 15G in a band 3 to 5 inches wide over the beet row (up to 2 to 4 true leaf stage of plant growth). Apply Pilot 15G at the rate of 6.5 to 9 oz per 1,000 feet of row (equivalent to 9.7 to 13.4 lb per acre based on a 22 inch row spacing). Incorporate Pilot 15G into the top 1/2 to 1 inch of soil using a suitable incorporation device.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**
- Granular insecticides, including Pilot 15G, may contribute to the stress of the sugar beet plant under certain environmental conditions. This stress may reduce plant stand or interfere with normal plant development. Herbicides used preplant incorporated may interact with insecticides and enhance this stress.

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 30 days before harvest.
- Do not make more than one application of Pilot 15G per year, or apply more than 2 lb ai chlorpyrifos per acre per season.
- Do not apply more than a total of 3 lb. ai chlorpyrifos per acre per year, or make more than 3 applications of products containing chlorpyrifos per season.
- The maximum single application rate is 1.35 oz ai chlorpyrifos per 1000 feet of row or 2 lb ai chlorpyrifos per acre based upon a 22-inch row spacing.
- Do not make a foliar application of any other product containing chlorpyrifos within 10 days of an at-plant application of Pilot 15G

Sunflowers

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate Ounces per 1,000 feet of row
cutworms	8.0

At Plant Band Treatment: Place the granules in a 7 inch wide band over the row behind the planter shoe in front of the press wheel and incorporate into the top 1 inch of soil using suitable equipment.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 42 days before harvest.

- Do not make more than 3 applications of any product containing chlorpyrifos per season with a maximum of 1 granular application and 2 liquid applications.
- The maximum single application rate is 1.25 oz ai chlorpyrifos per 1000 feet of row or 1.3 lb ai chlorpyrifos per acre based upon a 30-inch row spacing.
- The maximum single application rate is 2 lb ai chlorpyrifos per acre for preplant/at-plant incorporation and 1 lb ai chlorpyrifos per acre for foliar and postharvest application.
- Do not make a foliar application of any other product containing chlorpyrifos within 10 days of an at-plant application of Pilot 15G.

Sweet Potatoes

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate lb/acre
Wireworms *(conoderus)* Flea beetles *(Systena)* Sweet potato flea beetle	13.5

Preplant Broadcast Treatment: Use Pilot 15G to reduce the feeding damage caused by populations of the listed pests. Evenly broadcast the granules over the soil surface and then incorporate the granules into the soil to a depth of 4 to 6 inches using a rotary hoe, disc cultivator, or other suitable equipment. Plant the crop in the usual manner no later than 14 days after treatment (any delay in planting will reduce the length of time that Pilot 15G will protect against feeding damage). Pilot 15G will not control false wireworm or whitefringed beetle and other grubs that attack sweet potatoes.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 125 days before harvest.
- The maximum single application rate is 2 lb ai chlorpyrifos per acre.
- Do not make more than one application of Pilot 15G or other product containing chlorpyrifos per season.

Tobacco

Worker Restricted Entry Interval: Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 24 hours unless PPE required for early entry is worn.

Pests Controlled	Application Rate lb/acre
cutworms flea beetles mole crickets root maggots wireworms	13.5

Preplant Broadcast Treatment: Apply Pilot 15G one week before transplanting, using equipment that will evenly distribute the granules over a treated area. Immediately following application, incorporate the granules into the soil to a depth of 2 to 4 inches using suitable equipment. The application of Pilot 15G will also suppress movement of imported fire ant into treated field.

Specific Use Precautions:

- **Read and follow all Spray Drift Mitigation Measures (See Spray Drift Mitigation Measures section).**

Specific Use Restrictions:

- **Preharvest Interval:** Do not apply within 7 days before harvest.
- Do not make more than one application of Pilot 15G or other product containing chlorpyrifos per season.
- The maximum single application rate is 2.025 lb. ai chlorpyrifos per acre.

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Table 1
Application Rates Table-Application Rates/1,000 Ft. of Row and Equivalent/Acre at Different Row Spacing

Amount of Pilot 15G Per 1,000 Feet of Row	Pounds of Pilot 15G Required Per Acre from Various Row Spacing							
	40"	38"	36"	34"	32"	30"	22"	18"
3.7 ounces	3.0	3.2	3.4	3.6	3.8	4.0	5.5	6.7
4.0 ounces	3.3	3.4	3.6	3.8	4.1	4.4	5.9	7.3
4.5 ounces	3.7	3.9	4.1	4.3	4.6	4.9	6.7	8.2
6.0 ounces	4.9	5.2	5.4	5.8	6.1	6.5	8.9	10.9
6.5 ounces	5.3	5.6	5.9	6.2	6.6	7.1	9.7	11.8
7.5 ounces	6.1	6.4	6.8	7.2	7.7	8.2	11.1	13.6
8.0 ounces	6.5	6.9	7.3	7.7	8.2	8.7	11.9	14.5
9.0 ounces	7.4	7.7	8.2	8.6	9.2	9.8	13.4	16.3
12.0 ounces	9.8	10.3	10.9	11.5	12.3	13.1	17.8	21.8
15.0 ounces	12.3	12.9	13.9	14.4	15.3	16.3	22.3	27.2
16.0 ounces	13.1	13.8	14.5	15.4	16.3	17.4	23.8	29.0

General Instructions for Calibration of Equipment

Caution: The following chart lists suggested initial gauge settings for application of Pilot 15G with one hopper opening per row. Be sure to check the actual application rate under your operating conditions.

1. Fill hopper.
2. Attach a plastic bag to tube opening.
3. Set your planter to the initial settings shown on chart.
4. Measure off 1,000 row feet and drive your planter the pre- measured distance at your desired speed.
5. Each bag should contain 6 to 8 ounces (wt.) of granules depending on your desired rate.
6. If the result is over or under the desired rate, adjust the settings and repeat the calibration.

Table 2

Equipment Calibration and Calibration Settings for Different Types of Equipment
Application Rate, 8 oz. Per 1,000 ft row

	Speed (mph)									
	4		5		6		7		8	
	Application Rate, oz per 1,000 ft row									
	8	16	8	16	8	16	8	16	8	16
Planter Type	**Gauge Setting**									
Gandy[1]	21.4	30.2	23.7	32.4	26.0	36.0	27.7	39.0	30.2	41.0
John Deere[1] Max-Emerge[2]	20	44	26	46	30	49	35	52	40	54
John Deere[1] 7000 Max-Emerge *(Odd Nos. on Gate)*	14	22	16	24	18	26	19	28	21	30
John Deere[1] 7000 Max-Emerge (Even Nos. on Gate)	17	30	20	33	24	35	26	36	28	38
John Deere[2] 71 Flexi-Planter and Older Planters	1/30	2/17	2/5	2/22	2/9	2/27	2/13	2/31	2/16	3/16
John Deer[3] MaxEmerg Plus	18	-	23	-	29	-	33	-	39	-
Allis Chalmers[3] 70 Series	8	13	8	13	8	13	8	13	8	13
Allis Chalmers[4] 78 & 79 Series	1/9.0	3/3.0	2/33	3/9.5	2/6	4/3.0	2/9	5/4.0	3/2.5	6/0
Noble[1] (New)	11	19	14	22	16	25	17	28	19	31
White Planter	11	19	14	22	16	25	17	28	19	31
International Harvester[4]	1/9.0	3/3.0	2/3.3	3/9.5	2/6.0	4/3.0	2/9.0	5/4.0	3/2.5	6/0
Buffalo All-Flex[5] (Fleischer Mfg.)	4 7/8	10	4 7/8	10	4 7/8	10	-	-	-	-

[1] Gauge setting

[2] Gauge setting with range 1 & 2 - number is range/notch.

[3] An application rate of 16 oz per 1000 ft of row is not attainable with this equipment

[4] Gauge setting is constant regardless of speed.

[5] Gauge setting shown with stem gates & dial settings - number shown is gate/dial.

[6] Number of turns open on the adjustment nut.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose under normal conditions of use. This is the only warranty made on this product. Seller expressly disclaims any implied warranties of merchantability or fitness for any particular purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of the Seller. To the fullest extent permitted by law, in no event shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. To the fullest extent permitted by law all such risks shall be assumed by the Buyer. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

EPA Accepted: 05/27/2005
Amended: 12/31/2007 (Amended per RED)
Amended: (Drift Mitigation Measures)

Pilot® is a registered trademark of Gharda Chemicals Limited

Accent Registered Trademark of E.I. du Pont de Nemours and Company.
Beacon Registered Trademark of Syngenta Crop Protection.

EXHIBIT 7

January 6, 2023

The Honorable Michael S. Regan
Administrator, United States Environmental
Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos

Dear Administrator Regan:

We write on behalf of nineteen grower groups (representing thousands of farmers around the country who rely upon the pesticide product known as chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda Chemicals International, Inc. ("Gharda")) (collectively "Petitioners"). Over the last 30 years, the global agricultural system has managed to feed almost 2.5 billion more people whilst reducing per capita environmental impacts by 20%. America's farmers are committed to producing safe and affordable food for consumers in the U.S. and around the world. Around 98% of U.S. farms are family owned and on a daily basis these farming families work to ensure a sufficient, safe, and nutritious food supply exists. We respectfully request that EPA immediately stay or withdraw EPA's Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations dated December 14, 2022 ("NOIC"). This request is based on several reasons.

First, EPA's primary basis for its NOIC is that tolerances for all food uses of chlorpyrifos were revoked by way of EPA's Final Rule published August 30, 2021, and the chlorpyrifos registrations must be cancelled as a follow-up to the tolerance revocation. However, Petitioners have challenged EPA's Final Rule as to eleven high benefit food uses found safe by the Agency ("Safe Uses") in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.,* No. 22-1422 (8th Circuit) ("lawsuit"). There is no reason that EPA action with respect to chlorpyrifos registrations cannot await the Eighth Circuit's decision. As the Agency has said many times, once the tolerances expired, pesticide products containing chlorpyrifos could no longer be used on food crops. Registration cancellation does not alter or add to that result. The fact that EPA did not initiate the process until <u>15 months after the Final Rule</u> lends support for the fact that cancellation will not impact the reality that it is already illegal to use pesticide products containing chlorpyrifos on food crops. Thus, EPA's NOIC is unnecessary at this time and premature in light of the lawsuit. It will only add considerably to the costs of Petitioners and other adversely affected parties who seek to have their rights addressed as to the Safe Uses.

Second, there is no urgency that the NOIC seeks to address. There is no reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce, necessitating registration cancellation at this time. As noted above, EPA's tolerance revocations made distribution or use illegal as a matter of law. Moreover, in correspondence dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. The Agency threatened the immediate initiation of involuntary cancellation proceedings if Gharda did not do as the Agency had demanded. Gharda responded on March 30; *see* attached March 30, 2022, letter from Gharda to EPA. Gharda's response: (1) requested the voluntary cancellation of all of Gharda's food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda's commitment to the Agency well before the Final Rule); (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit." Nothing has changed since Gharda's commitment, and EPA has never responded to Gharda's letter.

Third, the timing of EPA's NOIC is highly questionable. Published the day before oral argument in the Eighth Circuit in the lawsuit and coupled with an inflammatory press release issued by EPA, the NOIC appears to be an effort to interfere with the jurisdiction of the Eighth Circuit with respect to the Safe Uses. The issuance of the NOIC also appears to be an attempt to signal urgency when, as noted above, none exists except for American growers' desperate need of the Safe Uses of chlorpyrifos for the 2023 growing season commencing in March. In sum, there is no need based on the law or the facts for EPA to issue the NOIC while the Eighth Circuit litigation is pending. Indeed, for the Agency to wait nine months after Gharda's commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, smacks of an effort to create urgency where EPA's conduct demonstrates none exists, thereby impeding fair consideration of the lawsuit by the Court. This is especially true given USDA's adamant opposition to the NOIC and tolerance revocation as to the Safe Uses.

Finally, issuance of the NOIC with a response deadline shortly after the holiday period seems punitive by any measure. As set forth above, there is simply no reason to force Petitioners and other adversely affected parties to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, the Petitioners respectfully request that EPA stay and/or withdraw the NOIC until after the Eighth Circuit's decision in the lawsuit. ***The Petitioners further request that EPA rule on this request as soon as possible in order to allow the Petitioners time to seek other relief, if necessary, consistent with this request.***

Sincerely,

South Dakota Soybean Association

By: ______________________
Jerry Schmitz
Executive Director

Red River Valley Sugarbeet Growers Association

By: ______________________
Brent Baldwin
Vice President

American Soybean Association

By: ______________________
Stephen Censky
Chief Executive Officer

American Sugarbeet Growers Association

By: ______________________
Luther Markwart
Executive Vice President

Iowa Soybean Association

By: ______________________
Kirk Leed
Chief Executive Officer

U.S. Beet Sugar Association

By: ______________________
Cassie Bladow
President

Missouri Soybean Association

By: ______________________
Matthew Wright
President

Southern Minnesota Beet Sugar Cooperative

By: ______________________
Paul Fry
Chief Executive Officer

Minnesota Soybean Growers Association

By: ______________________
Joseph Smentek
Executive Director

American Crystal Sugar Cooperative

By: ______________________
Thomas Astrup
President and Chief Executive Officer

Nebraska Soybean Association

By: ______________________
Lori Luebbe
Executive Director

Minn-Dak Farmers Cooperative

By: ______________________
Kurt Wickstrom
Chief Executive Officer

North Dakota Soybean Growers Association

By: ______________________
Kasey J. Bitz
President

Florida Fruit and Vegetable Growers Association

By: ______________________
Mike Aerts
Vice President

American Farm Bureau Federation

By: ______________________
Samuel Kieffer
Vice President, Public Affairs

Georgia Fruit and Vegetable Growers Association

By: ______________________
Chris Butts
Executive Vice President

Gharda Chemicals International, Inc.

By: ______________________
Ram Seethapathi
President

National Cotton Council of America

By: ______________________
Gary Adams
President and Chief Executive Officer

National Association of Wheat Growers

By: ______________________
Nicole Berg
President

Attachment

cc: Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: freedhoff.michal@epa.gov.

Edward Messina, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency: messina.edward@epa.gov.

Elissa Reaves, Pesticide Re-Evaluation Division, Office of Pesticide Programs, U.S. Environmental Protection Agency: reaves.elissa@epa.gov.

Dana Friedman, Branch Chief, Office of Pesticide Programs, Risk Management and Implementation Branch I (RMIB I), U.S Environmental Protection Agency: friedman.dana@epa.gov.

The Honorable Thomas J. Vilsack, Secretary, U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250

Gharda Chemicals International, Inc.

March 30, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Request for (1) Voluntary Cancellation of Certain Chlorpyrifos Food Use Registrations and (2) Sub-labels for Non-Food Uses

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the March 1, 2022 letter of the U.S. Environmental Protection Agency (EPA or Agency), in which EPA requested that Gharda voluntarily cancel registrations and/or uses impacted by EPA's decision to revoke all chlorpyrifos tolerances.

Consistent with its commitment to EPA in the weeks leading up to EPA's Final Rule revoking all chlorpyrifos tolerances, and pursuant to Section 6(f)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Gharda requests voluntary cancellation of the food use registrations identified in Table 1. These uses comprise all of Gharda's currently registered food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**).

Table 1: Gharda Chemicals International, Inc. Voluntarily Cancelled Food Uses

Product name	EPA Registration No.	Voluntarily Cancelled Food Uses
Chlorpyrifos Technical	93182-3	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **Asparagus** (**except** in MI), Banana, Blueberry, Caneberry, Cherimoya, **Citrus Fruits** (**except** in AL, FL, GA, NC, SC, TX), Corn, **Cotton** (**except** in AL, FL, GA, NC, SC,

		VA), Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, **Soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), Sunflowers, **Sugar Beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), Sugarcane, **Strawberries** (**except** in OR), Sweet Potatoes, Tree Fruit, (**apples** [**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV], pears, **cherries** [**except** tart cherries in MI], plums/prunes, **peaches** [**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV] and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY).
Pilot 4E Chlorpyrifos Agricultural Insecticide	93182-7	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **apple** (**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV), **asparagus** (**except** in MI), brassica (cole), leafy vegetables, radish, rutabaga, turnip, **citrus fruits and citrus orchard floors** (except in AL, FL, GA, NC, SC, TX), corn (field corn and sweet corn, including corn grown for seed) **cotton (except** in AL, FL, GA, NC, SC, VA), cranberries figs, grape, legume vegetables (succulent or dried, except soybean), onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), **soybean** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), **strawberry** (**except** in OR), **sugar beet** (**except** in IA, ID, IL, MI, MN, ND, OR,

		WA, WI), sunflower, sweet potato, almond, walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip) tree nuts (foliar sprays) tree nut orchard floors, **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY), **cherries** (**except** tart cherries in MI), and **peaches** (**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV).
Pilot 15G Chlorpyrifos Agricultural Insecticide	93182-8	**Citrus and citrus orchards** (**except** in AL, FL, GA, NC, SC, TX), broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions, radishes, rutabagas, sweet potatoes, corn, **asparagus** (**except** in MI), **alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), sorghum, **soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), peanuts, **sugar beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), turnips, and sunflowers.

Gharda understands that cancellation of the food uses outlined in Table 1 will result in cancellation of the same food uses for the supplemental distribution product identified below in Table 2.

Table 2: Supplemental Distribution Product

Distributor Product Number	**Distributor Company Name**	**Distributor Product Name**
93182-7-55467	Tenkoz, Inc.	Govern Insecticide

Gharda understands that a notice of receipt of this voluntary cancellation request will be published in the Federal Register, as required by Section 6(f) of FIFRA. Gharda further understands that the notice may allow up to a 180-day period after publication for public comment, during which time EPA may not approve or reject the request, and that the registrant may request that the comment period be waived. Gharda is not requesting waiver of the comment period. Gharda also understands that it is the Agency's policy to consider comments received during the public comment period before making its final determination on such a request.

Gharda is not in a position to voluntarily cancel its registration for the Eleven Uses at this time, given the litigation pending in the U.S. Court of Appeals for the Eighth Circuit. Gharda stands prepared to engage in a dialogue with EPA and/or the Department of Justice concerning the Eleven Uses at the appropriate time.

Gharda nevertheless understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses. Accordingly, Gharda has suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda is also prepared to accept return of its branded product from its distributors and dealers back to its possession and control for relabeling, export, or storage. Gharda is committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit.

With the Agency's permission, Gharda is prepared to submit a request to EPA for sub-labels for its technical and end-use products that would include only non-food uses. This would limit continued domestic distribution, sale, and use of Gharda's relabeled chlorpyrifos products to non-food uses only, consistent with EPA's revocation order. This request is faithful to EPA's revocation order and also preserves Gharda's rights in the ongoing litigation, consistent with the Federal Food, Drug, and Cosmetic Act and FIFRA. Gharda is prepared to work with the Agency on a plan for relabeling consistent with this request.

I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency's convenience.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

CC: Patricia Biggio
Melissa Grable

EXHIBIT 8

January 9, 2023

The Honorable Michael S. Regan
Administrator, United States Environmental
Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos

Dear Administrator Regan:

I write on behalf of the Cherry Marketing Institute to confirm that it joins in the request to withdraw or stay submitted to EPA on Friday, January 6, 2023. A copy of that request is attached hereto and incorporated in full by reference.

Sincerely,

Cherry Marketing Institute

By: ______________________________
Julie Gordon
President/Managing Director

Attachment

cc: Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: freedhoff.michal@epa.gov.

Edward Messina, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency: messina.edward@epa.gov.

Elissa Reaves, Pesticide Re-Evaluation Division, Office of Pesticide Programs, U.S. Environmental Protection Agency: reaves.elissa@epa.gov.

Dana Friedman, Branch Chief, Office of Pesticide Programs, Risk Management and Implementation Branch I (RMIB I), U.S Environmental Protection Agency: friedman.dana@epa.gov.

The Honorable Thomas J. Vilsack, Secretary, U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250

January 6, 2023

The Honorable Michael S. Regan
Administrator, United States Environmental
Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Request for Stay/Withdrawal of EPA's Notice of Intent to Cancel Registrations for Chlorpyrifos

Dear Administrator Regan:

We write on behalf of nineteen grower groups (representing thousands of farmers around the country who rely upon the pesticide product known as chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda Chemicals International, Inc. ("Gharda")) (collectively "Petitioners"). Over the last 30 years, the global agricultural system has managed to feed almost 2.5 billion more people whilst reducing per capita environmental impacts by 20%. America's farmers are committed to producing safe and affordable food for consumers in the U.S. and around the world. Around 98% of U.S. farms are family owned and on a daily basis these farming families work to ensure a sufficient, safe, and nutritious food supply exists. We respectfully request that EPA immediately stay or withdraw EPA's Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations dated December 14, 2022 ("NOIC"). This request is based on several reasons.

First, EPA's primary basis for its NOIC is that tolerances for all food uses of chlorpyrifos were revoked by way of EPA's Final Rule published August 30, 2021, and the chlorpyrifos registrations must be cancelled as a follow-up to the tolerance revocation. However, Petitioners have challenged EPA's Final Rule as to eleven high benefit food uses found safe by the Agency ("Safe Uses") in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.,* No. 22-1422 (8th Circuit) ("lawsuit"). There is no reason that EPA action with respect to chlorpyrifos registrations cannot await the Eighth Circuit's decision. As the Agency has said many times, once the tolerances expired, pesticide products containing chlorpyrifos could no longer be used on food crops. Registration cancellation does not alter or add to that result. The fact that EPA did not initiate the process until <u>15 months after the Final Rule</u> lends support for the fact that cancellation will not impact the reality that it is already illegal to use pesticide products containing chlorpyrifos on food crops. Thus, EPA's NOIC is unnecessary at this time and premature in light of the lawsuit. It will only add considerably to the costs of Petitioners and other adversely affected parties who seek to have their rights addressed as to the Safe Uses.

Second, there is no urgency that the NOIC seeks to address. There is no reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce, necessitating registration cancellation at this time. As noted above, EPA's tolerance revocations made distribution or use illegal as a matter of law. Moreover, in correspondence dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. The Agency threatened the immediate initiation of involuntary cancellation proceedings if Gharda did not do as the Agency had demanded. Gharda responded on March 30; *see* attached March 30, 2022, letter from Gharda to EPA. Gharda's response: (1) requested the voluntary cancellation of all of Gharda's food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda's commitment to the Agency well before the Final Rule); (2) recognized that "there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses"; and (3) "committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit." Nothing has changed since Gharda's commitment, and EPA has never responded to Gharda's letter.

Third, the timing of EPA's NOIC is highly questionable. Published the day before oral argument in the Eighth Circuit in the lawsuit and coupled with an inflammatory press release issued by EPA, the NOIC appears to be an effort to interfere with the jurisdiction of the Eighth Circuit with respect to the Safe Uses. The issuance of the NOIC also appears to be an attempt to signal urgency when, as noted above, none exists except for American growers' desperate need of the Safe Uses of chlorpyrifos for the 2023 growing season commencing in March. In sum, there is no need based on the law or the facts for EPA to issue the NOIC while the Eighth Circuit litigation is pending. Indeed, for the Agency to wait nine months after Gharda's commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, smacks of an effort to create urgency where EPA's conduct demonstrates none exists, thereby impeding fair consideration of the lawsuit by the Court. This is especially true given USDA's adamant opposition to the NOIC and tolerance revocation as to the Safe Uses.

Finally, issuance of the NOIC with a response deadline shortly after the holiday period seems punitive by any measure. As set forth above, there is simply no reason to force Petitioners and other adversely affected parties to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, the Petitioners respectfully request that EPA stay and/or withdraw the NOIC until after the Eighth Circuit's decision in the lawsuit. ***The Petitioners further request that EPA rule on this request as soon as possible in order to allow the Petitioners time to seek other relief, if necessary, consistent with this request.***

Sincerely,

South Dakota Soybean Association	Red River Valley Sugarbeet Growers Association
By: *[signature]*	By: *[signature]*
Jerry Schmitz Executive Director	Brent Baldwin Vice President

American Soybean Association

By: ______________________
Stephen Censky
Chief Executive Officer

American Sugarbeet Growers Association

By: ______________________
Luther Markwart
Executive Vice President

Iowa Soybean Association

By: ______________________
Kirk Leed
Chief Executive Officer

U.S. Beet Sugar Association

By: ______________________
Cassie Bladow
President

Missouri Soybean Association

By: ______________________
Matthew Wright
President

Southern Minnesota Beet Sugar Cooperative

By: ______________________
Paul Fry
Chief Executive Officer

Minnesota Soybean Growers Association

By: ______________________
Joseph Smentek
Executive Director

American Crystal Sugar Cooperative

By: ______________________
Thomas Astrup
President and Chief Executive Officer

Nebraska Soybean Association

By: ______________________
Lori Luebbe
Executive Director

Minn-Dak Farmers Cooperative

By: ______________________
Kurt Wickstrom
Chief Executive Officer

North Dakota Soybean Growers Association

By: ______________________
Kasey J. Bitz
President

Florida Fruit and Vegetable Growers Association

By: ______________________
Mike Aerts
Vice President

American Farm Bureau Federation

By: ______________________
Samuel Kieffer
Vice President, Public Affairs

Georgia Fruit and Vegetable Growers Association

By: ______________________
Chris Butts
Executive Vice President

Gharda Chemicals International, Inc.

By: ______________________________
Ram Seethapathi
President

National Cotton Council of America

By: ______________________________
Gary Adams
President and Chief Executive Officer

National Association of Wheat Growers

By: ______________________________
Nicole Berg
President

Attachment

cc: Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency: freedhoff.michal@epa.gov.

Edward Messina, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency: messina.edward@epa.gov.

Elissa Reaves, Pesticide Re-Evaluation Division, Office of Pesticide Programs, U.S. Environmental Protection Agency: reaves.elissa@epa.gov.

Dana Friedman, Branch Chief, Office of Pesticide Programs, Risk Management and Implementation Branch I (RMIB I), U.S Environmental Protection Agency: friedman.dana@epa.gov.

The Honorable Thomas J. Vilsack, Secretary, U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250

Gharda Chemicals International, Inc.

March 30, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Request for (1) Voluntary Cancellation of Certain Chlorpyrifos Food Use Registrations and (2) Sub-labels for Non-Food Uses

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the March 1, 2022 letter of the U.S. Environmental Protection Agency (EPA or Agency), in which EPA requested that Gharda voluntarily cancel registrations and/or uses impacted by EPA's decision to revoke all chlorpyrifos tolerances.

Consistent with its commitment to EPA in the weeks leading up to EPA's Final Rule revoking all chlorpyrifos tolerances, and pursuant to Section 6(f)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Gharda requests voluntary cancellation of the food use registrations identified in Table 1. These uses comprise all of Gharda's currently registered food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**).

Table 1: Gharda Chemicals International, Inc. Voluntarily Cancelled Food Uses

Product name	EPA Registration No.	Voluntarily Cancelled Food Uses
Chlorpyrifos Technical	93182-3	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **Asparagus** (**except** in MI), Banana, Blueberry, Caneberry, Cherimoya, **Citrus Fruits** (**except** in AL, FL, GA, NC, SC, TX), Corn, **Cotton** (**except** in AL, FL, GA, NC, SC,

		VA), Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, **Soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), Sunflowers, **Sugar Beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), Sugarcane, **Strawberries** (**except** in OR), Sweet Potatoes, Tree Fruit, (**apples** [**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV], pears, **cherries** [**except** tart cherries in MI], plums/prunes, **peaches** [**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV] and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY).
Pilot 4E Chlorpyrifos Agricultural Insecticide	93182-7	**Alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), **apple** (**except** in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV), **asparagus** (**except** in MI), brassica (cole), leafy vegetables, radish, rutabaga, turnip, **citrus fruits and citrus orchard floors** (except in AL, FL, GA, NC, SC, TX), corn (field corn and sweet corn, including corn grown for seed) **cotton (except** in AL, FL, GA, NC, SC, VA), cranberries figs, grape, legume vegetables (succulent or dried, except soybean), onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), **soybean** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), **strawberry** (**except** in OR), **sugar beet** (**except** in IA, ID, IL, MI, MN, ND, OR,

		WA, WI), sunflower, sweet potato, almond, walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip) tree nuts (foliar sprays) tree nut orchard floors, **wheat** (**except** spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY), **cherries** (**except** tart cherries in MI), and **peaches** (**except** in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV).
Pilot 15G Chlorpyrifos Agricultural Insecticide	93182-8	**Citrus and citrus orchards** (**except** in AL, FL, GA, NC, SC, TX), broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions, radishes, rutabagas, sweet potatoes, corn, **asparagus** (**except** in MI), **alfalfa** (**except** in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), sorghum, **soybeans** (**except** in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), peanuts, **sugar beets** (**except** in IA, ID, IL, MI, MN, ND, OR, WA, WI), turnips, and sunflowers.

Gharda understands that cancellation of the food uses outlined in Table 1 will result in cancellation of the same food uses for the supplemental distribution product identified below in Table 2.

Table 2: Supplemental Distribution Product

Distributor Product Number	**Distributor Company Name**	**Distributor Product Name**
93182-7-55467	Tenkoz, Inc.	Govern Insecticide

Gharda understands that a notice of receipt of this voluntary cancellation request will be published in the Federal Register, as required by Section 6(f) of FIFRA. Gharda further understands that the notice may allow up to a 180-day period after publication for public comment, during which time EPA may not approve or reject the request, and that the registrant may request that the comment period be waived. Gharda is not requesting waiver of the comment period. Gharda also understands that it is the Agency's policy to consider comments received during the public comment period before making its final determination on such a request.

Gharda is not in a position to voluntarily cancel its registration for the Eleven Uses at this time, given the litigation pending in the U.S. Court of Appeals for the Eighth Circuit. Gharda stands prepared to engage in a dialogue with EPA and/or the Department of Justice concerning the Eleven Uses at the appropriate time.

Gharda nevertheless understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses. Accordingly, Gharda has suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda is also prepared to accept return of its branded product from its distributors and dealers back to its possession and control for relabeling, export, or storage. Gharda is committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit.

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I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency's convenience.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

CC: Patricia Biggio
Melissa Grable

EXHIBIT 9

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA EMAIL, RETURN RECEIPT REQUESTED

January 11, 2023

To: Carrie Meadows, U.S. Beet Sugar Association

On behalf of: Julie Gordon, Cherry Marketing Institute
Jerry Schmitz, South Dakota Soybean Association
Brent Baldwin, Red River Valley Sugar Beet Growers Association
Stephen Censky, American Soybean Association
Luther Markwart, American Sugarbeet Growers Association
Cassie Bladow, U.S. Beet Sugar Association
Kirk Leed, Iowa Soybean Association
Matthew Wright, Missouri Soybean Association
Paul Fry, Southern Minnesota Beet Sugar Cooperative
Joseph Smentek, Minnesota Soybean Growers Association
Thomas Astrup, American Crystal Sugar Cooperative
Lori Luebbe, Nebraska Soybean Association
Kurt Wickstrom, Minn-Dak Farmers Cooperative
Kasey J. Bitz, North Dakota Soybean Grower Association
Mike Aerts, Florida Fruit and Vegetable Growers Association
Samuel Kieffer, American Farm Bureau Federation
Chris Butts, Georgia Fruit and Vegetable Growers Association
Gary Adams, National Cotton Council of America
Ram Seethapathi, Gharda Chemicals International, Inc.
Nicole Berg, National Association of Wheat Growers

Per your letter dated January 6, 2023, you requested that EPA immediately stay or withdraw EPA's Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations dated December 14, 2022 (the "NOIC")[1] until the issuance of the Eighth Circuit's decision in *RRVSG Assoc., et al. v. Michael Regan, et al.*, No. 22-1422, 22-1530 (8th Cir.).

EPA's rationale for the issuing NOIC is discussed in detail in the NOIC itself. *See, e.g.*, unit IV of the NOIC.[2] To summarize, the chlorpyrifos registrations identified in the NOIC each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products (i) pose unreasonable adverse effects on the environment under Federal Insecticide,

[1] 87 Fed. Reg. 76,474 (Dec. 14, 2022) (FRL-10108-01-OCSPP).
[2] *Id*. at 76,476-77 (Dec. 14, 2022).

Fungicide, and Rodenticide Act (FIFRA) section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

Therefore, between March 1 and March 9 of 2022, after EPA's publication of its order denying all objections, hearing requests, and requests to stay the Final Rule in the Federal Register (87 Fed. Reg. 11,222, February 28, 2022) (FRL–5993–05–OCSPP), EPA issued letters to all registrants of chlorpyrifos products with food uses confirming revocation of the tolerances and recommending that such registrants consider various cancellation and label amendment options. EPA requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food uses from product labels or to submit a voluntary cancellation for products where all uses are subject to the tolerance revocation by March 30, 2022. All chlorpyrifos registrants to whom that letter was sent have submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels, with the exception of Gharda, the registrant of products listed in the NOIC. While Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.,* it does not result in the removal of all food uses from those registered products); therefore, EPA issued the NOIC for the Gharda's products identified therein.

Under FIFRA section 6(b), the Agency may issue a notice of its intent to cancel a registration of a pesticide product whenever it appears either that ''a pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.'' 7 U.S.C. 136d(b). As noted in the NOIC, EPA concluded that those conditions for cancellation are met here. The registrations subject to the NOIC have not changed since the issuance of the NOIC, so EPA continues to believe that the conditions for cancellation are met. EPA therefore declines to withdraw or stay the NOIC consistent with your letter.

Per FIFRA section 6(b) and as noted in the NOIC, the cancellation proposed in the NOIC shall become final 30 days after publication of the NOIC, or the date the registrant receives the NOIC, whichever is later, unless the registrant makes the necessary corrections to the registrations, or a hearing is requested by a person adversely affected by the NOIC. The deadline for submitting corrections or a hearing request is Friday, January 13, 2023. Unless one of those submissions occurs by that date, the cancellation proposed in the NOIC will become final as of Friday, January 13, 2023.[3]

Sincerely,

MICHAEL GOODIS Digitally signed by MICHAEL GOODIS Date: 2023.01.11 14:16:18 -05'00'

Ed Messina
Director, Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
United States Environmental Protection Agency

Cc: Kimberly Nesci
Director, Office of Pest Management Policy
United States Department of Agriculture

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[3] 87 Fed. Reg. 76,474 at 76,480-81 (Dec. 14, 2022).

EXHIBIT 10

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

Petition for Review of Actions of the U.S. Environmental Protection Agency

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BRIEF OF RESPONDENTS

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GLOSSARY

APA	Administrative Procedure Act
EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

INTRODUCTION

Congress tasked EPA with establishing "tolerances," which allow maximum levels of pesticide residues in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. Under the FFDCA, EPA may establish or leave in place a tolerance for a pesticide *only* if it determines that the tolerance is "safe," and must revoke or modify an existing tolerance if EPA determines that the tolerance is not "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. "Safe" means a "reasonable certainty that no harm will result from aggregate exposure," including all anticipated dietary exposures. *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. The FFDCA's safety standard is strictly safety-based: EPA may not consider any other factors, such as economic costs or benefits, in determining whether tolerances are safe, and whether tolerances are "safe" is the exclusive basis for revoking, modifying, or setting tolerances.

In 2007, public interest groups petitioned EPA to revoke all chlorpyrifos tolerances based on neurodevelopmental impacts to infants and children, among other things. After years of administrative process and court rulings in response to the petition, the U.S. Court of Appeals for the Ninth Circuit concluded in 2021 that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 700–01 (9th Cir.

2021) (*"LULAC II"*). The Ninth Circuit chided EPA for "expos[ing] a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 702. The Court ordered EPA to, within 60 days, revoke all chlorpyrifos unless EPA could find by that time, based on the evidence regarding aggregate exposure to chlorpyrifos, that modified tolerances would be safe. *Id.* at 703.

On August 30, 2021, EPA promulgated a final rule revoking all chlorpyrifos tolerances. Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315 (Aug. 30, 2021) ("Final Rule"), AR 1, Pet'rs' Add. 1; *see also* Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222 (Feb. 28, 2022) ("Denial Order"), Pet'rs' Add. at 23. EPA determined that it could not make the safety finding necessary to leave in place the current tolerances for residues of chlorpyrifos because the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Specifically, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. In addition, there are laboratory studies and epidemiological data studying chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* Adhering to the

FFDCA's strict safety standard and the Ninth Circuit's mandate, EPA revoked all chlorpyrifos tolerances. AR 1 at 48316, Pet'rs' Add. at 2. Petitioners now ask this Court to do what both Congress and the Ninth Circuit forbade: leave *all* chlorpyrifos tolerances in place, even though the expert agency has concluded that they are not safe.

STATEMENT OF JURISDICTION

Petitioners have filed three petitions for review regarding EPA's revocation of chlorpyrifos tolerances. The Court dismissed Petitioners' first petition for lack of jurisdiction. *Red River Valley Sugarbeet Growers Ass'n v. Regan,* No. 22-1294, Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661. The Court has jurisdiction over the consolidated second and third petitions challenging EPA's Final Rule and Denial Order under FFDCA Section 408(h)(1). 21 U.S.C. § 346a(h)(1), Resp'ts' Add. at 12.

STATEMENT REGARDING ORAL ARGUMENT

Respondents agree with Petitioners that oral argument is appropriate and would be helpful to the Court. This case involves the application of important provisions of the FFDCA administered by EPA.

STATEMENT OF THE ISSUE

The Ninth Circuit ordered EPA to "immediately" revoke all chlorpyrifos tolerances unless the Agency could find, based on evidence available at that time, that modified tolerances were reasonably certain to avert harm from aggregate exposure to chlorpyrifos. EPA revoked all tolerances after determining that it could not make that finding. Was EPA's determination non-arbitrary and consistent with the FFDCA's strict-safety standard?

STATEMENT OF THE CASE

A. Statutory and regulatory background

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, Resp'ts' Add. at 1, and FIFRA, 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, EPA establishes "tolerances," which are rules establishing the maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. As originally enacted, the FFDCA instructed EPA to set tolerances that are "safe for use, to the extent necessary to protect the public health" while giving appropriate consideration to "the necessity for production of an adequate, wholesome, and economical food supply" and "the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture." H.R. Rep. No. 104-669, pt. 2 at 40 (1996). With the passage of the

Food Quality Protection Act ("FQPA") in 1996, Congress replaced that standard with a pure safety standard. *See id.* As amended, the FFDCA permits EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). EPA "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* Thus, under current law, "FFDCA review is limited to the sole issue of safety" and "explicitly prohibit[s] the EPA from balancing safety against other considerations, including economic or policy concerns." *LULAC II,* 996 F.3d at 696.

"Safe" under the FFDCA means a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. Congress understood "aggregate exposure" to include "all dietary exposures." H.R. Rep. 104–669, pt. 2, at 40 (1996). In another provision of the FFDCA describing "aggregate exposure," Congress required EPA to consider "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue . . . , including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources." 21 U.S.C. § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5. Additionally, infants and children are given special consideration: EPA must assess the risk of the pesticide residues to infants and children utilizing a presumptive tenfold (10X) margin of safety for threshold effects (the "FQPA safety factor"), unless "reliable data" shows that a lower margin will be safe. 21 U.S.C. § 346a(b)(2)(C), Resp'ts' Add. at 4-5.

Under Section 408(*l*), EPA is to coordinate the revocation of a tolerance with any related necessary action under FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. While EPA may establish, modify, or revoke tolerances under the FFDCA, it cannot require changes to pesticide registrations (like geographic or application restrictions) under the FFDCA.

2. The Federal Insecticide, Fungicide, and Rodenticide Act

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

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years, starting in 2006. *Id.* § 136a(g)(1)(A). During "registration review," EPA assesses all pesticide product registrations containing an active ingredient and must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account new scientific information and changes to risk-assessment procedures, methods, and data requirements. 40 C.F.R. §§ 155.40(c)(1), 155.53(a); 7 U.S.C. § 136a(g). EPA may propose measures to mitigate identified risks, including label or registration changes, in a proposed decision or proposed interim decision. *See* 40 C.F.R. §§ 155.56, 155.58(a)-(b). EPA may issue a final interim decision. *See id.* § 155.56. In addition, or instead of, a final interim decision, EPA will issue a proposed final decision. *Id.* EPA must issue a final registration review decision to conclude registration review. *See id.*

FIFRA registrations function as product-specific licenses. *See* 7 U.S.C. § 136a(a), (c)-(e). Registrants may submit a request to modify a pesticide registration, including labeling, under FIFRA. *See* 40 C.F.R. § 152.44. Registrants may submit requests to voluntarily cancel their pesticide registrations or terminate certain registered uses under 7 U.S.C. § 136d(f), or EPA may initiate cancellation proceedings under § 136d(b). The procedures for voluntary and involuntary cancellation differ dramatically. If a registrant wishes to voluntarily cancel its registration or terminate a specific use, it may do so at any time by submitting a request to EPA, which following publication in the Federal Register for public comment, the Agency may approve or deny. 7 U.S.C. § 136d(f)(1). By contrast, if EPA initiates cancellation proceedings, it must first provide a draft Notice of Intent to Cancel to the Secretary of Agriculture and the FIFRA Scientific Advisory Panel at least 60 days before publishing the final Notice in the Federal Register. 7 U.S.C. §§ 136d(b), 136w(d).[1] Any person adversely affected by the notice may request a hearing before an Administrative Law Judge. 7 U.S.C. §§ 136d(b). The Administrative Law Judge's decision may be appealed to the Environmental Appeals Board. 40 C.F.R. § 164.101. Registrants and other interested persons may seek judicial review of a final cancellation order within 60 days. 7 U.S.C. § 136n(b).

B. Factual background

1. 2007 petition to revoke all tolerances

Chlorpyrifos is a broad-spectrum insecticide and miticide registered for use on over 50 different food crops as well as in non-food settings, including turf. AR 40 at 11. In the 2006 Reregistration Eligibility Determination for chlorpyrifos,

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[1] EPA may also issue a notice of intent to hold a hearing on cancellation instead of publishing a Notice of Intent to Cancel. 7 U.S.C. § 136d(b).

EPA determined that chlorpyrifos tolerances were safe.[2] AR 33, Resp'ts' App. at 80.

In 2007, the Pesticide Action Network North America ("PANNA") and the Natural Resources Defense Council ("NRDC") filed a Petition to Revoke all Tolerances and Cancel All Registrations for Chlorpyrifos under 21 U.S.C. § 346a(d)(1)(A) (the "2007 Petition to Revoke"). AR 1 at 48318, Pet'rs' Add. at 4. Among other things, the petition argued that chlorpyrifos causes adverse neurodevelopmental effects in children. AR 1 at 48318–19, Pet'rs' Add. at 4-5. EPA believed that these neurodevelopmental claims raised important concerns and warranted further consideration in registration review, which EPA initiated in 2009. 87 Fed. Reg. at 11235, Pet'rs' Add. at 36. In the years that followed, EPA convened multiple meetings with the FIFRA Scientific Advisory Panel, and published multiple Human Health Risk Assessments, all of which analyzed these neurodevelopmental claims. AR 1 at 48320–22, Pet'rs' Add. at 6-8.

Dissatisfied with the pace of EPA's review, PANNA and NRDC filed a petition for mandamus in 2012, seeking an order requiring EPA to respond to the 2007 Petition to Revoke. The court denied the petition without prejudice, noting that EPA intended to issue a final response by February 2014. *In re Pesticide*

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[2] EPA issued decision documents called REDs for registered pesticides as part of the pesticide review program that predated registration review. *See* 7 U.S.C. 136a-1.

Action Network N. Am., 532 Fed. Appx. 649, 650–52 (9th Cir. 2013). After EPA failed to meet its self-imposed deadline, PANNA and NRDC filed a second petition. *In re Pesticide Action Network N. Am.*, 798 F.3d 809 (9th Cir. 2015). In that case, EPA told the court that due to its concerns about drinking water contamination, the Agency planned to issue a rule by April 2016 revoking all tolerances. *Id*. at 812–13. The Ninth Circuit granted the mandamus petition and directed EPA to issue, by October 31, 2015, either a proposed or final revocation rule or a full and final response to the 2007 Petition to Revoke. *Id*. at 811, 815. EPA published a rule proposing to revoke all tolerances. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (Nov. 6, 2015), Pet'rs' App. at 995. EPA's proposed revocation was based on a determination that drinking water concentrations of chlorpyrifos in some watersheds would exceed exposure levels that EPA considered "safe." *Id*. at 69083, Pet'rs' App. at 998.

The Ninth Circuit then ordered EPA to take final action on the proposed revocation rule by December 30, 2016. *In re Pesticide Action Network N. Am.*, 808 F.3d 402 (9th Cir. 2015). In 2016, EPA developed a revised Human Health Risk Assessment, which it released for public comment as additional support for the 2015 proposal.[3] To incorporate those additional comments, EPA sought a six-

[3] 2015 Proposed Rule. Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81049 (Nov. 17, 2016).

month extension of the December 30, 2016 deadline to issue a final response to the 2007 Petition to Revoke. *In re Pesticide Action Network N. Am.*, 840 F.3d 1014 (9th Cir. 2016). The court characterized EPA's request as "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action' that has been repeated for the past nine years." *Id.* at 1015 (quoting *In re Pesticide Action Network*, 798 F.3d at 811). The court ordered EPA to take final action by March 31, 2017. *Id*. Instead of finalizing the 2015 proposal, EPA subsequently denied the 2007 Petition to Revoke on the ground that the science concerning adverse neurodevelopmental effects remained uncertain and EPA would address those issues as part of its FIFRA registration review process. Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16581, 16583 (April 5, 2017).

Several states and organizations filed objections to this denial pursuant to FFDCA § 408(g), 21 U.S.C. § 346a(g), Resp'ts' Add. at 11-12. Many of them also sought relief in the Ninth Circuit without awaiting EPA's decision on their objections. *League of United Latin Am. Citizens v. Wheeler,* 899 F.3d 814 (9th Cir. 2018). A Ninth Circuit panel ordered EPA to revoke all chlorpyrifos tolerances. *Id*. at 829. On rehearing, the court vacated the panel's opinion and ordered EPA to issue a final order responding to the objections. *League of United Latin Am. Citizens v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc). EPA denied all objections in July 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555 (July 24, 2019). Petitions were filed challenging this denial order, which were referred to the same panel. *League of United Latin Am. Citizens v. Wheeler*, 940 F.3d 1126, 1127 (9th Cir. 2019).

2. EPA's 2020 Proposed Interim Registration Review Decision for Chlorpyrifos

Concurrent with its consideration of the petition under the FFDCA, EPA continued its FIFRA registration review. In December 2020, EPA released the Proposed Interim Registration Review Decision ("PID") for Chlorpyrifos pursuant to FIFRA. *See* AR 40, Pet'rs' App. at 366. The PID proposed to conclude that aggregate exposure (including exposures in food, drinking water, and residential settings) from all currently-registered uses of chlorpyrifos was unsafe. *Id.* at 19, Pet'rs' App. at 384. To reduce aggregate exposures to safe levels, under the FQPA's 10X safety factor, EPA proposed that uses of chlorpyrifos be limited to applications for eleven "high-benefit" uses in limited geographic areas: alfalfa, apple, asparagus, cherry (tart), citrus, cotton, peach, soybean, strawberry, sugar beet, wheat (spring and winter).[4] *Id.* at 40–41, Pet'rs' App. at 405–06. The proposal for retention of those uses also relied on application rate reductions

[4] These specific uses were identified as critical by a registrant or as high-benefit to growers by EPA. 87 Fed. Reg. at 11255, Pet'rs' Add. at 56.

consistent with rates that were assessed in EPA's 2020 drinking water assessment. *Id*. at 55-59, Pet'rs' App. at 420–24. In other words, EPA proposed that *if* use on those 11 crops was amended as indicated in the PID *and* all other uses were cancelled—both FIFRA actions—EPA could determine that the aggregate exposure to chlorpyrifos was safe and thus tolerances associated with those 11 specific uses could be left in place under the FFDCA.

As required under EPA's regulations, EPA solicited public comment on the PID. 40 C.F.R. § 155.58(a); AR 40 at 62, Pet'rs' App. at 427. Multiple groups submitted comments disagreeing with the subset of 11 uses EPA identified. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. Some commenters, including cranberry and banana growers, argued that their crops should also be retained; others, including advocacy and environmental groups, argued that a safety determination supporting even those limited 11 uses would contravene the available science. *Id.* at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not issued an interim or final registration review decision.

At the time of the issuance of the Final Rule, no chlorpyrifos registrant had submitted voluntary cancellation requests or applications for label amendments consistent with the proposed mitigation measures in the PID.

3. The Ninth Circuit's decision vacating EPA's denial of the petition

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the 2007 Petition and EPA's order denying related objections and concluded that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01 (listing six EPA and Scientific Advisory Panel assessments and notices from 2012 to 2016 that indicated that there is not a reasonable certainty of no harm under the FFDCA). Indeed, the Ninth Circuit found that since 2006, EPA had "consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of chlorpyrifos and for the susceptibility of the developing brain to chlorpyrifos." *Id.* at 697. The Ninth Circuit chided EPA for taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition," which was an "egregious delay [that] exposed a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 703. According to the Court, that EPA was in the midst of registration review under FIFRA did not justify the "total abdication of the EPA's statutory duty under the FFDCA," as registration review was "separate from [EPA's] continuous obligation to ensure safety under the FFDCA." *Id.* at 678, 691. The Ninth Circuit made clear that it was not remanding for further factfinding, as "further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." *Id.* at 702.

The Ninth Circuit instructed EPA to publish a final response to the 2007 Petition within 60 days after the issuance of its mandate, without notice and comment, "that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703 ("EPA's time is now up."). Regarding modification, the Ninth Circuit stated that "[i]f, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it *may* modify chlorpyrifos registrations rather than cancelling them." *Id.* (emphasis added). The Ninth Circuit also directed EPA to modify or cancel related FIFRA registrations "in a timely fashion." *Id.* at 704.

4. EPA's attempt to negotiate voluntary cancellations with Petitioner Gharda and other registrants

Shortly after the issuance of the Ninth Circuit's decision in *LULAC II*, EPA entered into good-faith negotiations with each of the technical registrants, including Gharda, regarding the voluntary cancellation of chlorpyrifos registrations.[5] None of the technical registrants, however, ultimately submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. Indeed, instead of proceeding quickly given the Ninth Circuit's 60-day deadline, Gharda repeatedly sought unreasonable cancellation terms:

- On May 12, 2021, Gharda stated that it was "willing to negotiate and execute an agreement with EPA" that contained nine separate terms, including allowing continued uses on several crops not listed in the PID; phasing out the production, sale, and distribution of chlorpyrifos products for certain uses through 2026; and retaining all import tolerances. Redacted Decl. of Ram Seethapathi, Ex. B, at 1–2, (Doc. ID 5133345 at 28-29), Pet'rs' App. at 1739-40.
- On June 7, 2021, Gharda committed to voluntarily cancel all currently approved agricultural uses except the subset of 11 uses identified in the PID if EPA agreed to nine other terms, including allowing: (1) use of chlorpyrifos on cotton in Texas (which was not proposed in the PID); (2) Gharda to import all finished technical product from Gharda's foreign warehouse for processing and sale in the United

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

States for all currently registered uses; and (3) Gharda to process and sell product in its possession for all currently registered uses. *Id.,* Ex. C at 1–2, Pet'rs' App. at 1743–44. Gharda also stated that it would reserve the right to withdraw from voluntarily cancelling uses in the event that the U.S. Supreme Court granted certiorari in *LULAC II*. *Id.* at 2.[6]

- On June 25, 2021, Gharda proposed new terms, including retention of nine of the 11 uses outlined in the PID; the formulation, distribution and sale of end-use products until December 31, 2022; the use of existing stocks until December 31, 2023; the use of aerial application through December 31, 2023; and retention of all import tolerances. Seethapathi Ex. G, at 1–2 (Doc. ID 513345 at 45–46), Pet'rs' App. at 1756–57. Gharda noted that "[t]erms will be set forth in a separate, written agreement" and that the company "reserves the right to withdraw from the written agreement in the event that the U.S. Supreme Court grants certiorari in the *LULAC II* case." *Id.* at 2, Pet'rs' App. at 1757.

- On July 6, 2021, Gharda stated that it was "willing to accept" the voluntary cancellation of certain uses, such as strawberry, asparagus,

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[6] No petition for certiorari was ultimately filed for *LULAC II*.

> cherry (tart) and cotton, that had been proposed for retention in the PID, if, "in return," EPA agreed to allow the formulation and distribution for all current uses through June 2022 and the use of existing stocks through June 2023, instead of EPA's proposals of February and August 2022. *Id.,* Ex. H, at 2 (Doc. ID 513345 at 51), Pet'rs' App. at 1762.

EPA did not agree to these conditions since they would not have adequately addressed the FFDCA requirement not to leave in place tolerances that are unsafe and due to concerns that such an extended existing stocks period would have been inconsistent with *LULAC II*. 87 Fed. Reg. at 11248, Pet'rs' Add. at 48. Ultimately, neither Gharda nor any of the other chlorpyrifos registrants submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

5. EPA's revocation rule

On August 30, 2021, EPA published a Final Rule revoking all tolerances for chlorpyrifos. AR 1, Pet'rs' Add. 1. Given the immediate deadline from the Ninth Circuit, and lack of an agreement on any new label terms or use deletions, EPA relied on its previously conducted aggregate assessments of chlorpyrifos, which covered all registered uses and included extensive information about the potential impacts of chlorpyrifos.

More specifically, chlorpyrifos inhibits acetylcholinesterase ("AChE"), an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. Thus, exposure to chlorpyrifos can lead to neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. *Id.* There is also an extensive body of information (epidemiological, mechanistic, and laboratory animal studies) studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children (including cognitive, anxiety and emotion, social interactions, and neuromotor functions), although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38.

EPA's decision relied on the effect of AChE inhibition for assessing risks from chlorpyrifos and retained the default FQPA 10X safety factor to account for scientific uncertainties around the potential for adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11237, Pet'rs' Add. at 38. Taking into account the available data and literature and the currently registered uses of chlorpyrifos, EPA determined that it could not make the safety finding to support leaving in place current tolerances. AR 1 at 48317, Pet'rs' Add. at 3. The

Agency's analysis indicated that although exposures from food alone did not exceed safe levels, EPA concluded that aggregate exposures from food, drinking water, and residential settings due to currently registered uses exceeded safe levels. 87 Fed. Reg. at 11237–38, Pet'rs' Add. at 38–39. Because EPA could not conclude that aggregate exposure to chlorpyrifos residues was safe, the Agency revoked all chlorpyrifos tolerances as required under FFDCA section 408(b)(2). *Id.* at 11238, Pet'rs' Add. at 39; *see also* AR 1 at 48334, Pet'rs' Add. at 20 ("EPA has determined that the current U.S. tolerances for chlorpyrifos are not safe and must be revoked.").

To ease the transition away from chlorpyrifos for growers and to accommodate international trade considerations, EPA allowed the tolerances to remain in place for six months following publication of the Final Rule, setting an expiration date of February 28, 2022, for the tolerances. AR 1 at 48334, Pet'rs' Add. at 20, 87 Fed. Reg. 11238, Pet'rs' Add. at 39.

On February 28, 2022, EPA published its Denial Order objecting to the Final Rule, requests for hearing on those objections, and requests to stay the Final Rule, 87 Fed. Reg. 11222, Pet'rs' Add. at 23, which reaffirmed EPA's conclusions in the Final Rule for revoking the chlorpyrifos tolerances.

6. The petition for review

On February 9, 2022, Petitioners filed a petition for review challenging the Final Rule. *Red River Valley Sugarbeet Growers Ass'n v. Regan*, No. 22-1294, Doc. ID 5126162. The next day, Petitioners moved to stay the February 28, 2022, expiration date in the Final Rule. Doc. ID 5126280. On February 18, 2022, EPA moved to dismiss that petition for lack of jurisdiction because EPA had not yet issued a final order denying objections to the Final Rule. Doc. ID 5129068, Pet'rs' App. at 1285.

On February 28, 2022, Petitioners filed a second petition for review challenging both the Final Rule and the Denial Order, and renewed their stay motion. Doc. IDs 5131400, 5132688 (No. 22-1422). On March 14, 2022, Petitioners filed a third petition for review of the Final Rule and the Denial Order. Doc. ID 5136561 (No. 22-1530), Pet'rs' App. at 1816.

On March 15, 2022, the Court denied Petitioners' stay motion and exercised jurisdiction over the second petition. Doc. ID 5136844. The following day, the Court dismissed the first petition for lack of jurisdiction. Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661, Pet'rs' App. at 1914.

7. Cancellation status of chlorpyrifos registrations under FIFRA

On April 28, 2022, EPA published in the Federal Register requests to voluntarily cancel 16 different chlorpyrifos registrations. Requests to Voluntarily Cancel Certain Pesticide Registrations, 87 Fed. Reg. 25256, 25257–58 (Apr. 28, 2022). EPA plans to initiate involuntary cancellation proceedings for every chlorpyrifos registration for which it has not received a voluntary cancellation request.

SUMMARY OF ARGUMENT

As required under the FFDCA, in determining whether chlorpyrifos tolerances could be left in place, EPA considered "aggregate exposure . . . , including *all* anticipated dietary exposures and other exposures" of chlorpyrifos based on existing registered (*i.e.,* legally permitted) uses. 21 U.S.C. §346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added). That assessment showed that the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Accordingly, EPA revoked all chlorpyrifos tolerances. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; AR 1 at 48316, Pet'rs' Add. at 2.

The ultimate relief sought by Petitioners in this case is the retention of *all* chlorpyrifos tolerances. But Petitioners' actual legal argument is more limited.

Specifically, they argue that EPA should not have assessed safety with respect to aggregate exposures, but was required to retain a specific geographically-limited subset of 11 uses that EPA proposed for retention in the PID and purportedly determined are safe. Petitioners' argument lacks merit for five reasons.

First, no one disputes that EPA must revoke or modify a tolerance that is not safe. Regarding chlorpyrifos, EPA concluded that exposure can lead to neurotoxicity and that there is an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11231, 11237, Pet'rs' Add. at 32, 38. Based on these and other findings, EPA reasonably concluded that aggregate exposure to chlorpyrifos exceeded safe levels and revoked all tolerances. *Id.* at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3.

Second, contrary to Petitioners' claim, the PID was not "final." The PID was a *proposed* determination as part of registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's proposed scientific assessment that a particular subset of 11 high-benefit uses would not pose potential risks of concern, using the 10X safety factor, if certain mitigation was adopted, including geographic and application restrictions. AR 40 at 40, Pet'rs' App. at 405. The proposed nature of the PID means that EPA's safety determination (and the subset of uses to be retained) might be adjusted or revised. EPA requested public comment on the PID, and some commenters disagreed with the retention of those 11 uses, while others advocated for a different combination of uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA could not fully consider those comments and reach a definitive conclusion in the timeframe the Ninth Circuit provided EPA to act under the FFDCA, and it has not yet issued an interim or final registration review decision.

Third, contrary to Petitioners' claim, the FFDCA does not require EPA to undertake a tolerance-by-tolerance analysis generally, nor is that analysis prudent in situations like this, where aggregate risk is not safe. EPA's consideration of all tolerances for a specific pesticide is consistent with the FFDCA's mandate (and the Ninth Circuit's edict) to assess "aggregate" exposure, as well as longstanding EPA policy. Moreover, Petitioners do not explain how, from a practical perspective, EPA could actually carry out a tolerance-by-tolerance approach in this case in a manner consistent with that mandate.

Fourth, EPA's consideration of all currently-registered uses, instead of only the 11 uses proposed in the PID, was entirely reasonable under the FFDCA's direction to consider "all anticipated dietary exposures." The FFDCA requires EPA to determine whether tolerances *are* safe. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. It does not allow EPA to leave tolerances in place if they *might* be safe *if* the suite of mitigation measures proposed under FIFRA might be implemented at some indeterminate time in the future. At the time of the Final Rule, no concrete steps under FIFRA had been taken by registrants that would have altered the universe of uses EPA needed to assess: EPA had received no cancellation requests or applications to amend labels to geographically limit uses or limit applications consistent with the mitigation proposed in the PID. The proposed mitigation measures in the PID are not self-executing, and without efforts to make changes to the registrations, they do not, by themselves, support an assumption that aggregate exposures would be limited to that subset of uses. Nor would the revocation of tolerances associated with uses other than the subset of 11 alone have supported a safety determination without the necessary geographic and application restrictions occurring on those 11 uses, which would need to occur under FIFRA. Thus, EPA's consideration of all existing chlorpyrifos registrations in its assessment of "anticipated" exposures was reasonable.

Fifth, EPA was not required to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. Petitioners point to the FFDCA's direction that "[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocation of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704. Given the length of time an involuntary cancellation proceeding can take, Petitioners' view could force EPA to leave in effect pesticide tolerances it had found unsafe long after making that finding, contrary to the FFDCA.

Ultimately, EPA reasonably considered aggregate exposure from all anticipated sources based on all currently registered uses in determining that the continued use of chlorpyrifos did not meet the FFDCA's strict safety standard, and that all tolerances therefore must be revoked.

STANDARD OF REVIEW

The APA provides the standard of review for this case. *See* 5 U.S.C. § 706. Under this standard of review, EPA's Final Rule and Denial Order can be overturned only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A)). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). That standard requires the court to "affirm the EPA's rules if the agency has considered the relevant factors and articulated a 'rational connection between the facts found and the choice made.'" *Allied Local and Reg'l Mfrs. Caucus v. EPA,* 215 F.3d 61, 68 (D.C. Cir. 2000) (quoting *Motor Vehicles Mfrs. Ass'n,* 463 U.S. at 43).

ARGUMENT

I. EPA reasonably revoked chlorpyrifos tolerances based on its determination that those tolerances were not safe.

There is no dispute that the statutory criteria for leaving a tolerance in place or revoking a tolerance is whether the residue is "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; *see also LULAC II*, 996 F.3d at 696 (amendments to the FFDCA "explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns."). If EPA cannot conclude that a tolerance is safe, it "shall" revoke or modify it. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.

EPA's scientific analysis of chlorpyrifos is complicated, but its conclusion is not: "Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71. Because EPA concluded that aggregate exposure to chlorpyrifos residues from all registered uses was not safe, it revoked all chlorpyrifos tolerances. *Id.* As noted above, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. *Id.* Moreover, there is also an extensive body of information studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children, although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38. Although EPA did not identify risks of concern based on exposure to residues of chlorpyrifos in food alone, it concluded, consistent with the FFDCA, that aggregate exposure to residues of chlorpyrifos in food, drinking water, and residential settings from currently registered uses exceeded safe levels. *Id.* at 11237–38, Pet'rs' Add. at 38-39.

Petitioners' claim that "the sole dietary exposure source of concern . . . is drinking water" is a red herring. Pet'rs' Br. at 39. It does not matter what the "sole" or "primary" source of exposure is that drives risk concerns. The FFDCA directs EPA to consider "aggregate" exposure in making a safety determination. If aggregate exposure—taking all the relevant sources of exposure together—is not safe, then EPA cannot find that the tolerances are safe.

Amicus curiae State of Missouri's claim that, contrary to the statute, EPA "failed to make any finding—either that the tolerances for any food were unsafe or safe" similarly misreads the Final Rule, as well as the statute. *See* Missouri Br. at 5, 7-8. First, EPA did conclude that chlorpyrifos tolerances were not safe. AR 1 at 48317, Pet'rs' Add. at 3 ("[T]he Agency's analysis indicates that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels. . . "). Second, the FFDCA permits EPA to "leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). Put differently, EPA is required to revoke or modify any tolerance for which it cannot make a safety finding. *LULAC II,* 996 F.3d at 694.

Petitioners and *amicus curiae* State of North Dakota attempt to undercut EPA's conclusions about adverse impacts to infants' and children's developing brains by arguing that, without chlorpyrifos, growers will experience "dramatic adverse reduction in its yield" and "crippling economic losses" that "will ultimately be felt by U.S. consumers." Pet'rs' Br. at 15-16; N. Dakota Br. at 19; *see also* Missouri Br. at 10 ("EPA has forced a disruptive change that endangers agricultural yields that are critical to Missouri's economy.") Those arguments conflate two *different* statutory standards, attempting to import FIFRA's "unreasonable adverse effects" standard—which considers economic and social costs and benefits—into the FFDCA's strict safety standard. The FFDCA, however, imposes "an uncompromisable limitation: the pesticide must be determined to be safe for human beings." *LULAC II*, 996 F.3d at 678; *see* 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.[7]

Similarly without merit are Petitioners' and North Dakota's claims that the Final Rule and Denial Order failed to sufficiently account for their reliance interests in the continued use of chlorpyrifos. North Dakota purports to have "reasonably relied on" EPA's safety finding in the 2006 Reregistration Eligibility Determination for chlorpyrifos. N. Dakota Br. at 12–13; AR 33, Resp'ts' App. at 80. But the Ninth Circuit concluded in 2021 that, based on subsequent evidence before the Agency, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01. And in fact, since 2006, EPA's extensive scientific analyses of chlorpyrifos provided North Dakota with ample notice that EPA's 2006 safety finding could change. Moreover, the Ninth Circuit's mandate to revoke all tolerances unless the Agency could make a safety finding supporting modification left no room for EPA to consider reliance reasons, even absent such a safety

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[7] Petitioners and North Dakota rely in large part upon materials from outside of the administrative record for their economic arguments. These extra-record materials are not properly before the Court. *See Newton Cty. Wildlife Ass'n. v. Rogers,* 141 F.3d 803, 807 (8th Cir. 1998) ("APA review of agency action is normally confined to the agency's administrative record."); *CTS Corp. v. E.P.A.,* 759 F.3d 52, 64 (D.C. Cir. 2014) ("[A] reviewing court [in an APA case] should have before it neither more nor less information than did the agency when it made its decision.") (internal quotations and citations omitted).

finding. *Cf. Brachtel v. Apfel,* 132 F.3d 417, 419–20 (8th Cir. 1997) (applying law-of-the-case doctrine to administrative agencies on remand). Accordingly, North Dakota's purported reliance on the 2006 RED was unreasonable.

Petitioners' purported reliance on the 2020 PID was also unreasonable. Petitioners argue that *Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) and *Encino Motorcars, LLC v. Navarro,* 136 S. Ct. 2117, 2126 (2016) impose a more demanding requirement for justifying an action that deviates from a prior policy. Pet'rs' Br. at 61; *see also* CropLife Br. at 15–16. But both cases specifically addressed changes from "longstanding policies" that may have "engendered serious reliance interests that must be taken into account." *Encino Motorcars,* 136 S. Ct. at 2126 (quoting *F.C.C. v. Fox TV Stns., Inc.,* 129 S. Ct. 1800, 1811); *Dep't of Homeland Sec.,* 140 S. Ct. at 1913. That is not the case here. First, the PID was a *proposed* determination—not an Agency policy—signed only nine months before the Final Rule was published and heavily caveated. 40 C.F.R. § 155.58(b)(1) (the PID contained "proposed findings"); *compare* AR 40 (signed Dec. 3, 2020), Pet'rs' App. at 366, with Final Rule (published Aug. 30, 2021), Pet'rs' Add. at 1. Second, the Ninth Circuit's April 29, 2021 decision in *LULAC II* explicitly contemplated that EPA would, absent a safety finding, revoke all chlorpyrifos tolerances in response to that decision. 996 F.3d at 703.

Accordingly, any reliance by Petitioners on the PID was unreasonable, not to mention irrelevant to the Agency's safety analysis under the FFDCA.

In sum, consistent with the FFDCA's strict safety standard, EPA reasonably and properly revoked all chlorpyrifos tolerances when it found that aggregate exposure to chlorpyrifos was unsafe.

II. The PID was not final, and neither EPA nor Gharda treated it as such.

Petitioners claim that EPA "unquestionably believed that its scientific findings concerning tolerances [in the PID] were final and actionable." Pet'rs' Br. at 59. But that assertion is contradicted by the plain language of the PID itself, FIFRA regulations regarding registration review, and the APA.

The PID was a *proposed* determination as part of a registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's scientific assessment that, based on the evidence available at the time, a subset of 11 high-benefit uses with geographic and application rate restrictions would not pose potential risks of concern with the 10X safety factor, *if* other uses contributing to aggregate exposures were cancelled. AR 40 at 40. Accordingly, EPA determined that those 11 uses "may be considered for retention." *Id.*

The proposed nature of the PID means that EPA's safety determination might be adjusted or revised. EPA requested public comment on the PID, and some commenters, including cranberry and banana growers, argued that their crops should be retained as well. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. Others, including advocacy and environmental groups, argued that a safety determination supporting even those 11 uses would contravene the available science. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not fully considered these comments and has not yet issued a final interim decision. Petitioners' contention (at 55–61) that the PID nevertheless was final disregards that the APA and FIFRA regulations require that EPA address those comments. *See* 5 U.S.C. 553(c); 40 C.F.R. § 155.58(c); *U.S. Satellite Broad. Co., Inc. v. FCC,* 740 F.2d 1177, 1188 (D.C. Cir. 1984) (Agency must respond "in a reasoned manner to significant comments received."). FIFRA regulations also contemplate that there may be changes to the mitigation measures in a proposed interim decision, which the Agency is required to explain. 40 C.F.R. § 155.58(c). As a practical matter, mitigation measures in a proposed interim decision are often modified in the final interim decision, which establishes the legally-required mitigation and label changes. For example, the Interim Registration Review Decision for oxadiazon strengthened certain mitigation measures from the proposed interim decision, including requiring thorough post-application irrigation to mitigate post-application risks of concern and designating oxadiazon as a Restricted Use Pesticide. Oxadiazon: Interim Registration Review Decision Case

Number 2485, EPA Docket No. EPA-HQ-OPP-2014-0782 (Mar. 31, 2022) at 6, Resp'ts' App. at 626.

Petitioners claim that the PID was labeled a "proposal" solely because EPA needed to complete its Endangered Species Act analysis and endocrine screening for registration review. Pet'rs' Br. at 58. Petitioners are wrong. First, EPA's regulations require EPA to publish a proposed registration review decision for every registration review case for at least 60 days of public comment. 40 C.F.R. § 155.58(a). As explained above, EPA was required to consider comments submitted on the PID, including comments on the proposed subset of 11 uses. Second, as EPA explained in the PID, the Agency still needed to consider the forthcoming 2020 FIFRA Scientific Advisory Panel's latest recommendations, which could impact the human health risk assessment and the proposed mitigation measures. AR 40 at 10, 40 ("EPA's conclusions about risk, and thus proposed mitigation measures, may be revised.").

Nor did the Ninth Circuit treat the PID as final. Recognizing EPA's proposal in the PID for modifying certain tolerances and the intervening Scientific Advisory Panel, the Ninth Circuit noted that "*[i]f*, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." *LULAC II*, 996 F.3d at 703 (emphasis added).

Petitioners' claim (at 61) that "[a]t all times, Gharda understood that the Safe Uses would be retained" is contradicted by the record of negotiations between EPA and Gharda. At one point, Gharda asked EPA to retain cotton use in Texas (even though it was not proposed for retention in the PID), while later Gharda was willing to eliminate four uses—strawberry, asparagus, cherry (tart) and cotton—that had been proposed for retention in the PID. Seethapathi Ex. H, at 2; (Doc. ID 5133345 at 51), Pet'rs' App. at 1762; *see also* Ex. G, at 1; (Doc. ID 5133345 at 45), Pet'rs' App. at 1756.

Accordingly, the PID did not represent EPA's final position on which uses, if any, could be retained for chlorpyrifos. But ultimately that question is not the deciding one here. The PID's proposed continuation of a limited subset of chlorpyrifos uses was conditioned on the cancellation of all other uses under FIFRA and the implementation of new geographic and application restrictions. AR 40 at 40, 55. At the time of the Final Rule, EPA had not received a single voluntary cancellation request or label amendment from any of the chlorpyrifos registrants, and, as discussed *infra* at 54, FIFRA does not provide EPA with another way to quickly cancel or modify existing registrations. With the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision based upon an assessment of the science and facts that actually existed. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49.

In sum, the PID was not final, and neither EPA nor Gharda treated it as such. And, even if it were final, because EPA had not received any voluntary cancellation requests or label amendments at the time of the Final Rule, it reasonably made a decision based on its scientific assessment of the registrations that actually existed.

III. EPA reasonably assessed "aggregate" exposure under the FFDCA.

Petitioners argue that the Final Rule and Final Order were arbitrary and capricious because EPA did not utilize a "tolerance-by-tolerance approach." *See* Pet'rs' Br. at 43–46. Petitioners are wrong. EPA's consideration of all tolerances together is consistent with the FFDCA's mandate to assess "aggregate" exposure, as well as longstanding EPA practice. While tolerances may be established or modified individually, the assessment of exposures required to support such actions necessarily includes exposures from all tolerances and other drinking water and residential exposures from registered uses of the pesticide, and this is especially true in the case of a decision to "leave" tolerances "in place." *See supra* at 5 (describing the aggregate exposure assessment required by the FFDCA).

A. EPA's approach is consistent with the text of the FFDCA.

Petitioners and CropLife argue that the plain text of the FFDCA commands an individual tolerance-by-tolerance approach. Pet'rs' Br. at 43–47; CropLife Br. at 15–16. As an initial matter, they have waived this statutory argument because they did not raise it in their objections to the Final Rule. *See Friends of the Norbeck v. U.S. Forest Serv.,* 661 F.3d 969, 974 (8th Cir. 2011). Petitioners and CropLife also fail to explain what, in their view, such an approach would entail. Most importantly, they ignore that the FFDCA explicitly directs EPA to assess "*aggregate* exposure to the pesticide chemical residue" based on "*all* anticipated dietary exposures and *all* other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added); *see also id.* at § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5 (requiring EPA to consider when leaving in effect or revoking a tolerance, "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue*, and exposure from other non-occupational sources.") (emphasis added). Congress's use of the word "aggregate" and the plural for both "all anticipated dietary exposure***s***" and "all other exposure***s***" plainly indicates that something more than any one tolerance for a specific pesticide is to be considered at a time. For this reason, EPA's standard practice is to assess all exposures from all tolerances for a specific pesticide chemical (as well as from drinking water and residential uses) whenever making a safety determination for any given pesticide. AR 16 at 25, Resp'ts' App. at 26.

Nowhere does the FFDCA instruct EPA to employ a tolerance-by-tolerance approach. Petitioners nevertheless argue, without explanation, that the statute's use of "*a* tolerance" instead of "*the* tolerances" mandates such an approach. *See* Pet'rs' Br. at 44; *but cf.* 1 U.S.C. § 1 ("unless the context indicates otherwise—words importing the singular include and apply to several persons, parties or things."). But the use of singular versus plural in this case is irrelevant, as the statute mandates EPA to assess aggregate exposure. *See* 21 U.S.C. §§ 346a(b)(2)(A)(ii), (D)(vi), Resp'ts' Add. at 2-3, 5. Accordingly, the safety finding for any particular tolerance would be the same as for all tolerances together—either way, EPA is required to assess the aggregate exposure caused by *all* tolerances. *See* Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59608, 59675 (Nov. 18, 2009) ("The consequence of this requirement [to consider aggregate exposures] is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels.")

Petitioners also argue that the FFDCA's provision for modifying a tolerance if it is not safe further supports their argument that the text of the FFDCA requires an individual tolerance-by-tolerance approach. Pet'rs' Br. at 45. Specifically, they argue that because the statute provides that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," 21 U.S.C. § 346a(b)(1), Resp'ts' Add. at 2, the term "modify" can only mean "to narrow permissible uses." Pet'rs' Br. at 45. Thus, Petitioners argue, "EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe." *Id.* at 45–46. This, too, misses the mark.

Just because EPA has the authority to lower or revoke tolerances to reduce the number of approved uses for a pesticide does not mean that the FFDCA compels the Agency to do so, nor does the statute automatically provide the Agency with all of the necessary criteria or tools.[8] Instead, this record needs to be developed and evaluated by EPA in the context of each relevant action. As discussed above, at the judicially-mandated time for EPA's decision here, the Agency lacked an appropriate record basis to make such a decision. Finally, if EPA were to revoke certain tolerances and leave others in place consistent with the PID, EPA would still need to find that the tolerances left in place were safe, which EPA could not do in this case because no changes had been made to (nor had

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[8] The term "modify" can also mean to lower a tolerance level. *See, e.g.,* MCPA; Pesticide Tolerances, 86 Fed. Reg. 71152 (Dec. 15, 2021) (reducing MCPA tolerances for clover commodities).

applications been submitted for) the underlying registrations to incorporate the PID's geographic, rate and application restrictions at the time of the Final Rule.

Petitioners do not explain, from a practical perspective, how EPA could conduct, for a pesticide with multiple tolerances, a tolerance-by-tolerance analysis in a manner consistent with the FFDCA's requirement to assess aggregate exposure. With regard to chlorpyrifos, the PID proposed a subset of uses that could fit within the "risk cup,"[9] subject to geographic, rate and application method restrictions, as part of the FIFRA registration review process. But there were likely other possible combinations of uses and restrictions that could have resulted in safe levels of aggregate exposure. 87 Fed. Reg. at 11245, Pet'rs' Add. at 46. EPA specifically noted in its 2020 Drinking Water Assessment that the analysis focused solely on the limited subset of 11 crops to assess whether there were any areas where the estimated drinking water concentrations would not exceed EPA's safe levels of exposures; it did not evaluate every possible combination of uses and restrictions to assess whether a different subset could also result in safe aggregate exposures. *Id.* EPA's 2016 Refined Drinking Water Assessment had already shown that estimated concentrations of chlorpyrifos in drinking water from all uses

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[9] The "risk cup" is the total exposure allowed for a pesticide considering its toxicity and required safety factors and is equal to the maximum safe exposure for the duration and population being considered. 87 Fed. Reg. at 11222, Pet'rs' Add. at 23.

would exceed levels of concern, *see* AR 37 at 124, Resp'ts' App. at 464; therefore, EPA's 2020 Drinking Water Assessment focused on whether aggregate exposures might be safe if only some uses were retained. Given the large number of registered chlorpyrifos uses, EPA focused its registration review resources on a subset of potentially higher-benefit uses. AR 38 at 8, Resp'ts' App. at 473.

Even if EPA had adopted the proposed subset of 11 uses from the PID in its tolerance action under the FFDCA, as Petitioners advocate, it is not clear that all stakeholders would agree that EPA had selected the appropriate combination of chlorpyrifos tolerances. For example, some commenters on the PID advocated that bananas and cranberry be included in the list of continued uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. And in its negotiations with EPA, Gharda proposed the retention of uses for corn, mint, and grapes. Seethapathi Ex. B at 2. (Doc. ID 5133345 at 29), Pet'rs' App. at 1740. Critically, the FFDCA, which does not permit the consideration of benefits in determining whether to leave a tolerance in place, provides no basis for EPA to unilaterally choose one tolerance over another where aggregate exposures for tolerances overall are unsafe.

FIFRA and the FFDCA are complementary but different statutes with separate requirements. As it did under FIFRA, EPA may propose in the PID (and specify in the Interim Decision) label modifications and product or use cancellations that are necessary in order for the product to meet FIFRA's unreasonable adverse effects standard. 40 C.F.R. § 155.56. Consistent with FIFRA, the proposed measures consider the benefits of those uses. AR 40 at 41–42. When registrants comply with EPA's requirements in an interim decision to voluntarily cancel registrations or amend pesticide product labels, then the pesticide, as assessed, is one step closer to meeting the FIFRA registration standard because the aspects found to cause unreasonable adverse effects no longer exist. *See*, *e.g.*, Oxadiazon: Interim Registration Review Decision Case Number 2485 (Mar. 31, 2022) at 70, Resp'ts' App. at 690 (finding that oxadiazon does not meet the FIFRA registration standard without the specified changes to the affected registrations and their labeling).

By contrast, in assessing the safety of a tolerance under the FFDCA, EPA is required to consider whether aggregate exposures from all anticipated dietary exposures and all other exposures *are* safe. *See* 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. When EPA finds that tolerances are not safe, EPA's sole option under the FFDCA is to modify or revoke tolerances; EPA cannot modify the underlying registrations. Any changes to underlying registrations to reduce aggregate exposures to safe levels occur under FIFRA, not under the FFDCA. *See* 40 C.F.R. § 152.44. Since that is not what happened here, *see supra* at 18, EPA could not base its FFDCA safety analysis on a potentially more limited universe of uses that did not actually exist yet in the real world. In sum, because the sole consideration under the FFDCA is safety, and safety requires consideration of aggregate exposures, the statute does not provide EPA with any basis upon which to choose which uses to retain. As the Ninth Circuit explained in *LULAC II*, although FIFRA review includes a safety assessment under the FFDCA, it also requires EPA to assess a pesticide's economic, social, and environmental costs and benefits, including impacts on agricultural production and food prices. 996 F.3d at 692–93. But "Congress's decision to give the EPA discretion to set FIFRA priorities does not translate to the FFDCA." *Id.* at 693. Thus, while EPA might be able to conclude that some uses contribute lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment, consideration of those relative benefits is not permitted under the FFDCA in determining whether a tolerance is safe.

B. EPA's approach in the Final Rule and Denial Order is consistent with Agency practice for assessing aggregate exposures when determining whether tolerances are safe.

Contrary to Petitioners' and CropLife's claims (at 44–45, 47 and 16–17), it has not been EPA's practice to conduct a tolerance-by-tolerance analysis along the lines suggested by Petitioners, particularly where the aggregate exposure level is unsafe. To the contrary, as EPA has previously explained, the FFDCA "does not compel EPA to determine the appropriate subset [of tolerances] that would meet the safety standard." Carbofuran Order, 74 Fed. Reg. at 59675[10]; *see also* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 Fed. Reg. 3421, 3423 (Jan. 19, 2011) (proposing to grant request to stay promulgation of sulfuryl fluoride tolerances because aggregate exposure was unsafe). Indeed, EPA's general practice when the Agency has determined that aggregate exposures are unsafe (making tolerances overall not safe) is not to independently select a subset of uses that meets the safety standard, but instead to engage in a public process that allows registrants and the public to indicate which of the various subsets of tolerances are of sufficient importance to warrant retention. 74 Fed. Reg. at 59675; *see also* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. EPA attempted to work in this way with Gharda and other chlorpyrifos registrants here, but ultimately was unable to reach an agreement with any registrant regarding voluntary cancellations and label amendments before the Ninth Circuit's 60-day deadline. *See supra* at 15–18.

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[10] The U.S. Court of Appeals for the D.C. Circuit denied the portion of a petition for review that challenged EPA's revocation of domestic carbofuran tolerances, but granted the portion challenging EPA's revocation of import tolerances for carbofuran. *Nat'l Corn Growers Ass'n v. EPA,* 613 F.3d 266 (D.C. Cir. 2010). There, EPA had concluded that carbofuran exposure from import tolerances alone would be safe. *Id.* at 275. EPA has made no such conclusion with regard to import tolerances for chlorpyrifos nor has EPA determined that the subset of 11 uses would be safe in the absence of changes to the registrations under FIFRA.

Despite EPA's consistency in addressing tolerances for which aggregate exposures are unsafe, Petitioners and CropLife claim that EPA's tolerance actions on flonicamid, tebuconazole, fludioxonil, and ethalfluralin show that "tolerances do not have to rise or fall together." *See* Pet'rs' Br. at 46-47; CropLife Br. at 11–12. Petitioners and CropLife's examples miss the point, as the individual tolerances to which Petitioners and CropLife refer were not assessed in a vacuum; instead, EPA assessed all tolerances together as part of an aggregate exposure analysis in response to petitions requesting new tolerances. In EPA's tolerance actions for those pesticides, the Agency was able to increase or decrease existing tolerances and/or establish new tolerances because aggregate exposure levels—*i.e.,* exposures from the newly requested tolerance plus all existing tolerances and uses contributing to aggregate exposure—fit within the "risk cup."[11] Put differently, EPA could establish tolerances requested by those petitioners because aggregate exposure levels were safe. By contrast, EPA determined that aggregate exposure to chlorpyrifos was unsafe. Therefore, none of these examples contradicts EPA's position of not independently selecting the subset of uses that meets the safety standard, when, as is the case with chlorpyrifos, aggregate exposure levels are

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[11] Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30425 (May 19, 2022); Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60932 (Nov. 12, 2019); Fludioxonil; Pesticide Tolerances, 85 Fed. Reg. 51354 (Aug. 20, 2020); Ethalfluralin; Pesticide Tolerances, 85 Fed. Reg. 45336 (July 28, 2020).

unsafe. If anything, they support the general principle that EPA considers aggregate exposures when assessing whether tolerances are safe. *See* 21 U.S.C. § 346a(b)(2), Resp'ts' Add. at 2-3.

CropLife argues that "with the EPA's new policy of revoking all tolerances whenever the risk cup overflows—even though modification of tolerances would achieve a safe risk cup—registrants and other stakeholders would have no basis to rely on EPA's ability to negotiate and work with them to determine what specific subsets of uses warrant retention." CropLife Br. at 19. CropLife's characterization of EPA's course of action with regard to chlorpyrifos as a "new policy" is incorrect.

First, EPA had a tight timeframe to revoke or modify tolerances as a result of the Ninth Circuit's order, much of which Gharda spent repeatedly seeking unreasonable terms for cancellations and label amendments under FIFRA. Second, as explained above, EPA's actions regarding chlorpyrifos are fully consistent with longstanding Agency policy. Third, where changes to registrations need to occur under FIFRA for remaining tolerances to be found safe by a date certain, EPA cannot leave those tolerances in place when it has no reason to believe that those changes are imminent. Finally, EPA does attempt to work with registrants to cancel or modify registrations and labels in order to lower aggregate exposure where aggregate exposure exceeds the risk cup. For example, in the case of bifenthrin, registrants cancelled certain registrations and amended others to address residential application risks identified during registration review. *See* Bifenthrin; Pesticide Tolerances, 86 Fed. Reg. 68150, 68154 (Dec. 1, 2021); Product Cancellation Order for Certain Pesticide Registrations, 86 Fed. Reg. 38339 (July 20, 2021). These actions created sufficient room in the risk cup for EPA to establish tolerances for certain food uses. *See* 86 Fed. Reg. at 68151, 68154. The tolerance actions for bifenthrin also contradict Petitioners', CropLife's, and Missouri's claims that EPA's approach effectively reads the term "modify" out of the FFDCA. Pet'r's Br. at 46; CropLife Br. at 12-13, Missouri Br. at 9.

In sum, EPA's process for considering aggregate exposure was consistent with the FFDCA and past policy and practice and, therefore, reasonable.

IV. When assessing all "anticipated" exposures, EPA reasonably considered all currently registered uses of chlorpyrifos.

Petitioners argue (at 43) that by evaluating exposure from all registered chlorpyrifos uses, EPA essentially replaced the statute's use of the word "anticipated" with the word "existing." This argument misinterprets the FFDCA's mandate to assess *all anticipated exposures* in making EPA's safety determination. 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. In guidance developed after the FQPA amendments to the FFDCA, EPA established that "[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of *proposed* and *approved* uses for the pesticide,"[12] which are determined by use patterns on labels of the proposed and registered products. AR 16 at 44–45, Resp'ts' App. at 45-46 (emphasis added); *see, e.g.,* Fluoxastrobin; Pesticide Tolerances, 84 Fed. Reg. 38138, 38140 (Aug. 6, 2019) (considering petitioned-for tolerances and existing tolerances). Accordingly, EPA's consideration of all registered chlorpyrifos uses when determining which exposures are "anticipated" was consistent with the ordinary reading of the statute and long-standing Agency guidance and practice.

Citing EPA's tolerance action on benzobicyclon, Petitioners assert that EPA's consideration of registered uses for chlorpyrifos was not a consideration of "anticipated uses." *See* Pet'rs' Br. at 46–47 (citing Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60368 (Nov. 2, 2021)). Petitioners again misunderstand how EPA assesses tolerances and implements the aggregate exposure directive of the FFDCA. For benzobicyclon, EPA received a petition to increase one tolerance. In response, the Agency considered the "anticipated" aggregate exposures, which included exposures from uses already registered as well as what was anticipated from the new use if it was approved. 86 Fed. Reg. at 60370–71. This example is

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[12] The term "approved uses" refers to uses that have already been approved or registered by EPA, *see* 40 C.F.R. § 152.112; "proposed uses" refers to new uses for which an application has been submitted for registration. *See* 40 C.F.R. § 152.3 (definition of "new use" referring to "proposed use pattern").

consistent with EPA's chlorpyrifos action. The "anticipated exposures" for chlorpyrifos reasonably included exposures from registered uses because no registrant had submitted any label amendment applications to align uses with the Agency's proposal in the PID to potentially retain certain tolerances.

Critically, EPA cannot require changes to registered pesticides under the FFDCA. Changes such as application rate restrictions or geographical limitations can only be accomplished through amendments to the label approved under FIFRA, which EPA cannot do unilaterally. *See infra* at 54, n.13. When a tolerance for residues of a pesticide on a particular food is revoked, that pesticide may no longer be registered for use on that food. *See* 21 U.S.C. § 346a(a), Resp'ts' Add. at 1; 7 U.S.C. § 136(bb). However, for chlorpyrifos, it would not be as simple as revoking all but the 11 uses proposed for retention in the PID. Aside from the fact that it was not a final determination, EPA's proposal to find the 11 uses safe was also contingent on restrictions being made to the underlying labels under FIFRA, *i.e.*, restricting applications to specific geographic areas and ensuring that application rates reflected the usage rates assessed in EPA's 2020 Drinking Water Assessment. Without those labeling changes, the 11 uses EPA identified would not be consistent with the proposal in the PID. *See* 87 Fed. Reg. 11246, Pet'rs' Add. at 47 (explaining that tolerances are broadly applicable rules without geographic limitations, and in order to limit geographic use, associated

FIFRA labels would need to be amended). Put differently, EPA could not modify tolerances under the FFDCA in a way that would render those 11 proposed uses safe, because additional changes to associated labeling would still need to occur under FIFRA, and at the time of the Final Rule no applications for label revisions had been submitted or approved under FIFRA. Until the universe of chlorpyrifos uses reflected the subset proposed in the PID—or at least until EPA had a reasonable basis to believe that would happen—the Agency could not conclude that the subset of 11 geographically restricted uses proposed in the PID comprised the "anticipated" exposures under the FFDCA. *Id.*

Gharda's argument to the contrary portrays its negotiations with EPA as final and complete because it "had submitted to EPA a written commitment to conform its registration to EPA's safety finding." *See* Pet'rs' Br. at 52. Typically, a formal request for voluntary cancellation of registered uses includes a letter requesting cancellation of product or uses along with applications to amend relevant labels. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. EPA received neither from Gharda. *Id.* Even Gharda's final proposal to EPA stated only that it was "willing to accept" certain voluntary cancellations if, "in return," EPA agreed to extended terms for formulation, sale, distribution, and use of existing stocks. Seethapathi Decl. Ex. H, at 2, (Doc. ID 5133345 at 51), Pet'rs' App. at 1762.

Conditional proposals such as Gharda's do not provide EPA with a reasonable basis to conclude that uses will be cancelled and exposures reduced. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. Gharda defends its inaction by claiming that it was merely "standing by awaiting word from EPA on when to submit a formal voluntary cancellation request." Pet'rs' Br. at 53. But there was no need to wait: FIFRA permits any registrant to submit a voluntary cancellation request to EPA at any time. 7 U.S.C. § 136d(f)(1).

EPA also could not have completed involuntary cancellation proceedings prior to the Ninth Circuit's 60-day deadline. *See supra* at 8. Without cancellation and label amendment requests in hand from Gharda and the other chlorpyrifos registrants, or the ability to quickly complete involuntary cancellation proceedings, EPA lacked a reasonable basis for concluding that chlorpyrifos uses would be limited as proposed in the PID. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

Gharda is not without a remedy. Namely, it may petition to establish new chlorpyrifos tolerances, and EPA would be required to evaluate any such request. Instead, Petitioners ask this Court to restore *all unsafe* chlorpyrifos tolerances (by vacating EPA's revocation). Restoring all chlorpyrifos tolerances would also undermine judicial comity among sister circuits and stand in considerable tension with the Ninth Circuit's explicit instruction to immediately revoke or modify all tolerances.

Finally, Gharda's suggestion (at 28–29) that EPA did not permit it to meaningfully participate in the revocation process rings hollow. Since the petition to revoke chlorpyrifos tolerances was filed nearly 15 years ago, EPA has solicited comments on revocation multiple times. After years of administrative process in response to the 2007 Petition to Revoke, in which registrants were afforded numerous opportunities to participate, and in light of the extensive scientific record EPA developed indicating chlorpyrifos is unsafe at current exposures, the Ninth Circuit said enough is enough and directed EPA to modify or revoke the chlorpyrifos tolerances "immediately" and without notice and comment. *LULAC II*, 996 F.3d at 702–03. No additional notice of its decision to revoke tolerances was required. *See* 21 U.S.C. § 346a(d)(4)(A)(i), Resp'ts' Add. at 9 (authorizing EPA to issue a "final regulation" without notice and comment in response to a petition to revoke).

For these reasons, EPA's assessment of registered uses in its aggregate exposure analysis was reasonable.

V. The FFDCA does not require EPA to cancel chlorpyrifos registrations before revoking tolerances.

Petitioners appear to argue that the FFDCA required EPA to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. *See* Pet'rs' Br. at 45-48. This argument misreads the FFDCA.

In support of their argument, Petitioners point to the FFDCA's direction that "the Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Thus, the FFDCA does not require EPA to cancel registrations *before* revoking tolerances. *See* Carbofuran; Final Tolerance Revocations Rule, 74 Fed. Reg. 23046, 23069 (May 15, 2009) ("Nothing in this provision establishes a predetermined order for how the Agency is to proceed to resolve dietary risks.") Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704.

Petitioners accuse EPA of trying to "have it both ways" by "claim[ing] that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses." Pet'rs' Br. at 49-50. Petitioners' apparent suggestion that the FFDCA requires EPA to utilize any FIFRA-specific process or considerations prior to revoking tolerances lacks any basis under the statute. And, in these particular circumstances, where the Ninth Circuit gave EPA a 60-day deadline to act and rejected EPA's argument that a decision on tolerances should be delayed pending completion of registration review, EPA reasonably assessed the registrations that existed at the time. *See LULAC II,* 996 F.3d at 678, 691, 702. That assessment led to the Final Rule revoking all tolerances, *see supra* at 18–20, and then, after issuing the Final Rule, EPA began the extensive process under FIFRA of conforming registrations to the Final Rule.

Similarly without merit is Petitioners' suggestion (at 50–52) that EPA may modify registrations quickly without registrants' consent, such that the Agency could have cancelled or modified all registrations before the 60-day deadline to leave in place tolerances for the proposed subset of 11 uses. To the contrary, registrants whose registrations are subject to involuntary cancellation have substantial process rights, including the right to a hearing, appeal to the Environmental Appeals Board, all *before* the registration is actually cancelled, and judicial review. *See supra* at 8.[13]

Petitioners also ignore that EPA is proceeding with the cancellation of chlorpyrifos registrations in a timely manner. Following the expiration of

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[13] Relatedly, EPA lacks the authority to unilaterally modify pesticide labels. Instead, the registrant must submit an application to amend the label, which EPA may then approve. *See* 40 C.F.R. § 152.44(a). Where registrants do not submit revised labels for approval, EPA may take appropriate action under FIFRA, which may include initiating cancellation. *See* 7 U.S.C. § 136d(b); 40 C.F.R. § 155.58(d).

chlorpyrifos tolerances, EPA received several requests for voluntary cancellation of chlorpyrifos registrations and published a notice regarding 16 voluntary cancellations. 87 Fed. Reg. 25256 (Apr. 28, 2022). Moreover, EPA has consistently stated its intention to initiate involuntary cancellation proceedings for all registrations for which it does not receive a voluntary cancellation request.

Petitioners claim (at 53) that EPA's practice has been to modify or revoke tolerances to reflect analyses that a subset of uses are safe, and then modify registrations to reflect changes to those tolerances. Petitioners are wrong. For example, in the case of bifenthrin, after the registrants cancelled certain uses and amended labels to address residential application risks, there was sufficient room in the "risk cup" to establish new tolerances. *See* Bifenthrin, 86 Fed. Reg. at 68154; 86 Fed. Reg. at 38339. Petitioners cite (at 54) dicloran as a contrary example, claiming that there EPA first modified the tolerances for dicloran and later modified the registrations to reflect the tolerance modifications. But, in fact, EPA first terminated the uses of dicloran on potatoes and carrots in response to voluntary cancellation requests by the registrant. Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71022 (Nov. 16, 2011); Dicloran; Cancellation Order for Amendment to Terminate a Use of DCNA Pesticide Registrations, 75 Fed. Reg. 16105 (March 31, 2010). EPA subsequently revoked the tolerances for dicloran on potatoes and carrots. Dicloran and

Formetanate; Tolerance Actions, 77 Fed. Reg. 40812 (July 11, 2012).[14] Moreover, the dicloran tolerance actions were not taken to address safety, and instead served only to remove tolerances that were no longer necessary because of action by the registrant.

In sum, the FFDCA does not require that EPA cancel chlorpyrifos registrations before revoking tolerances.

CONCLUSION

For the foregoing reasons, EPA respectfully requests that the Court deny Petitioners' request to vacate the Final Rule and Denial Order. Petitioners' request for vacatur would leave all chlorpyrifos tolerances in place, despite the expert agency's conclusion that they are unsafe.

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[14] Petitioners also cite Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4651 (Feb. 1, 2018) in support of their claim, however that order canceled uses unrelated to the cited tolerance actions.

Respectfully submitted,

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July 22, 2022

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 12,796 words.

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

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EXHIBIT 11

In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITIONERS' OPENING BRIEF

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SUMMARY OF THE CASE AND ORAL ARGUMENT REQUEST

This case concerns an arbitrary and capricious U.S. Environmental Protection Agency ("EPA" or "Agency") rule effectively banning the insecticide chlorpyrifos, a crop protection tool growers have relied on for decades. Petitioners challenge EPA's denial of objections to the rule and the rule itself as contrary to the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Agency's own scientific findings. *See* AR 1[1], Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"); Add. 1[2]; Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("Denial Order"); Add. 23.

Petitioners respectfully request oral argument in this case due to the novel and important issues raised, and in light of the ramifications of EPA's Final Rule and Denial Order on Petitioners and the agricultural community. Petitioners respectfully request 20 minutes to present their case.

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[1] "AR" refers to EPA's Certified Index to the Administrative Record. Case No. 22-1422, Doc ID: 5146142 (under seal).

[2] "Add." refers to the Addendum filed with this Brief.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure Petitioners submit the following corporate disclosure statement:

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International, Inc**. states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

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JURISDICTIONAL STATEMENT

I. THIS COURT HAS JURISDICTION OVER PETITIONERS' CLAIMS

This Court has jurisdiction to review Petitioners' challenge to the EPA's Denial Order and to the Final Rule under FFDCA § 408(h)(1). 21 U.S.C. § 346a(h)(1) ("any person . . . adversely affected by" an order on objections to a final rule revoking tolerances "may obtain judicial review . . . in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business"). This action properly lies in this circuit because most of the Petitioners reside within the Eighth Circuit. Eleven of the nineteen Grower Petitioners[3] are all based in States located within the Eighth Circuit. *See id.* An additional five Petitioners[4] have members located within the Eighth Circuit. The aggregate value of the eleven crops adversely affected by

[3] These eleven Petitioners are Red River Valley Sugarbeet Growers Association, Minn-Dak Farmers Cooperative, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, and North Dakota Soybean Growers Association.

[4] These five Petitioners are U.S. Beet Sugar Association, American Sugarbeet Growers Association, American Farm Bureau Federation, National Association of Wheat Growers, and National Cotton Council.

the revocation of chlorpyrifos tolerances to the U.S. economy is more than $59 billion annually.[5] A large share of those crops are grown within the Eighth Circuit.

II. PETITIONERS HAVE STANDING TO BRING THIS CASE

Petitioners have standing to seek review of EPA's Final Rule and Denial Order. To satisfy Article III's standing requirements, a petition must show: (1) a "concrete and particularized" and "actual or imminent" "injury in fact"; (2) that is "fairly traceable" to the conduct complained of; and (3) that will be "redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citations omitted). An association has standing to sue on its members' behalf "when its members would otherwise have standing, . . . the interests at stake are germane to the organization's purpose," and the claim and requested relief do not require the individual members' participation in the lawsuit. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

[5] USDA, National Agricultural Statistics Service, www.nass.usda.gov.

"[W]here one plaintiff establishes standing to sue, the standing of other plaintiffs is immaterial to jurisdiction." *Jones v. Gale*, 470 F.3d 1261, 1265 (8th Cir. 2006); *Nat'l Wildlife Fed'n v. Agric. Stabilization & Conservation Serv.*, 955 F.2d 1199, 1203 (8th Cir. 1992) (internal quotation marks omitted). "[A] regulated party generally has standing to challenge an agency action regulating its behavior." *Ameren Servs. Co. v. FERC*, 893 F.3d 786, 792 (D.C. Cir. 2018).

The Grower Petitioners, on their own behalf or on behalf of their members, demonstrate a "concrete and particularized" and "actual or imminent" injury in fact because EPA's unlawful revocation action has deprived them of a pest control tool that is critical for their crops, including sugarbeets, cherries, and soybeans. *See, e.g.*, Pet. App. 1374[6] ¶ 8; Pet. App. 1384–85 ¶ 10; Pet. App. 1394 ¶ 9; Pet. App. 1405 ¶ 9; Pet. App. 1418–19 ¶¶ 13–14; Pet. App. 1427–28 ¶ 12; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1455–56 ¶ 9; Pet. App. 1463–64, 1466–74 ¶¶ 4, 9–22; Pet. App. 1479–81 ¶¶ 10–15; Pet. App. 1486–93 ¶¶ 6–19; Pet. App. 1499–501 ¶¶ 11–14; Pet. App. 1508–09 ¶¶ 12–16; Pet. App. 1516–18 ¶¶ 12–18; Pet. App. 1525–26 ¶¶ 11–14; Pet. App. 1535 ¶¶ 12–14;

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[6] "Pet. App." refers to the Petitioners' Appendix.

Pet. App. 1543–44 ¶¶ 11–15; Pet. App. 1560–63 ¶¶ 4–16; Pet. App. 1568–69 ¶ 8; Pet. App. 1579–80 ¶¶ 10–14; Pet. App. 1586–87 ¶¶ 12–14; *see also Lujan*, 504 U.S. at 560; *Ameren Servs.*, 893 F.3d at 791.

As a result of EPA's revocation of tolerances, any commodity treated with chlorpyrifos as of the rule's February 28, 2022, effective date is deemed "adulterated," 21 U.S.C. §§ 342(a), 346a(a)(1), and subject to seizure, *id.* § 334(a)(1), and any grower who applies chlorpyrifos to commodities in interstate commerce is subject to criminal sanctions, *see id.* §§ 331, 333. The inability to lawfully apply chlorpyrifos will likely cause the growers represented by Grower Petitioners financial harm from reduced crop yields due to an increase in pest pressure, *see, e.g.*, Pet. App. 1378 ¶ 21; Pet. App. 1396 ¶ 14; Pet. App. 1405, 1407 ¶¶ 10, 16; Pet. App. 1419 ¶ 14; Pet. Ap. 1431–32 ¶ 22; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1386–87 ¶¶ 10–15; Pet. App. 1458 ¶ 14; Pet. App. 1471–72 ¶ 18, as well reputational harm, *see, e.g.*, Pet. App. 1397–98, 1399 ¶¶ 21, 25; Pet. App. 1472–73 ¶ 20; Pet. App. 1492 ¶ 17. This harm would be remedied for the 2023 growing season and beyond by a favorable decision from this Court.

Petitioner Gharda also has standing as the chlorpyrifos registrant and primary supplier of chlorpyrifos for agricultural use in the United States. *See Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 870 (8th Cir. 2013) (injury based on members' interest in Clean Water Act permits); *Coteau Props. Co. v. Dep't of Interior*, 53 F.3d 1466, 1472 (8th Cir. 1995) (applicant for surface mining permit had standing). Gharda similarly has a "concrete and particularized" interest in the tolerances and the harm to that interest is "actual or imminent," *Lujan*, 504 U.S. at 560, because EPA's Final Rule has denied Gharda the necessary authorizations for Gharda to manufacture and sell chlorpyrifos for use on food, 7 U.S.C. § 136(bb). These concrete injuries are directly caused by EPA's revocation of tolerances and would be remedied by a decision from this Court vacating the Final Rule and Denial Order with respect to those uses. *See Lujan*, 504 U.S. at 560–61.

STATEMENT OF ISSUES

Whether EPA's Final Rule and Denial Order revoking all food tolerances for chlorpyrifos are arbitrary and capricious, an abuse of discretion, and otherwise contrary to law in light of:

1. EPA's disregard of its own scientific evidence supporting the retention of eleven uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in specifically designated regions the Agency unequivocally found safe (the "Safe Uses").

2. The plain text and intent of the FFDCA, which require a forward-looking, individual review of tolerances, based on the latest scientific developments.

3. EPA's failure to coordinate its actions under the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as the statutes require and consistent with prior Agency practice.

4. EPA's failure to offer a reasoned explanation justifying its departure from its own scientific findings.

Apposite statutory provisions and cases for issue 1: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State*

Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *Chlorine Chemistry Council v. E.P.A.*, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000).

Apposite statutory provisions and cases for issue 2: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 3: 21 U.S.C. § 346a(l)(1); 7 U.S.C. § 136(bb); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 4: *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

STATEMENT OF THE CASE

III. EPA'S REGULATION OF FOOD USE PESTICIDES UNDER TWO INTERRELATED STATUTES: THE FFDCA AND FIFRA

Pesticides are among the most heavily regulated substances in the United States. EPA regulates pesticides used on food under a comprehensive, science-based regime arising primarily under two separate but interrelated federal statutes: the FFDCA, 21 U.S.C. § 346a, and FIFRA, 7 U.S.C. §§ 136–136y. Congress made clear that it intends for EPA to coordinate its actions under the two laws. H.R. Rep. No. 104-669(II), 104th Cong. at 51 (1996) ("The Committee expects EPA to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties.").

A. The FFDCA

The FFDCA requires EPA to set food safety "tolerances," which are maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a. EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* § 346a(b)(2)(A)(i). Food containing pesticide residues that exceed an established tolerance level is deemed "adulterated" under the FFDCA and may not be moved in interstate commerce. *Id.* §§ 331, 342. In considering whether to establish, modify, or revoke a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." *Id.* § 346a(b)(2)(D)(i).

In 1996, Congress amended the FFDCA with the passage of the Food Quality Protection Act ("FQPA") which, among other things, established a new safety standard for pesticide tolerances covering pesticide residues in or on raw agricultural commodities. A tolerance is deemed "safe" under the FFDCA if "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). This includes exposure from food, drinking water, and in residential settings, but does not include occupational exposure. In assessing reasonable certainty of no harm, EPA is to apply an additional tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" but EPA has discretion to apply a different margin of safety if there is "reliable data" to support that determination.[7] *Id.* § 346a(b)(2)(C)(ii).

While application of "reasonable certainty of no harm" to tolerances for raw agricultural commodities was new to EPA when the

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[7] The FFDCA does not define "reliability" or "reliable data." In a February 2002 guidance document, EPA counseled that "the data and information" relied upon to inform a safety factor determination "must be *sufficiently sound* such that [EPA's Office of Pesticide Programs] could routinely rely on such information in taking regulatory action." AR 9, *EPA*, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance* (Feb. 28, 2002) at A-6; Pet. App. 536 (emphasis added). Data that are not replicable are not reliable. AR 24, *EPA, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (Dec. 28, 2016) at 30; Pet. App. 1055 ("[R]eliability general[ly] refers to the ability to reproduce results. . . .").

FQPA was passed, EPA and the Food and Drug Administration ("FDA") had used the same standard for decades when establishing tolerances for processed foods under FFDCA § 409. And the FDA used the same standard in approving food additives under FFDCA § 409.[8]

B. FIFRA

EPA also regulates pesticides under FIFRA. Under FIFRA, all pesticides must be registered by EPA before they can be marketed, distributed, or sold in the United States. 7 U.S.C. § 136a(a). FIFRA registrations operate as "product-specific license[s]" and confer on registrants legally protectable property rights. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 36 (D.D.C. 2011); Add. 79–80, *Ctr. for Biological Diversity v. E.P.A.*, No. 11-cv-00293-JCS, 2013 WL 1729573, at *6–7 (N.D. Cal. Apr. 22, 2013) ("[O]wners of the pesticide

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[8] In the 1958 amendments to the FFDCA, Congress made clear that a safety determination under the "reasonable certainty of no harm" standard does not require absolute proof of safety: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rep. No. 85-2422, 85th Cong., reprinted in 1958 U.S.C.C.A.N. 5300, 5305; *see also* H.R. Rep. No. 83-2284, 83rd Cong (1958).

registrations . . . have property and financial interests in the registrations.”).

As originally enacted, “FIFRA was primarily a licensing and labeling statute.” *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). Through a series of amendments to the law in the 1970s, Congress transformed FIFRA into a “comprehensive regulatory statute” under which EPA exercises broad authority. H.R. Rep. No. 92-511, 92d Cong., at 1 (1971).

To approve a pesticide registration, EPA must determine, based on a review of extensive scientific data, that use of the product in accordance with its label will not pose “unreasonable adverse effects” on humans or the environment. 7 U.S.C. § 136a(c)(5)(D). The product label establishes the scope of the FIFRA registration, and is submitted to and approved by EPA as a core element of every registration. *See, e.g., id.* § 136a(c)(1)(C). Every registered product is required to display an EPA-approved label that identifies the approved crop uses, applications, and directions for use. Use of a pesticide in a manner inconsistent with that label is unlawful. *Id.* § 136j(a)(2)(G).

FIFRA also requires EPA to conduct comprehensive reevaluations of all registered pesticides every fifteen years, a process known as registration review. This process ensures that all pesticides and their approved uses continue to satisfy FIFRA's safety standard as scientific capabilities improve and agricultural practices change over time. *Id.* § 136a(g)(1)(A)(iii)–(iv); 40 C.F.R. § 155.40(a). During registration review, EPA reviews available data and information and conducts a number of risk assessments. EPA makes these assessments available for public comment, conducts further scientific analyses, and revises its assessments, as necessary.

C. Congress's Intended and Purposeful Harmonization of the FFDCA and FIFRA

FIFRA and FFDCA cross-reference one another and are intended to be carried out in harmony. For pesticides used on food, FIFRA's "unreasonable adverse effects" registration standard expressly incorporates FFDCA's "reasonable certainty of no harm" safety standard. 7 U.S.C. § 136(bb). Thus, when EPA registers a pesticide for use on food, it must determine that doing so will not cause higher amounts of pesticide residue on food commodities than the approved tolerances allow. Moreover, through the FQPA, Congress amended

FIFRA to adopt the fifteen-year registration review process: part of the purpose of this update to the law was to ensure that existing tolerances are consistent with current science. *See* 142 Cong. Rec. H8127-02, 104th Cong. (1996), at H8147 (contemplating that tolerance assessments would "take advantage of the latest scientific advances"); *see also* Add. 99, EPA Testimony on Pesticide Regulations Before the H.R. Subcomm. on Health & Env't and Comm. on Com., 1995 WL 347288 (June 7, 1995) (fifteen-year registration review process will "ensure that tolerances keep pace with advances in scientific knowledge").

Additionally, the FFDCA mandates that when revoking a tolerance EPA "shall coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(l)(1). For example, EPA may modify or cancel the pesticide's registration and enter an "existing stocks" order to "permit the continued sale and use of existing stocks" of a pesticide whose registration is being cancelled. 7 U.S.C. § 136d(a), (b).

IV. CHLORPYRIFOS AND ITS IMPORTANCE TO U.S. AGRICULTURE

A. Chlorpyrifos Has Benefited U.S. Farmers and Contributed to a Safe and Affordable Food Supply for Decades

Chlorpyrifos is an organophosphate insecticide that has been approved for use in the United States since 1965. Chlorpyrifos is a vitally important agricultural tool that protects valuable U.S. food crops from destruction due to insect pests. *See* AR 62 (EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos, EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits")); Pet. App. 299. Growers rely on chlorpyrifos due to its broad-spectrum efficacy against multiple pests, low cost, and minimal impact on beneficial insects. It is the leading active ingredient to control a wide variety of difficult-to-control insect pests and is often relied on as the first line of defense against new or unknown insect pests. For some growers represented by Grower Petitioners, chlorpyrifos is the only effective crop protection tool available. *See* Pet. App. 1373–74 ¶ 7; Pet. App. 1385–86 ¶ 10; Pet. App. 1393–94 ¶ 8; Pet. App. 1405 ¶ 9; Pet. App. 1417 ¶ 8; Pet. App. 1427–28 ¶ 12; Pet. App. 1440–41 ¶ 11; Pet. App. 1455–56 ¶ 9; Pet. App. 1466–67

¶ 10; Pet. App. 1568–69 ¶ 8; Pet. App. 1586 ¶ 10; *see also* AR 62 at 2; Pet. App. 301.

The eleven crops adversely affected by the revocation of chlorpyrifos tolerances contribute more than $59 billion to the U.S. economy annually. Access to chlorpyrifos as a crop protection tool protects growers' crops and income and benefits consumers who enjoy affordable, healthy, and high quality produce throughout the year.

B. EPA's Revocation Decision Threatens the Viability of Essential U.S. Food Crops

EPA's revocation decision will have a significant, negative impact on the agricultural economy. Without chlorpyrifos, some crops will be left without viable alternatives, putting those crops and their growers' livelihoods at risk. Lack of access to chlorpyrifos will significantly diminish the production capabilities of many growers, causing crippling economic losses. *See* Pet. App. 1500–01 ¶ 13; Pet. App. 1489–90 ¶ 13; Pet. App. 1386, 1387 ¶¶ 11, 14; Pet. App. 1455–56 ¶ 9; Pet. App. 1444–46 ¶¶ 20–21; Pet. App. 1431–32 ¶ 22; Pet. App. 1471–72 ¶ 18. In particular, loss of chlorpyrifos threatens the continued viability of sugarbeet production in the United States. *See* Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc ID 5132688 (Mar. 3, 2022) at 4–5.

These economic impacts will ultimately be felt by U.S. consumers, who are already experiencing staggering inflation and supply chain disruptions.

V. EPA'S SHIFTING REGULATORY OVERSIGHT OF CHLORPYRIFOS LEADING UP TO THE 2020 PID

A. EPA Reaffirms Chlorpyrifos's Safety In a 2006 Reregistration Action

EPA has long evaluated the safety of chlorpyrifos based on its potential to inhibit acetylcholinesterase ("AChE"), an enzyme necessary for proper nervous system function in target pests and other organisms, as well as in humans. AChE inhibition can be measured at very low levels in the blood, enabling EPA to determine safe levels of exposure to humans, in accordance with its safety standard under FIFRA and the FFDCA. EPA has concluded that exposure to chlorpyrifos below levels that cause 10% red blood cell AChE ("RBC AChE") inhibition does not adversely affect human health. This conclusion is supported by decades of scientific review and an extensive and complete database of toxicology studies. AR 1 at 48,323; Add. 9.

Since it was first registered in 1965, EPA has reviewed chlorpyrifos several times to ensure that it continues to meet FIFRA and FFDCA safety standards. In 2006, EPA completed "reregistration" of chlorpyrifos, a review of older pesticides required by FIFRA, which included a reassessment of existing tolerances. In a final decision, EPA reauthorized all existing agricultural uses and determined that all chlorpyrifos food tolerances are "safe," meaning there is "a reasonable certainty that no harm will result from aggregate exposure" to chlorpyrifos. AR 33, EPA, Reregistration Eligibility Decision for Chlorpyrifos (2006); Pet. App. 546–48; 21 U.S.C. § 346a(b)(2)(A)(ii). That decision remained undisturbed until the Final Rule.

B. A 2007 Administrative Petition Spurs Inconsistent Regulatory Action

In 2007, a group of nongovernmental organizations that oppose pesticide use petitioned EPA to revoke all chlorpyrifos tolerances. The petition was based principally on an epidemiology study claiming associations between trace levels of chlorpyrifos (below those that cause 10% RBC AChE) in umbilical cord blood and neurodevelopmental effects in children later in life.

In response to the administrative petition, EPA accelerated registration review of chlorpyrifos. As part of that process, EPA conducted multiple risk assessments and sought public comment on those assessments. EPA also convened several sessions of its FIFRA

Scientific Advisory Panel ("SAP"), an independent advisory committee of scientific experts, *see* 7 U.S.C. § 136w(d)(1), to evaluate several scientific issues relating to chlorpyrifos, including the epidemiology study. The SAP looked closely at the epidemiology data and concluded that they contained numerous deficiencies and were insufficient to support a new regulatory standard.[9]

From 2007 to 2015, EPA gave every indication that it intended to deny the administrative petition. In March 2015, in litigation challenging EPA's response to the administrative petition, EPA informed the Ninth Circuit that it planned to deny the petition, having determined based on its 2014 Revised Human Health Risk Assessment that the petition's claims did not provide a basis to revoke tolerances. *See* Status Rep. at 2, *In Re Pesticide Action Network North America*, No.

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[9] *See, e.g.*, AR 27 at 19; Pet. App. 914 (2012 SAP concurring with EPA that the epidemiology data "are not adequate enough to obtain a point of departure (POD) for the purposes of quantitative risk assessment."); AR 41 at 46; Pet. App. 853 (2008 SAP stating that "the Panel agreed with the Agency that there were limitations in the . . . epidemiological studies that precluded them from being used to directly derive the [point of departure] or the uncertainty factor"). "Point of departure" refers to the maximum level of pesticide exposure for which there are no observable adverse effects. It is the "starting point" for EPA's risk calculations. *See* AR 1 at 48,322; Add. 8.

14-72794 (9th Cir. Mar. 31, 2015), ECF No. 14. EPA also informed the court that the scientific evidence was "insufficient" to depart from the 10% RBC AChE inhibition regulatory standard upon which its 2006 safety determination was based. *Id.*, Attach. 1 at 3.

Later in 2015, EPA changed course, not due to any newfound concern related to the administrative petition, but instead based on drinking water issues the Agency was in the process of studying. In response to a court deadline, EPA issued a Proposed Rule to revoke tolerances, published on November 6, 2015. Pet. App. 994, Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080 (Nov. 6, 2015) (the "Proposed Rule").[10] EPA made clear that the Proposed Rule was based on a preliminary drinking water assessment it was working to refine, not food or other exposures, which EPA said in the Proposed Rule "*are safe*." *Id.* at 996, 1021 (emphasis added). EPA reiterated that "AChE inhibition remains the most robust quantitative dose response

[10] Some regulatory materials referenced in Petitioners' Statement of the Case are not included in EPA's AR. While these materials do not bear directly on the issues before the Court, they are cited here as background and context for Petitioners' arguments. If the Court would like copies of any of these documents, Petitioners will be pleased to provide them.

data for chlorpyrifos and thus continues to be the critical effect for the quantitative risk assessment." *Id*. at 1002. EPA acknowledged that its drinking water assessment was ongoing and stated that it "may update this action with new or modified analyses as EPA completes additional work." *Id*. at 999.

In April 2016, EPA took a radical regulatory detour, convening an SAP to review an unprecedented proposal that would base a new regulatory standard for chlorpyrifos directly on cord blood concentrations reported in the epidemiology study. EPA, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies (Mar. 11, 2016). The SAP rejected EPA's proposal: "[T]he majority of the Panel considers the Agency's use of the results from a single longitudinal study to make a decision with immense ramifications based on the use of cord blood measures of chlorpyrifos as a [point of departure] for risk assessment as premature and possibly inappropriate." AR 28 at 25, EPA, Scientific Advisory Panel for Chlorpyrifos; Analysis of Biomonitoring Data (Apr. 19–21, 2016).

Ignoring the SAP's admonition, in November 2016 EPA proposed and sought comment on yet another new regulatory standard, also based solely on the same epidemiology study previously rejected.[11] *See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049 (Nov. 17, 2016). The proposal was severely criticized in public comments, including by the Obama Administration U.S. Department of Agriculture. *See* Pet. App. 1078, USDA Comments on the Risk Assessment Underlying the Reopened Proposed Rule "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment" (EPA-HQ-OPP-2015-0653-0648), Jan. 17, 2017 (expressing "grave concerns that ambiguous response data from a single, inconclusive study are being combined with a mere *guess* as to dose levels . . . to underpin a regulatory decision about a pesticide chemical that is vital to U.S. agriculture, and whose removal from market would have a major economic impact on growers and consumers").

[11] Rather than accept the weaknesses the SAP identified with the cord blood data, EPA's new 2016 proposal doubled down and used a dose reconstruction approach to develop a new point of departure. Under this approach, EPA interviewed New York City pesticide applicators in 2016 to estimate the amounts of chlorpyrifos the study subjects might have been exposed to 15–20 years earlier.

In April 2017, EPA retreated from pursuing novel regulatory approaches based on unreliable, previously rejected epidemiology data. EPA denied the administrative petition, finding the epidemiology data urged in support of the petition were not sufficiently valid, complete, or reliable. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Pet. to Revoke Tolerances, 82 Fed. Reg. 16,581 (Apr. 5, 2017). The NGO petitioners filed objections and simultaneously challenged EPA's petition denial order in the Ninth Circuit. *League of United Latin American Citizens v. Wheeler*, Case No. 17-71636 (9th Cir.) ("*LULAC I*"). An *en banc* panel of the Ninth Circuit found that it had no jurisdiction to review EPA's petition denial but ordered EPA to act on the objections by July 18, 2019. *LULAC I*, 922 F.3d 443 (9th Cir. 2019). EPA then denied the objections to its petition denial order, again finding concerns about neurotoxicity of chlorpyrifos at levels below 10% RBC AChE inhibition unsupported by valid, complete, and reliable data. *See* Chlorpyrifos; Final Order Denying Objs. to Mar. 2017 Pet. Denial Ord., 84 Fed. Reg. 35,555, 35,563 (July 24, 2019). The NGO petitioners challenged the objection denial order in the Ninth Circuit. *LULAC v. Wheeler*, Case No. 19-71979 (9th Cir.) ("*LULAC II*").

VI. EPA FINDS ELEVEN CROP USES SAFE AND BEGINS NEGOTIATIONS WITH THE REGISTRANT TO MODIFY LABEL USES ACCORDINGLY

A. EPA's 2020 Proposed Interim Decision ("PID") Finds Eleven Critical Crop Uses Safe

On December 7, 2020, as part of its ongoing registration review of chlorpyrifos,[12] EPA published its PID. Pesticide Registration Review; PID for Chlorpyrifos; Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020); AR 40, PID for Chlorpyrifos; Pet. App. 366. The PID is supported by a number of underlying risk and benefits assessments, including: EPA's September 21, 2020, Third Revised Human Health Risk Assessment (the "2020 RHHRA"), AR 2; Pet. App. 157, which in turn relied on EPA's September 15, 2020, Updated Chlorpyrifos Refined Drinking Water Assessment (the "2020 DWA"), AR 38; Pet. App. 1. EPA's PID and the risk assessments on which it relies reflect a fulsome, measured, and well-reasoned evaluation by EPA's expert scientists of potential human health and drinking water risks of chlorpyrifos. In these assessments, EPA reaffirmed its reliance on its long-standing 10%

[12] Registration review for chlorpyrifos is scheduled to be completed by October 2022.

RBC AChE endpoint as the appropriate standard for assessing human health risks. AR 2 at 5; Pet. App. 161.

The PID was also based on EPA's 2020 DWA, which updated and refined the Agency's 2016 drinking water assessment (the "2016 DWA"). The 2020 DWA is one of the most sophisticated drinking water analyses EPA has conducted and relied on EPA's most highly refined methods for assessing drinking water risks. *See* Pet. App. 1774–75 ¶¶ 9–11. EPA subjected the 2020 DWA to peer review by nine EPA expert scientists, an unprecedented level of peer review for an assessment of its kind. *Id.* ¶ 12. In the 2020 DWA, EPA considered eleven crop uses identified as high-benefit, critical uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) (the Safe Uses). AR 38 at 9, 17, 19–21; Pet. App. 10, 18, 20–22. The 2020 DWA conducted an analysis of these crops in select regions of the country where estimated drinking water concentrations are below the drinking water level of concern. AR 38 at 27–28; Pet. App. 28–29.

In the 2020 RHHRA and PID, EPA assessed potential risk to human health from aggregate exposure to chlorpyrifos residues. EPA determined that there were *no* potential risks of concern from exposure to chlorpyrifos in food or residential uses alone. AR 2 at 12; Pet. App. 168; AR 40 at 14, 18; Pet. App. 379, 383. With respect to drinking water, EPA determined that risks exceeded safe levels taking into account all registered uses. But, relying on its 2020 DWA, EPA found that risks were *below* the drinking water level of concern benchmark when anticipating use only on the Safe Uses. AR 40 at 18; Pet. App. 383.

In its 2020 RHHRA and PID, EPA presented two approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to the Safe Uses, or (ii) application of a 1X FQPA safety factor, which would allow for the retention of *all* currently registered uses. Regarding the first approach, EPA was unequivocal that it had found the Safe Uses safe: "[the Safe Uses] are the high-benefit agricultural uses that ***the agency has determined*** *will not pose potential risks of concerns with an FQPA safety factor of 10X*." AR 40 at 40 (emphasis added); Pet. App. 405. EPA acknowledged that it was "currently in discussions with the registrants regarding the proposed/considered mitigation measures." AR 40 at 40; Pet. App. 405. EPA stated that it would "consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine *if any other limited uses may be retained*." AR 40 at 40; Pet. App. 405 (emphasis added). In other words, the Safe Uses were the minimum subset of uses that EPA said it would retain, which EPA would consider expanding through review of public comment and further analysis.

B. EPA Negotiates with Petitioner Gharda a Voluntary Narrowing of Chlorpyrifos Uses Consistent With Its Safety Finding

In early April 2021, EPA approached Gharda about a possible agreement to voluntarily cancel some uses of chlorpyrifos. Pet. App. 1611–12 ¶ 21. In these initial discussions, EPA urged Gharda to accept a voluntary phase-out of all uses other than the Safe Uses. *Id*.

On April 29, 2021, the Ninth Circuit issued a decision in *LULAC II*. The Ninth Circuit held that EPA's denial of objections to its 2017 denial of the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition. *LULAC II*, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit gave weight to EPA's proposals in 2015 and 2016 in which EPA suggested that existing tolerances were not sufficiently health protective, *see id.* at 677—proposals that were based on drinking water analyses the Agency later refined and on epidemiology data it ultimately deemed insufficient. Crediting these proposed findings by the Agency, the Ninth Circuit ordered EPA "*either* to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "*or* to revoke all chlorpyrifos tolerances." *Id.* at 678 (emphasis added).

In making this ruling, the court acknowledged that EPA's scientific analyses were ongoing and expressly recognized the importance of the PID. The court observed that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." *Id.* at 703. The court also acknowledged the need to harmonize EPA's proposed tolerance action with action under FIFRA, ordering EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." *Id.* at 678.

After the Ninth Circuit decision in *LULAC II*, EPA continued discussions with Gharda about a voluntary narrowing of chlorpyrifos uses. Pet. App. 1613–14 ¶ 23. The PID continued to provide the backdrop for these discussions, as they culminated in Gharda's *written commitment* to EPA to voluntarily cancel all uses of chlorpyrifos except the Safe Uses. *Id.* 1614–15 ¶ 24. As part of these discussions, Gharda and EPA actively discussed and exchanged written proposals for the orderly phase-out of existing stocks of all *other* uses. *Id.* 1613–22 ¶¶ 23–33. As the parties neared an agreement, EPA informed Gharda that it would likely need a written voluntary cancellation letter to reference quickly in the Final Rule and thanked Gharda for its "continued patience and engagement." *Id.* 1621–23 ¶¶ 33–35. Gharda was standing by awaiting guidance from EPA on when to submit the voluntary cancellation letter when EPA abruptly terminated the discussions, without explanation. *Id.* 1622–25 ¶¶ 34–40.

VII. EPA DOES A REGULATORY TURNABOUT AND INEXPLICABLY ISSUES A FINAL RULE REVOKING CHLORPYRIFOS TOLERANCES FOR *ALL* CROP USES

To the shock of growers and registrants, EPA then did a regulatory 180-degree turn and, in August 2021, announced the Final

Rule revoking *all* chlorpyrifos tolerances. AR 1 at 48,315; Add. 1. EPA stated that, "taking into consideration the *currently registered uses* for chlorpyrifos," it is unable to make ***any*** safety finding under the FFDCA. AR 1 at 48,315, 48,317; Add. 1, 3 (emphasis added).

In reaching this conclusion, EPA did not rely on any new data or scientific analyses, nor did it attempt to walk back in any way its scientific conclusions in the PID. In fact, the scientific analysis in the Final Rule is largely consistent with that outlined in the PID. For example, EPA's Final Rule reaffirmed its long-standing 10% RBC AChE standard as the appropriate regulatory endpoint for assessing human health risks. AR 1 at 48,325; Add. 11 ("EPA has determined that the most appropriate toxicological endpoint for deriving points of departure for assessing risks of chlorpyrifos is 10% RBC AChE inhibition."). And as in the PID, EPA stated that it "remains unable to make a causal linkage between chlorpyrifos exposure and the [neurodevelopmental] outcomes reported" in epidemiology data. AR 1 at 48,324; Add. 10.

As to the aggregate exposure assessment, EPA confirmed in the Final Rule, as it had found in the PID, that "exposures from food and non-occupational exposures individually or together do not exceed

EPA's levels of concern." AR 1 at 48,333; Add. 19. EPA agreed that it is only drinking water exposures, when combined with food and non-occupational (residential) exposures, that create risks of concern. AR 1 at 48,333; Add. 19. As to drinking water, the Final Rule acknowledged EPA's findings in the PID that drinking water exposures do not exceed levels of concern when assuming use on only the Safe Uses. AR 1 at48,333; Add. 19.

Nevertheless, and despite admitting that it had found eleven uses safe, EPA claimed that because it is required to assess aggregate exposure taking into account all "currently registered uses," and based on the 2016 DWA, it could not find that aggregate exposures to chlorpyrifos are safe. AR 1 at 48,333; Add. 19. The Agency stated, without explanation or any reference to Gharda's commitment to drop all but the Safe Uses, that it lacked "effective mitigation upon which to base a reduced aggregate exposure calculation." AR 1 at 48,333; Add. 19. The Final Rule stated that the tolerances would expire six months later, on February 28, 2022.[13] AR 1 at 48,334; Add. 20.

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[13] EPA's press release announcing the Final Rule made statements that are not supported by the Final Rule or its scientific findings, including that tolerance revocation would ensure

Petitioners timely submitted objections to the Final Rule, pursuant to Section 408(g) of the FFDCA. 21 U.S.C. § 346a(g)(2)(A). In light of the irreparable harm revocation of tolerances would cause, several Petitioners also sought an administrative stay of the Final Rule pending EPA's review of the objections. *See, e.g.*, AR 44–47, 49, 51, 54–56, 58–59, 67, 69, 71–72, 75–78, 80–84; Pet. App. 1085–284.

VIII. EPA'S INACTION ON PETITIONERS' OBJECTIONS AND STAY REQUESTS LEADS TO LITIGATION

EPA refused to act on the objections and stay requests for months, despite Petitioners' claims of irreparable harm and the approaching effective date of the Final Rule. Accordingly, on February 9, 2022, Petitioners petitioned this Court for review of the Final Rule and EPA's constructive denial of the objections and stay requests. *Red River Valley Sugarbeet Growers Ass'n v. Regan* (No. 22-1294), Doc. ID 5126162 (the "First Petition"). Petitioners also filed a motion for partial stay of the Final Rule on February 10, 2022, Doc. ID 5126280. On

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"farmworkers . . . are protected from the potentially dangerous consequences of this pesticide" and that EPA was "follow[ing] the science." AR 63, Press Release, EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health (Aug. 18, 2021) https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.

February 18, 2022, EPA filed a motion to dismiss the First Petition, contending that this Court had no jurisdiction because EPA had not yet made a "final" decision on the objections and stay requests. *See* Pet. App. 1285–306; Resp't Opp. to Pet'rs' Mot. to Stay Pending Review, Doc. ID 5129078 at 7, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 18, 2022).

The following business day, EPA released its 193-page Denial Order, denying all of Petitioners' objections and requests for an administrative stay. *See* Resp'ts Rule 28(j) Notice of Issuance of Final Order, Doc. ID 5130160 at 1, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 24, 2022). The Denial Order was published in the Federal Register on February 28, 2022, the same day the Final Rule took effect. Add. 23. EPA's Denial Order, like the Final Rule, did not retreat from any scientific findings in the PID. *Id.* at 42 ("EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [*i.e.*, the Safe Uses]."). EPA's Denial Order instead repeated the rationale for revocation outlined in the Final Rule: that EPA is required to assess aggregate exposure under the FFDCA based on "currently registered uses," which it acknowledged as a "legal matter." *Id.*

On the same day the Final Rule was published, Petitioners filed a second Petition for Review in this Court, incorporating all issues raised in the First Petition as well as a challenge to EPA's Denial Order. Pet. App. 1355–67 (the "Second Petition"). Petitioners also renewed their motion to stay the Final Rule ("Renewed Motion to Stay"). Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc. ID 5132688. In the midst of the briefing, EPA asserted a novel, unprecedented argument that the Court lacked jurisdiction to hear the Second Petition because it was filed fewer than fourteen days after publication of the Denial Order in the Federal Register. Pet. App. 1343. For avoidance of doubt, on March 14, 2022, Petitioners filed a third petition for review, Pet. App. 1816–913, incorporating the Second Petition and its attachments in their entirety, as well as the Renewed Motion to Stay.

On March 15, 2022, the Court entered an order stating that it is exercising jurisdiction in this matter and denying Petitioners' Motion for a Partial Stay Pending Review. Thereafter, the parties submitted and the Court granted a stipulation consolidating the Second and Third Petitions and setting a briefing schedule. Pet. App. 1914–15.

SUMMARY OF THE ARGUMENT

This action challenges EPA's arbitrary and capricious decision to revoke all tolerances for chlorpyrifos, effectively banning an agricultural tool farmers in the Midwest and around the country depend on to protect their crops and investment from destructive insect pests. Without adequate protection, an infestation of insect pests can cripple crop production and threaten farmers' livelihoods. This reality is especially stark for some of the growers represented by Petitioners here, for whose crops there exist no effective alternatives. *Supra* § IV.

The Final Rule was an abrupt and unexpected change in position not only because chlorpyrifos has been safely used for over fifty years but because just months earlier, EPA completed a rigorous scientific human health assessment that unequivocally found that use of chlorpyrifos on eleven high-benefit crops in select regions is safe. This assessment was based on a highly sophisticated Agency drinking water assessment that had undergone unprecedented peer review. After completing this assessment, EPA then spent months negotiating with

Petitioner Gharda to modify the approved uses on the label consistent with its safety finding. And Gharda committed to do just that.

Then, EPA abruptly ceased those discussions and pulled the rug out from under the regulated community by revoking *all* tolerances. EPA did so at a time when growers and consumers already face severe supply chain shortages and record-high inflation.

In revoking all tolerances, EPA did not back away from the scientific findings supporting its safety finding as to the eleven uses. Rather, in a flawed and unheard-of interpretation of the law, EPA claimed that it is required to assess safety by considering exposure from all currently approved uses, and that it is powerless to order changes to the product labels consistent with the science.

EPA's refusal to act on its own scientific evidence is arbitrary and capricious, an abuse of discretion, and contrary to law. EPA has a statutory mandate to review tolerance safety based on current science. This is reflected in the FFDCA's forward-looking text, which compels EPA to review tolerances on an individual basis, considering "anticipated" exposures based on the "reliable information" at its disposal. It is confirmed in the legislative history in which Congress explicitly directed EPA to periodically review tolerance safety "based on the latest advancements in the science." EPA's position that it is confined to review only currently approved uses reads EPA's authority to "modify" tolerances out of the statute, and disregards EPA's obligation to coordinate its tolerance actions with registration actions under FIFRA. It is also at odds with the Agency's consistent historical practice of using tolerance modification and corresponding FIFRA action as a risk mitigation tool.

None of the reasons EPA offers to justify its revocation decision are defensible. EPA claims that a court order mandated this result, but that court in fact recognized EPA's ongoing scientific assessment and directed EPA to "act based on the evidence." While it ordered EPA to revoke or modify tolerances in sixty days, it gave EPA flexibility to modify related FIFRA registrations in a "timely fashion." EPA's attempt to diminish its scientific findings as "proposals" also fails. Scientific evidence confirmed by numerous expert Agency scientists is not entitled to less weight because it is summarized in a document labeled a proposal. The record also reflects that EPA believed its scientific findings were final and actionable, and that EPA relied on them to negotiate corresponding label changes with the registrant.

The Agency's revocation decision was not driven by science or any reasonable reading of the statute. It therefore appears to be a pretext for an unexplained policy change. The law is clear that EPA must provide a reasoned, science-based explanation for its change in position, especially given the harms its revocation decision have caused and will continue to cause the growers, registrants, and consumers. For reasons outlined more fully below, this Court should vacate EPA's arbitrary and capricious Final Rule and Denial Order.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews EPA's Final Rule and Denial Order for compliance with the FFDCA under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Under the APA, the court shall hold unlawful and set aside an agency action found to be "in excess of statutory jurisdiction, authority, or limitation. . ." or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A), (C).

An agency decision is arbitrary and capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *accord Nebraska v. E.P.A.*, 812 F.3d 662, 666 (8th Cir. 2016). When an agency changes course, it must "supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42. A reviewing court "'may not supply a reasoned basis for the agency's action that the agency itself has not given.'" *Id.* at 43 (quoting *SEC v. Chenery Corp.,* 332 U.S. 194, 196 (1947)).

II. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT DISREGARDS THE AGENCY'S OWN SCIENTIFIC EVIDENCE

EPA's scientific review of chlorpyrifos over the past fifteen years has examined a number of different issues, and not always in a consistent manner. But the current scientific record before the Agency is not the subject of dispute.

EPA previously (in 2015 and 2016) explored proposals to address claims of neurodevelopmental effects below the current regulatory standard. EPA has since consistently concluded (under prior and current leadership) that the data urged in support of those claims are insufficient. EPA has accordingly maintained its longstanding 10% RBC AChE regulatory standard, and it has chosen to address potential neurodevelopmental risks by application of an FQPA Safety Factor of 10X. EPA's Final Rule and Denial Order unequivocally reaffirmed those scientific conclusions. AR 1 at 48,317; Add. 3, 23.

EPA does not dispute that the sole dietary exposure source of concern—and therefore the focal point of the Agency's latest human health risk assessment of chlorpyrifos—is drinking water, and only in certain parts of the country. While EPA years ago issued a Proposed Rule to revoke all tolerances for chlorpyrifos based on drinking water concerns, it did so in response to a court mandamus deadline and in reliance on its incomplete drinking water assessment. Pet. App. 995, 999. EPA has since updated, refined, and completed that assessment—a process that culminated in the 2020 DWA.

The 2020 DWA is EPA's most cutting edge, sophisticated drinking water assessment yet, that reflects the most advanced, updated tools and methodologies for assessing drinking water exposures and risks.

AR 38 at 9–11; Pet. App. 10–11, 1774 ¶ 9. It has undergone an unprecedented level of peer review by nine expert Agency scientists. Pet. App. 1774 ¶ 9. In the 2020 DWA, EPA analyzed risks from exposures from eleven high-benefit agricultural uses in select regions where estimated drinking water concentrations of chlorpyrifos are below EPA's benchmark level of concern (the Safe Uses). EPA's PID relied on the 2020 DWA and unequivocally found those uses *safe*:

> To mitigate potential dietary exposure to chlorpyrifos, the agency is proposing to limit application to select uses in certain regions where the [estimated drinking water concentrations] are lower than the [drinking water benchmarks of concern]. . . . [T]he agency has determined that [those uses] ***will not pose potential risks of concerns*** with an FQPA safety factor of 10X . . .

AR 40 at 40; Pet. App. 405 (emphasis added). The PID and the 2020 DWA on which it relied reflect a careful, conservative, and well-reasoned scientific assessment.

EPA nevertheless cast these assessments aside in the Final Rule and Denial Order and refused to apply their findings. EPA's refusal to act on its scientific evidence is arbitrary and capricious. *See, e.g.*, *Chlorine Chemistry Council*, 206 F.3d at 1290–91 (D.C. Cir. 2000) (vacating EPA rule that "openly overrode" its own science); *Dow*

AgroSciences LLC v. Nat'l Marine Fisheries Serv., 707 F.3d 462, 472–73 (4th Cir. 2013) (finding arbitrary and capricious agency reliance on older data that was not "representative of current and future pesticide uses and conditions" and failure to adequately explain its decision "despite the existence of new data and the potential drawbacks of using the older data") (internal quotations omitted); *Sierra Club v. E.P.A.*, 671 F.3d 955, 966–68 (9th Cir. 2012) (EPA action was arbitrary and capricious for not utilizing a more recent model); *Am. Wildlands v. Norton*, 193, F. Supp. 2d 244, 257 (D.D.C. 2002) (finding agency action arbitrary and capricious where agency "ignored scientific data and existing models"); *cf. Sugule v. Frazier,* 639 F.3d 406, 412 (8th Cir. 2011) (rejecting agency action where weight of evidence went against agency decision).

EPA's refusal to follow its scientific evidence was not due to any error in the science—the Final Rule and Denial Order do not attempt to walk back the PID or 2020 DWA's scientific findings. *See* Add. 42 (EPA admitting that it "does not dispute its own scientific conclusions and findings in the 2020 PID" regarding the Safe Uses, and ultimately the issue is "whether EPA properly interpreted its obligation under the

FFDCA in assessing aggregate exposure to chlorpyrifos," which is "a question of law and not one of fact"). Rather, EPA's sole basis for revoking all tolerances and effectively banning an agricultural tool growers have depended on for decades is that EPA could not conclude that tolerances are safe taking into account all "currently registered uses" of chlorpyrifos. *Id.* at 47–48. None of the arguments EPA has put forward in support of this newly fashioned rationale hold water.

As outlined below, EPA has abused its discretion, and its Final Rule and Denial Order are arbitrary and capricious and otherwise contrary to law, because they disregard the text and intent of the FFDCA and FIFRA, are contrary to the record, and are contrary to the Agency's own past practice.

III. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS AND CONTRARY TO LAW BECAUSE IT IGNORES THE TEXT AND INTENT OF THE FFDCA AND FIFRA

A. The FFDCA Compels a Forward-looking, Individual Tolerance Approach That Is Driven by Science

EPA's rationale that it must assess safety by considering only currently registered uses is contrary to the FFDCA's plain language and Congress's expressed intent that tolerance actions be driven by science.

EPA's construction defies Congress's forward-looking mandate that EPA find "there is a reasonable certainty that no harm *will result* from aggregate exposure" to the pesticide residue from "all *anticipated* dietary exposures and all other exposures for which there is *reliable information*." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). If Congress intended for EPA to assess safety of existing exposures only, based on tolerances previously approved, it would have referred to existing exposures rather than using the word "anticipated." *United States ex rel. Harlan v. Bacon*, 21 F.3d 209, 210 (8th Cir. 1994) ("When construing a statute, we are obliged to look first to the plain meaning of the words employed by the legislature," and the court "must give effect to the unambiguously expressed intent of Congress") (internal quotations omitted).

EPA's position is also at odds with FFDCA's mandate that the Agency reassess tolerance safety by employing a tolerance-by-tolerance approach. In drafting the FFDCA, Congress specified that EPA "may establish or leave in effect *a tolerance* . . . if the Administrator determines that *the tolerance* is safe . . . [and] shall modify or revoke *a tolerance* if the Administrator determines *it* is not safe." 21 U.S.C. §

346a(b)(2)(A)(i) (emphasis added); *accord id.* § 346a(b)(2)(C). Congress reiterated in setting forth the standard for the safety determination that it is to be made "with respect to *a tolerance* for a pesticide chemical residue. . . ." *Id.* § 346a(b)(2)(A)(ii) (emphasis added). The FFDCA's use of "*a* tolerance" rather than "*the* tolerances" shows Congress intended for EPA to make safety determinations for each tolerance on an individual basis—not based on "the universe of currently registered chlorpyrifos uses" as EPA urges. Add. 45; *see Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 742 (2017) (courts must give meaning to the particular words Congress chose in drafting a statute, including its choice between the singular and plural form).

An approach focused on currently registered uses is also inconsistent with Congress's directive that tolerance assessments be driven by advancements in science. Indeed, the legislative history underlying the FQPA makes Congress's intent abundantly clear: the "reasonable certainty of no harm" standard was intended to promote "the efficient, science-based administration of FIFRA and the [FFDCA]" by ensuring that tolerance assessments are based on "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8147. EPA is to assess safety based on the latest, reliable scientific evidence at its disposal and then leave in effect, modify, or revoke in accordance with that evidence.

Congress's decision to provide for modifying a tolerance if it is found not safe further supports an individual tolerance, science-based approach. The FFDCA encourages EPA to "modify *or* revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). The statute clarifies that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," and therefore to "modify" can only mean to *narrow* permissible uses. *Id.* § 346a(b)(1) (emphasis added). Thus, EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe.

EPA's position that all of the tolerances must rise or fall together and that it is required to assess currently registered uses effectively reads modification out of the statute. If accepted, it would lead to the absurd result that EPA would never be able to narrow uses based on new or updated scientific data. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("interpretations of a statute which would produce absurd results are to be avoided"). By EPA's logic, any time it found currently registered uses cumulatively unsafe, it would have to revoke *all* tolerances. But that is not what the law says: EPA plainly has authority to modify tolerances by narrowing the uses.

EPA's own practice also undermines its contention that it must consider only registered uses, and not anticipated uses as the statute says, in making its safety determination. For example, EPA increased the tolerance for residues of benzobicyclon in or on rice grain without changing the tolerances for other uses. Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60,368 (Nov. 2, 2021). There, EPA explained that it could make a "determination on aggregate exposure for benzobicyclon, including exposure resulting from the tolerance established by this action," *id.* at 60,369, and considered "cumulative exposures . . . (based on proposed and registered pesticidal uses at the time the assessment was conducted)," *id.* at 60,370.

Relatedly, EPA has also previously amended individual tolerances, showing that tolerances do not have to rise or fall together. For instance, on May 18, 2022, EPA established in a final rule a new tolerance for the insecticide flonicamid in or on small fruit vine, and amended the existing tolerance for flonicamid in or on alfalfa (hay) by increasing it from 1.0 ppm to 7.0 ppm. Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30,425 (May 19, 2022). According to EPA, the establishment of these new tolerances for flonicamid were based upon EPA's authority under section 408 of the FFDCA and the Agency's review of "available scientific data and other relevant information." *Id.* at 30,426. EPA also established tolerances of tebuconazole "in or on multiple commodities" while modifying other tebuconazole tolerances. Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60,932 (Nov. 12, 2019).

In short, EPA's position that it could not consider its scientific evidence because it is required to assess currently registered uses finds no support in the FFDCA's text or underlying legislative history. It is also contrary to the Agency's prior practice.

B. EPA Failed to Coordinate Its Action Under the FFDCA with FIFRA, as the Statutes Require

EPA's Final Rule and Denial Order are also contrary to law because EPA failed to harmonize its safety determinations under the FFDCA with FIFRA, as the statutes require. *Supra* § III.

FIFRA's registration standard expressly incorporates the FFDCA "reasonable certainty of no harm" standard. 7 U.S.C. § 136(bb). The approved food uses identified on a pesticide label must conform to EPA's safety determinations under the FFDCA. The FFDCA, for its part, mandates that once EPA has made a safety determination with respect to individual tolerances, it is required to modify or cancel the FIFRA registrations accordingly. 21 U.S.C. § 346a(l)(1) ("[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]."). This is also consistent with the forward-looking approach specified in the FFDCA: the "anticipated exposures" considered as part of EPA's safety determination, *id.* § 346a(b)(2)(A)(ii), are the future uses that will be in effect based on EPA's coordinated action under FIFRA, *id.* § 346a(l)(1).

Congress's directive that EPA coordinate its actions under the two laws to reflect the latest science could not have been more clear. And yet, EPA has taken the never-before-asserted position that its actions under the two statutes are "separate," *see* Add. 45, and that, short of action by the registrant, it is powerless to modify the FIFRA registrations to conform to its safety findings, *see id.* at 47. EPA's rationale is untenable and cannot be squared with the law or the Agency's prior conduct.

1. *<u>EPA's Denial Order Is Internally Inconsistent Regarding FIFRA</u>*

EPA's Denial Order is riddled with statements that cannot be reconciled with one another or with the statutory directives. EPA claims that it has discretion to determine the proper order of its actions under FFDCA and FIFRA, and challenges the notion that the Agency cannot lawfully revoke tolerances unless it "has first cancelled—or simultaneously cancels—associated pesticide registrations under FIFRA." *Id.*

EPA's argument actually supports Petitioners' reasoning. EPA's revocation decision must be reviewed based on the adequacy of its rationale—and EPA's sole explanation for not following the science is that it could *not* legally retain a subset of uses found safe without conforming FIFRA registrations in place. EPA cannot have it both ways—it cannot claim that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses. EPA cannot claim that the FIFRA and FFDCA actions are separate, and then state that it "could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations [in the

2020 DWA and PID], *unless all other uses were canceled*." *Id.* at 57 (emphasis added).

2. *EPA's Claim That Harmonization Was "Not Practicable" Fails*

EPA next claims that it did attempt to harmonize its tolerance actions under the FFDCA with cancellation actions under FIFRA but that coordination ultimately was "not practicable." *Id.* at 48–50 (citing 21 U.S.C. § 346a(l)(1)). First, EPA claims that the Ninth Circuit did not give it sufficient time to coordinate its FIFRA and FFDCA actions. *Id.* This argument is unavailing. While the Ninth Circuit gave EPA sixty days to either modify or revoke tolerances, it imposed no time limit on EPA's corresponding action under FIFRA—ordering only that EPA modify or cancel related FIFRA registrations "in a timely fashion." *LULAC II*, 996 F.3d at 678. The Ninth Circuit thus expressly recognized EPA's authority to modify tolerances and then update the FIFRA registrations accordingly. The Ninth Circuit further acknowledged that FIFRA actions would take more time and follow EPA's tolerance action.

Second, EPA claims that it did not have a "reasonable basis" to believe registrations would be amended consistent with its safety finding because it did not have voluntary cancellation requests. Add. 47. This argument ignores law and reality. Congress conferred on EPA broad authority to regulate the safe use of pesticides on food under two comprehensive federal statutes, and directed that the Agency administer those statutes in an "efficient, science-based" manner that reflects "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8145-46. This includes the authority to initiate cancellation actions to conform FIFRA registrations to the Agency's safety determinations, with or without the registrant's cooperation. 7 U.S.C. § 136d(b), (f); *see also* 40 C.F.R. § 155.58(d) (EPA "may take appropriate action under FIFRA" if a registrant fails to comply with a registration review decision). EPA's assertion that it is incapable of acting on its scientific evidence without some affirmative action by a regulated party strains credulity. EPA is not only empowered to conform its FIFRA registrations to its scientific findings but compelled to do so by law.

Indeed, EPA admits registrant negotiations are largely irrelevant to the validity of its actions under the FFDCA: "Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question." Add. 49. This is precisely Petitioners' point: EPA made a scientific finding that the Safe Uses are safe. AR 40 at 40; Pet. App. 405. EPA did not back away from that safety finding either in its Final Rule or Denial Order. EPA was thus required to follow that scientific determination and modify the tolerances and registrations accordingly.[14]

In any event, EPA downplays that it *had* a voluntary cancellation commitment from Petitioner Gharda, the primary supplier of chlorpyrifos for agricultural use in the United States. Pet. App. 1611–21 ¶¶ 21–32. EPA and Gharda had spent months negotiating voluntary cancellation terms, and Gharda had submitted to EPA a written commitment to conform its registration to EPA's safety finding. *Id.*

[14] EPA states in the Denial Order that cancellation proceedings under FIFRA require a number of time-consuming procedural steps. EPA cannot claim that it did not have time to complete these steps because the Ninth Circuit required only that it take action under FIFRA "in a timely fashion." 996 F.3d at 678. More importantly, aggregate exposures would not have exceeded those analyzed and found safe in the PID during the pendency of any cancellation proceeding because the tolerance revocation and modification consistent with the PID would have ensured as much. 21 U.S.C. § 346a(a)(1).

1626–27 ¶ 43. Gharda was standing by awaiting word from EPA on when to submit a formal voluntary cancellation request reflecting the agreed terms when EPA abruptly ceased discussions. *Id.* 1622–23 ¶¶ 34–35. Weeks later, EPA took a 180-degree turn and revoked all tolerances. *Id.* 1623 ¶ 37.

3. *EPA Has Consistently Coordinated Its Tolerance Actions With FIFRA In the Past*

Where, as here, EPA has conducted a tolerance assessment based on thorough and detailed scientific analyses and found, based on that scientific evidence, that a subset of uses are safe, it must leave in effect the uses found safe, and modify or revoke tolerances to narrow the scope of permissible uses as the science dictates. It is then empowered to modify or cancel the FIFRA registrations in accordance with that science. This is how EPA has consistently applied the law in the past. *See Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) ("existing practice" evidence of agency interpretation).

EPA routinely mitigates risks identified in its tolerance assessments by taking corresponding action to modify or cancel FIFRA registrations. For example, EPA modified some, but not all, tolerances for dicloran and later modified the FIFRA registrations for dicloran.

See Acephate, Cacodylic, Dicamba, Dicloran, et al.; Tolerance Actions, 75 Fed. Reg. 60,232 (Sept. 29, 2010); Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71,022 (Nov. 16, 2011); Dicloran and Formetanate; Tolerance Actions, 77 Fed. Reg. 40,812 (July 11, 2012); Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4,651 (Feb. 1, 2018). EPA's action with respect to chlorpyrifos is not consistent with this prior practice. Such "inconsistent treatment" by the Agency "is the hallmark of arbitrary agency action." *Clean Wisconsin v. E.P.A.*, 964 F.3d 1145, 1163 (D.C. Cir. 2020).

IV. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT OFFERS NO REASONED EXPLANATION LET ALONE ONE THAT ADEQUATELY ADDRESSES THE RELEVANT FACTORS AND EVIDENCE

It is a foundational principle of administrative law that agencies must provide a reasoned explanation for departing from prior conclusions. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Northport Health Services of Arkansas, LLC v. HHS*, 14 F.4th 856, 873 (8th Cir. 2021). "Reasoned decision-making requires that when departing from precedents or practices, an agency must 'offer a reason to distinguish them or explain its apparent rejection of their approach.'" *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020) (quoting Sw. *Airlines Co. v. FERC*, 926 F.3d 851, 856 (D.C. Cir. 2019); *see also Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978) (greater scrutiny applies to agency actions departing from prior norms and "it is at least incumbent upon the agency carefully to spell out the bases of its decision when departing from prior norms"). An agency may not "gloss[] over or swerve[] from prior precedents without discussion." *Sw. Airlines Co.*, 926 F.3d at 856 (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970).

EPA admits that its revocation decision disregards the Agency's safety finding in the PID. EPA's primary reason for revoking all tolerances is that EPA claims it was required to consider all currently registered uses because EPA had no reason to believe that the registrations would be amended. As outlined above, that reasoning is plainly contrary to the statute and the Agency's prior course of dealing. *Supra* §§ III.A–B. EPA's additional arguments for departing from the scientific evidence are not defensible.

A. EPA Cannot Escape from the Scientific Evidence by Disguising It as A "Proposal"

EPA does not attempt to argue that the scientific findings as to the Safe Uses are wrong. Instead, EPA tries to assert that the PID was simply a "proposal," and thus, EPA was not required to consider it. Add. 45–48. EPA is wrong.

The Ninth Circuit in *LULAC II* expressly recognized that EPA issued the PID proposing to modify tolerances while that proceeding was pending, such that the PID was not part of the record before the Ninth Circuit when it issued its decision. The Ninth Circuit nevertheless acknowledged the PID in ordering EPA to act, stating that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." 996 F.3d at 703. The Court made clear that "*EPA must act based upon the evidence*." *Id.* (emphasis added). The PID was *evidence* before the Agency that EPA was required to act on or, at a minimum, offer a reasoned explanation before departing from it.

EPA cannot disregard the scientific evidence before it simply because it may later be revised. In *Chlorine Chemistry Council*, 206

F.3d at 1291, the D.C. Circuit vacated an EPA rule that blatantly disregarded the Agency's own scientific evidence. In doing so, the court rejected EPA's characterization of its scientific findings as not representing the Agency's "ultimate conclusions" as "semantic summersaults." *Id.* The court observed that "[a]ll scientific conclusions are subject to some doubt," and "however desirable it may be for EPA to consult [a Scientific Advisory Board] and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime." *Id.* at 1290–91.

Moreover, EPA's claim that it was permitted to simply ignore the scientific findings in the PID because it was merely a "proposal" is at odds with the record. The PID may have been labeled a "proposed" interim decision, but that is because EPA still needed to complete two additional assessments: (1) the Endangered Species Act analysis and (2) the endocrine screening for the chlorpyrifos registration review. *See* EPA Registration Review Process, https://www.epa.gov/pesticide-reevaluation/registration-review-process (last visited May 16, 2022) (explaining that during Registration Review "EPA may issue a proposed interim decision *when the Agency needs to conduct additional* *assessments such as an endangered species assessment or endocrine screening*") (emphasis added). Neither of those issues is relevant to the safety determination for purposes of establishing or leaving in effect tolerances under the FFDCA. 21 U.S.C. § 346a(b)(2).[15]

As to the safety findings in the PID, EPA made clear that further analyses and review of public comment on its tolerance assessments would only *expand* the scope of permissible uses, not contract them. AR 40 at 40; Pet. App. 405 ("[T]he agency will consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if *any other limited uses may be retained*.") (emphasis added). EPA went on to state in the PID that it could issue a final decision for chlorpyrifos without issuing an interim decision. AR 40 at 62; Pet. App. 427; *see also* https://www.epa.gov/pesticide-reevaluation/registration-review-process (explaining that interim decisions may be issued to, among

[15] That EPA's scientific findings are reflected in Agency proposals does not diminish their weight. The Ninth Circuit credited scientific findings in EPA proposals in ordering EPA to "act based on the evidence" and issue a final order revoking or modifying tolerances. *See LULAC II*, 996 F.3d at 703. It recognized that EPA could act on the PID. *Id.*

other things, explain changes to or respond to comments on a proposed interim decision). EPA thus unquestionably believed that its scientific findings concerning tolerances were final and actionable. Indeed, there is no logical reason EPA would have devoted enormous resources to developing a sophisticated drinking water assessment based on a limited subset of uses, and then a proposed interim decision based on that assessment, if it did not believe that decision could support corresponding regulatory action.

EPA's actions treating the PID as final are not an anomaly. EPA regularly takes action to amend uses in response to a proposed interim registration review decision. For instance, a registrant agreed to make certain changes to uses for the fungicide famoxadone based on EPA's proposed interim registration review decision for that product. Corteva Agriscience, Response Comments to: Famoxadone: Proposed Interim Registration Review Decision (Dec. 17, 2021), https://downloads.regulations.gov/EPA-HQ-OPP-2015-0094-0067/attachment_1.pdf (last visited May 15, 2022).

B. EPA Treated Its Scientific Findings In the PID As Final

Even more, EPA has treated the scientific findings in the PID as its final decision on the safety of chlorpyrifos under the FFDCA. *Cf. FWS v. Sierra Club*, ___ U.S. ___, 141 S. Ct. 777, 786 (2021) (decision is final where agency treats it as such). EPA relied on the PID when attempting to reach an agreement with Gharda on a voluntary narrowing of uses consistent with the PID.

For months, EPA and Gharda actively exchanged proposals for the retention of uses, for which the PID was the backdrop. At all times, Gharda understood that the Safe Uses would be retained. Pet. App. 1611–18 ¶¶ 21–29. For example, during these discussions EPA rejected a proposal by Gharda to retain chlorpyrifos for use on cotton in Texas, saying that "[t]he PID indicated that if cotton were maintained, it could be used in AL, FL, GA, NC, SC, and VA," but "Texas would not be an option." *Id.* 1746; *see Am. Maritime Ass'n v. Blumenthal*, 458 F. Supp. 849, 858 (D.D.C. 1977) (agency action is final where it "represents the final, crystallized agency position on the matter"). EPA never backed away from the scientific findings in the PID or hinted that they were not final and subject to change. Ultimately, Gharda put forward a written commitment to modify its label consistent with the safety finding in the PID. Pet. App. 1743–44, 1756–58.

EPA could not have entertained these proposals, and all of these months of negotiations would have been pointless, unless EPA believed that its PID could support a coordinated modification of registered uses under FIFRA. Thus, in treating and relying on the PID as a final Agency action, and in causing regulated parties to rely on the PID accordingly, EPA has cemented the finality of the PID with respect to the Safe Uses. *See Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)) ("When an agency changes course, . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'"). EPA has given no reasoned explanation for ignoring this final safety determination and so its decision is arbitrary and capricious. *Supra* § IV.

CONCLUSION

For all of the foregoing reasons, Petitioners respectfully request that EPA vacate the Denial Order and Final Rule.

May 24, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief compiles with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,170 words. I further certify that Petitioners' Brief complies with the typeface and type style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), as it was prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Pursuant to Eighth Circuit Rule 28A(h)(2), I certify that the electronic version of this Brief has been scanned for viruses and is virus-free.

/s/ Nash E. Long
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 24, 2022, a true and accurate copy of the foregoing Petitioners' Opening Brief was electronically filed with the United States Court of Appeals for the Eight Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, Petitioners will serve each party separately represented with a paper copy of the Brief.

I further certify that ten (10) paper copies of the foregoing Brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Rule 28A(d).

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EXHIBIT 12

In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review of an Order of the
U.S. Environmental Protection Agency

PETITIONERS' REPLY BRIEF

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INTRODUCTION

After working with registrants in 2019 to identify key U.S. crop uses for chlorpyrifos, the Environmental Protection Agency ("EPA" or the "Agency") used up-to-date science to determine that the tolerances for a subset of uses, on eleven crops, meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act ("FFDCA") (the "Safe Uses"). Despite that finding, which EPA announced in its Proposed Interim Decision ("PID") in 2020 and reaffirmed in the Final Rule and several times since, EPA elected to revoke ***all*** tolerances, including those the Agency found safe, at the expense of farmers across the country. Petitioners brought this action to preserve the Safe Uses and uphold EPA's own scientific analysis supporting them.[1]

EPA's various explanations for its overbroad decision all fail to meet the standard of reasonableness the Administrative Procedure Act ("APA") demands. EPA claims it could not have modified the tolerances

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[1] EPA claims that Petitioners ask the Court to leave *all* chlorpyrifos tolerances in place. EPA Br. at 22 ("The ultimate relief sought by Petitioners in this case is the retention of *all* chlorpyrifos uses."). But Petitioners' request is more limited: that the Court direct EPA to act consistent with its safety finding and retain the Safe Uses, which Petitioners have made clear is a subset of all the tolerances. Pet'rs' Br. at 34.

consistent with its pre-existing safety finding in a timely fashion as directed by the Ninth Circuit, even though EPA had already done the necessary work to specify where and how chlorpyrifos can be used safely. The FFDCA's plain text required EPA to consider that safety determination and the underlying scientific data supporting it in issuing the Final Rule.

EPA seeks to distinguish that safety finding by advancing a new reading of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and FFDCA as entirely separate statutory regimes. But Congress linked the two statutory regimes in the Food Quality Protection Act ("FQPA"), mandating that the two statutes have ***the same safety standard*** for food use pesticides. There is no basis for EPA to claim its safety finding for chlorpyrifos applied only to FIFRA registration reviews and not to FFDCA tolerance decisions.

EPA also argues modification of tolerances under the FFDCA consistent with its safety finding was impossible without cancellations and label amendments under FIFRA. But neither FIFRA nor FFDCA require the Agency to have cancellation and label amendment requests in hand before modifying tolerances. As the Ninth Circuit recognized, modification of tolerances could be followed by appropriate and orderly registration action. *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 703–04 (9th Cir. 2021) ("*LULAC II*"). Contrary to EPA's argument, the Ninth Circuit set no deadline for such action. *Id*.

Next, EPA shifts its position in this litigation regarding its obligations under the FFDCA. Although EPA first said it had no authority to allow continuation of a subset of tolerances that meet the safety standard, EPA now ***admits*** in its opposition brief it "has the authority to lower or revoke tolerances to reduce the number of approved uses for a pesticide." EPA Br. at 39. Nevertheless, EPA claims it could not do so "when it [had] no reason to believe that . . . changes [to the registrations were] imminent." EPA Br. at 46.

EPA's attempt to reframe the issue, from a matter of law to whether it had an "appropriate record" upon which to act, also fails. Revocation of tolerances means the pesticide can no longer be used on food crops, and is tantamount to cancellation of associated registrations under FIFRA. EPA should have reasonably expected growers to follow the law and that registrants would submit the corresponding label amendments. In any event, if EPA genuinely believed registration amendments were needed to support a safety finding, it was obligated under 21 U.S.C. § 346a(f)(1) to formally request such amendments from the registrants, subject to revocation of all tolerances for non-compliance. In disregard of the statute, EPA never did so. Instead, EPA cut off discussions with Gharda at the last minute in an apparent attempt to ensure the record did not contain a "reasonable basis" on which the Agency could rely. This was neither lawful nor reasonable.

At the end of the day, this Court has a legal question to decide—not a scientific one: may EPA cast aside its own science, the language of the FFDCA, and its prior practice, to make a counterfactual finding that no use of chlorpyrifos would be safe? EPA agrees "this is ultimately a question of law and not one of fact." Pet. Add. 42. For the reasons set forth in Petitioners' Opening Brief and those set forth below, the answer to this legal question is clear: EPA cannot do so.

The Court should vacate the Final Rule and remand it with instructions to issue a rule conforming to the evidence and retaining tolerances for the Safe Uses.

ARGUMENT

I. EPA made the required safety finding, determining eleven food uses for chlorpyrifos are safe.

A. EPA's safety finding, announced in the PID as a determination made by the Agency, was the product of rigorous scientific analysis that EPA does not dispute.

In its 2020 PID, EPA announced it had identified eleven Safe Uses of chlorpyrifos "that the agency has determined will not pose potential risks of concern" within the ten-fold margin of safety required by the FQPA. A.R. 40 at 40; Pet. App. 405.[2] EPA had a well-reasoned basis for focusing its safety analyses on the eleven uses, following a fulsome, methodical process for selecting those uses.[3] EPA based its PID determination that the Safe Uses are safe on, among other findings, the conclusions in EPA's third revised human health risk assessment and

[2] As discussed below, the FQPA established a unified safety standard under FFDCA and FIFRA for food use pesticides such as chlorpyrifos. *Infra* at Part I.C.

[3] Six uses (alfalfa, citrus, cotton, soybean, sugarbeet, and wheat) were identified as "critical" in EPA's meetings with the lead registrant in 2019. *See* A.R. 40 at 41–42; Pet. App. 406–07; *see also* Supp. Pet. App. 1 (summarizing three EPA meetings with then-lead registrant Corteva regarding "critical uses" of chlorpyrifos). EPA identified the remaining uses (apple, asparagus, cherry, peach, and strawberry) as high-benefit uses, based on its own analyses.

its 2020 drinking water assessment ("the Scientific Assessments") concerning what uses of chlorpyrifos had "reasonable certainty of no harm" for human health. A.R. 40 at 12–19; Pet. App. 377-84. The Scientific Assessments were the result of extensive analysis by EPA's expert scientists, and underwent an unprecedented level of peer review. A.R. 2, 38; Pet. App. 1, 157. EPA's Scientific Assessments were complete and detailed in Agency memoranda spanning hundreds of pages. A.R. 2, 38; Pet. App. 1, 157. Because the Agency considered the scientific evidence final, EPA stated in the PID that "the agency has determined" the Safe Uses would pose no potential risks of concern under the FQPA's most protective safety standard. A.R. 40 at 40; Pet. App. 405. Even now, EPA does not question the findings of its Scientific Assessments.

> EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [the Safe Uses]. . . .

Pet. Add. 42.

EPA's decision to strike down the tolerances associated with the Safe Uses had nothing to do with the state of the science. Nowhere does

EPA make the argument that the relief requested by Petitioners—preservation of the Safe Uses—would not be safe. In fact, EPA has suggested ***additional*** uses could also be found safe. A.R. 40 at 40; Pet. App. 405.

Although EPA's Brief references studies claiming associations between chlorpyrifos and neurodevelopmental effects in an effort to defend the Final Rule, EPA Br. at 27–28, that is not what EPA's science or EPA's scientists say. The Final Rule and Denial Order, Pet. Add. 23–74, did nothing to retreat from the PID's safety finding and EPA's determination that studies on alleged neurodevelopmental effects are not strong enough to change the current regulatory standard, A.R. 40 at 40. Applying that standard and a ten-fold margin of safety to protect infants and children, EPA's scientists found the Safe Uses are indeed safe. A.R. 40 at 10, 40; Pet. App. 375, 405.

B. EPA cannot disregard its own scientific conclusions and findings as a mere "proposal."

EPA would have this Court cast aside the Scientific Assessments underpinning the PID because EPA summarized them and announced its safety determination in a document labeled as a "proposed" decision. EPA Br. at 32–36. Such a label cannot mask the truth: EPA "does not dispute its own scientific conclusions and findings" announced in the PID and agrees they "could support a safety determination" for the Safe Uses at the time it issued the Final Rule. Pet. Add. 42.

Moreover, invoking the "proposed" label cannot cure EPA's violation of law by ignoring its own scientific conclusions and findings described in the PID. 21 U.S.C. § 346a(b)(2)(D), which identifies the "factors" EPA must consider in making tolerance decisions, states no fewer than six times EPA "shall" base such decisions on "available data" and "available information." 21 U.S.C. §§ 346a(b)(2)(D)(i), (iii), (iv), (v), (vi), and (vii); *see also* Pet'rs' Br. at 8. This repeated statutory command is not qualified—if the specified information and data are available, then EPA must consider them regardless of whether such data and information have been through notice and comment rulemaking. Those repeated commands are reinforced by the plain text of § 346a(d)(4)(A)(i). That section, applicable to the Final Rule, requires EPA to consider "***any*** other information available to the Administrator" in issuing a final rule in response to a petition, and to do so "***without*** further notice and ***without*** further period for public comment." *Id.* § 346a(d)(4)(A)(i) (emphases added); *see* A.R. 1 at 48,316; Pet. Add. 2 (purporting to proceed under 21 U.S.C. § 346a(d)(4)(A)(i)).

The "available data" and "available information" when EPA issued the Final Rule plainly include the Scientific Assessments underlying the PID and EPA's determination that the Safe Uses meet the FFDCA safety standard. Pet'rs' Br. at 56. The FFDCA therefore ***required*** EPA to consider the Scientific Assessments and EPA's safety determination, even though EPA claims it had not completed review of comments on the PID. 21 U.S.C. § 346a(d)(4)(A)(i) (EPA "shall" consider "***any*** other information available" (emphasis added)); *see Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) ("[r]ead naturally, the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'"). The FFDCA's plain text defeats EPA's argument that EPA could ignore the PID as a "proposal."[4]

[4] Similarly, the Ninth Circuit acknowledged the PID and noted that if, on this basis, EPA could conclude certain tolerances were safe, EPA could then modify chlorpyrifos tolerances rather than cancelling them. *LULAC II*, 996 F.3d at 702–03. The Ninth Circuit, with full knowledge of the PID, ordered the Agency to act on the available evidence ***without*** going through any further notice and comment procedures. *Id.*

Moreover, EPA's argument conflates the process through which the Agency announced its safety determination (the PID) with the determination itself and the Scientific Assessments undergirding it. This is clear in the text of the PID, which refers to a determination the Agency has made on the safety of the Safe Uses, A.R. 40 at 40; Pet. App. 405, and announced EPA would take comment on whether ***additional*** uses could also be found safe under the FFDCA safety standard. A.R. 40 at 40; Pet. App. 405. EPA cannot ignore its Scientific Assessments and safety determination just because they are part of a proposal made under FIFRA to narrow the uses of chlorpyrifos.[5]

In any event, as Petitioners have explained, EPA often takes action based on proposed interim registration review decisions. For example, in the case of the fungicide famoxadone, "a registrant agreed to make certain changes to uses . . . based on EPA's proposed interim registration review decision." Pet'rs' Br. at 59. To this point, EPA's brief has no response. Nor could it, because this was precisely the course of dealing EPA followed with Gharda, in the extensive

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[5] As explained below, EPA's settled approach is to make FFDCA safety findings on the basis of "proposed" uses—the very thing set forth in the PID. *Infra* at pp. 17–18, 19 n.13.

negotiations that occurred between issuance of the *LULAC II* order and EPA's silent termination of discussions in the weeks leading up to the revocation of all tolerances. Pet. App. 1611–25. If the PID's safety determination was meaningless, EPA would not have used it as a baseline for negotiation with Gharda on narrowing uses in the record leading up to the Final Rule. Pet'rs' Br. at 60–61. EPA's response makes no attempt to reconcile this course of dealing with its litigation position.[6]

C. EPA's PID safety finding applies to action on tolerances under the FFDCA.

Unable to sideline the PID's safety finding and EPA's scientific conclusions as a "proposal," EPA tries to distinguish them instead—claiming incorrectly that the PID was a FIFRA-based analysis, separate from the "reasonable certainty of no harm" safety standard applicable to tolerances under the FFDCA. EPA Br. at 23, 32. But under both

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[6] EPA cites the example of oxadiazon in an attempt to justify ignoring the PID and its scientific conclusions. EPA Br. at 33–34 (noting a change from the PID to the final decision). But oxadiazon has no tolerances because it is not a food use pesticide. Resp'ts' App. 647, 656, 689. It therefore has nothing to do with the question presented here: what the FFDCA requires EPA to consider in making a tolerance decision.

FIFRA and FFDCA, there is only one definition of "safe" applicable to food use pesticides such as chlorpyrifos. Congress, in passage of the FQPA in 1996, required the same safety standard for food use pesticides for both FIFRA and FFDCA. Food Quality Protection Act, 110 Stat. 1489 (1996). Congress did so by making the FIFRA "unreasonable adverse effects" standard expressly incorporate the FFDCA's "reasonable certainty of no harm" standard. 7 U.S.C. § 136(bb)(2). There has been no "separate" definition for the safety of food use pesticides under FIFRA and FFDCA, as EPA claims, EPA Br. at 41, since passage of the FQPA in 1996. *LULAC II*, 996 F.3d at 680 ("FIFRA incorporates the FFDCA safety standard for food uses . . . ."). When EPA announced in the PID it had determined the Safe Uses "will not pose potential risks of concern with an FQPA safety factor of 10X [i.e., a ten-fold margin of safety]," A.R. 40 at 40, Pet. App. 405, that finding satisfies both FIFRA's and FFDCA's requirements concerning safety.

EPA cannot now claim otherwise. It acknowledged the relevance of the PID to the FFDCA safety determination when it brought the PID to the attention of the Ninth Circuit using FRAP 28(j)—reserved for "pertinent and significant authorit[y]" on issues before an appellate court. Fed. R. App. P. 28(j); Supp. Pet. App. 33. And the Ninth Circuit clearly understood the "pertinen[ce]" and "significan[ce]" of the PID, as EPA intended: referencing the PID and noting EPA could, based upon this "further research," "modify chlorpyrifos registrations rather than cancelling them." *LULAC II*, 996 F.3d at 703.[7]

The PID announced the necessary safety determination that would support continuation of the tolerances associated with the Safe Uses. Pet. Add. 42 (EPA's "own scientific conclusions and findings in the 2020 PID . . . could support a safety determination" for the Safe Uses). EPA's attempt to distinguish the PID's safety determination simply has no basis.

[7] Although EPA implies *LULAC II* supports its new paradigm of FIFRA/FFDCA "separat[ion]," EPA Br. at 14, that is not the case. In *LULAC II*, the Ninth Circuit admonished EPA for deferring action on a petition raising safety concerns until completion of registration review. 996 F.3d at 678, 691. Here, in contrast, EPA had ***already made*** a safety determination as to the Safe Uses, consistent with its obligations under the FFDCA. The Ninth Circuit's timing concerns related to a petition do not justify EPA's inaction on an existing safety determination. The Ninth's Circuit's recognition that the FFDCA "requires that the EPA make a safety determination based on whatever 'information' is 'available'," *id.* at 698, and that EPA could modify chlorpyrifos tolerances on the basis of the PID, *id.* at 703, confirms EPA should have considered the PID in the Final Rule.

II. The FFDCA and APA required EPA to act on its safety finding and modify the chlorpyrifos tolerances accordingly.

A. EPA must make tolerance decisions individually based on the available scientific evidence.

As Petitioners have shown, the text of the FFDCA requires EPA to make tolerance decisions individually and on the basis of available data and information—not "in gross" or in a counterfactual manner. Pet'rs' Br. at 42–47.[8] The FFDCA requires EPA to "modify or revoke ***a*** tolerance if the Administrator determines ***it*** is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). This clearly prescribes aligning specific tolerances with EPA's safety determination—leaving in effect those individual tolerances found safe and modifying or revoking the remainder. Pet'rs' Br. at 43–44. EPA's position would rewrite the FFDCA to say EPA may

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[8] EPA claims Petitioners waived the argument that EPA violated the FFDCA by not taking a tolerance-by-tolerance approach. EPA Br. at 37. Not true. Petitioners made that argument and quoted to EPA the same sections of the FFDCA relied upon here. "To fail to leave in effect the 11 tolerances for which the PID's science-based conclusions have already supported a safety finding runs afoul of the express direction in Section 408(b)(2)." A.R. 45 at 6; Pet. App. 1150. As explained earlier in that discussion, "Section 408(b)(2) of the FFDCA directs that EPA may 'leave in effect a tolerance . . . if the Administrator determines that the tolerance is safe.' And '[t]he Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.'" A.R. 45 at 6; Pet. App. 1150; *see also* Pet. App. 1653–54, 1669–70.

"revoke ***all*** tolerances if the Administrator determines that ***any*** is not safe." Such text is nowhere in the statute. Moreover, that interpretation would read out of the statute the provisions on modification of tolerances. *Id.* 42–47.[9] Because EPA did not consider the available evidence and its safety determination for the Safe Uses—revoking all tolerances instead of modifying them to conform to its existing safety determination—EPA violated the FFDCA.

EPA attempts to justify ignoring the available data and information, and making the counterfactual finding that no tolerance would be safe, by advancing novel and erroneous interpretations of the FFDCA. In the course of this case, EPA has contradicted itself numerous times on the meaning of the FFDCA. EPA previously argued the FFDCA prohibited it from eliminating certain uses and making a safety finding for the remainder. Supp. Pet. App. 22. EPA now ***agrees*** the FFDCA allows it to do just that—abandoning its prior position—while trying to maintain it is not required to do so. EPA Br. at 39.

[9] EPA argues its regulation of carbofuran supports its decision here. EPA Br. at 38, 43–44. But there, EPA did not have a PID concluding that a subset of uses were safe. The carbofuran example provides no support for EPA's Final Rule.

EPA's new litigation position that it is not required to eliminate certain uses while maintaining those it found safe is just as flawed, as discussed below.

B. The FFDCA does not confine EPA to assess tolerance safety based on "existing registered uses" alone.

EPA claims the FFDCA requires it to consider aggregate exposure "based on existing registered (i.e., legally permitted) uses." EPA Br. at 22. But the language quoted from EPA's brief is not found in the statute. *See Lamie v. U.S. Tr.*, 540 U.S. 526, 538 (2004) (rejecting construction that "would have us read an absent word into the statute"). Instead, the FFDCA refers to safety decisions based upon "anticipated" exposures. 21 U.S.C. § 346a(b)(2)(A)(ii). "Anticipated" has a plain meaning—something "expected" or "looked forward to."[10] It does not mean "existing." If EPA could consider only existing uses, and on that basis had to make a single up-or-down safety determination applicable to the entire set, then EPA could never revoke or modify tolerances

[10] Anticipated, Merriamwebster.com, https://www.merriam-webster.com/dictionary/anticipated (last visited Sept. 1, 2022).

selectively to reduce the number of uses. But EPA now admits it can do just that. EPA Br. at 39.

EPA points to another provision of the FFDCA, 21 U.S.C § 346a(b)(2)(D)(vi), as support for its argument that anticipated exposures means exposures from existing registered uses. EPA Br. at 37. But the FFDCA's structure makes clear that consideration of existing approved uses is only the starting point for a safety determination—including this as one of nine factors EPA should consider in addition to available data and information in 21 U.S.C. §§ 346a(b)(2)(D)(i)-(ix), along with "anticipated" exposures, *id.* § 346a(b)(2)(A)(ii). EPA has elsewhere confirmed the universe of approved uses is just the "***starting point***" for EPA's risk assessment, which will also consider "proposed uses." A.R. 16 at 44–45; Resp'ts' App. 46–47 (emphasis added).[11]

Although the FFDCA requires EPA to assess "aggregate exposure" in making the safety determination, this cannot be read as code that re-

[11] The PID provided just such a proposal for limited uses. A.R. 40 at 40; Pet. App. 405. No authority exists for the proposition that only registrants have the power to define the "proposed" uses for EPA's FFDCA safety finding, or a formal proposal issued by EPA limiting such uses must be ignored.

writes the explicit text of the statute. The FFDCA requires EPA to make individualized safety determinations, 21 U.S.C. § 346a(b)(2)(A)(i), on the basis of available data and information, *id.* § 346a(b)(2)(D)(i), including any proposed uses and the corresponding "anticipated" exposures, *id.* § 346a(b)(2)(A)(ii). The reference to "aggregate exposure" naturally fits with these other provisions of the statute to instruct EPA to consider, in making its individual tolerance determinations, all the exposures a person is anticipated to encounter.[12]

This is in fact the approach EPA employed in the PID. EPA considered all chlorpyrifos tolerances "in effect" and concluded those uses would not fit within the metaphorical "risk cup." EPA then analyzed a subset of uses—the eleven Safe Uses—which would reduce

[12] EPA wisely elects not to invoke *Chevron* or any other argument for deference to its litigation position. Where an agency ignores the plain text of the statute and its settled application, and advances inconsistent interpretations in the very course of litigation, it can make no claim to deference. *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (collecting cases). And because EPA does not seek deference, this Court can provide none. *See Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 140 S. Ct. 789, 790 (2020) (court should not apply *Chevron* deference where agency fails to invoke it).

risk to acceptable levels, made a safety finding as to those uses, and set forth its conclusions in the PID.[13]

C. EPA does not need cancellations and label amendments from registrants to act on its FFDCA safety finding.

EPA argues it had to have cancellation and label amendment requests from all registrants in hand, narrowing the permitted uses to those set forth in the PID, before acting on its safety finding. EPA Br. at 49. This ignores the plain text of the FFDCA and FIFRA and the legal and practical effect of tolerance modification.

The FFDCA says EPA must consider "anticipated" exposures. If a tolerance does not satisfy the "reasonable certainty of no harm" safety standard, the FIFRA registration standard for that use is also not satisfied. *See* 7 U.S.C. § 136(bb)(2). Without a tolerance or existing stocks provision in place, it is illegal to distribute and sell a product

[13] Petitioners have pointed to several examples in which EPA made individual tolerance determinations for other pesticides. Pet'rs' Br. at 46–47. EPA claims these examples are distinguishable, because in those instances aggregate exposures did not exceed levels of concern. EPA Br. at 45. EPA ignores the fact that the FFDCA's text and structure do not change depending upon whether the "risk cup" overflows. Congress mandated that EPA make individual tolerance determinations based upon the available science and "anticipated" exposures, which requires EPA to analyze proposed uses.

labeled for that use. *See, e.g.*, 7 U.S.C. § 136j(a)(2)(S) (unlawful to violate regulation issued under FIFRA); 40 C.F.R. § 152.50(i) (establishing a tolerance as a requirement for registration of a food use pesticide). Moreover, foods containing residues not covered by a tolerance are deemed adulterated and may not be distributed in interstate commerce. 21 U.S.C. § 331(a); *id.* § 342(a)(2)(B). Thus, if EPA had in the Final Rule followed the science and revoked all tolerances other than those corresponding to the Safe Uses, it would have effectively banned any food uses other than the Safe Uses. EPA confirmed this in a Federal Register notice on the cancellation of some chlorpyrifos registrations. Cancellation Order for Certain Chlorpyrifos Registrations, 87 Fed. Reg. 53,471, 53,472 (Aug. 31, 2022) ("Once the tolerances expired, pesticide products containing chlorpyrifos could no longer be used on food crops."). EPA therefore certainly should have "anticipated" that regulated parties would follow the law and give up uses made unlawful by a tolerance revocation. Indeed, it would have been unreasonable and arbitrary and capricious for an agency to assume otherwise. *See Shays v. FEC*, 511 F. Supp. 2d 19, 28–29

(D.D.C. 2007) (rejecting agency argument that assumed regulated entities would not comply with rules unless prosecuted).

D. EPA's failure to act on its safety finding violates the APA.

Petitioners maintain the FFDCA by its plain terms required EPA to follow the science (specifically, the "available data" and "available information" on risk) and make safety decisions on individual tolerances by continuing those associated with the Safe Uses and revoking the rest. *Supra* at Part I.B. Importantly, however, this Court does not need to reach that issue in order for Petitioners to prevail. EPA's concession that it has the authority under the FFDCA to eliminate uses and make a safety finding on tolerances for the remainder, EPA Br. at 39, means EPA's failure to do so in this instance violated the APA.

The APA deems arbitrary and capricious agency actions that "run[] counter to the evidence." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must "examine the relevant data and articulate a satisfactory explanation for its action"); 5 U.S.C. § 706(2)(A). EPA had at its disposal scientific evidence—developed by expert Agency scientists in highly sophisticated, peer-reviewed risk assessments—that the Safe Uses are safe within the meaning of the FFDCA. *Supra* at Part I.A. EPA was required by the FFDCA and the APA (and the Ninth Circuit decision in *LULAC II*) to act on the evidence before it, which included the Scientific Assessments. 21 U.S.C. § 346a(b)(2)(D)(i); 5 U.S.C. § 706(2)(A); 996 F.3d at 703. Based on these Scientific Assessments, EPA "determined" in 2020 the Safe Uses met the FFDCA safety standard with a tenfold margin of safety. A.R. 40 at 40. EPA's decision to disregard the best available scientific evidence and its existing safety determination, and therefore revoke all tolerances, is arbitrary and capricious.[14]

III. EPA's new argument that it lacked the necessary record basis to act on its safety finding ignores the plain language of the statute and the undisputed facts.

As noted above, the latest evolution in EPA's argument concedes the FFDCA allows EPA to revoke or modify tolerances to conform to its safety finding, but contends it did not have a sufficient record upon which to do so. Specifically, EPA now claims it could modify tolerances to conform them to its PID safety finding as long as it had a "reasonable

[14] EPA's response ignores the case law cited in Petitioners' brief making it clear an agency may not disregard scientific evidence just because it may later be revised. *See* Pet'rs' Br. at 40–41, 56.

basis" to believe FIFRA registrations would be modified accordingly and within the time prescribed by the Ninth Circuit. EPA Br. at 49–51. The Ninth Circuit set no deadline for action on FIFRA registrations, ordering instead that they follow the tolerance decisions "in a timely fashion" after action on the tolerances. 996 F.3d at 704.[15] This "deciding question," as EPA characterizes it, thus boils down to whether some "reasonable basis" existed to believe registrations would be modified to eliminate all but the Safe Uses.

There is no question EPA had a "reasonable basis" to expect modification of chlorpyrifos registrations. As explained above, the practical effect of tolerance revocation is a ban on the use of the pesticide. *Supra* at pp. 19–20. For that reason, conforming voluntary cancellations and label amendment requests follow tolerance decisions with no less regularity than night following day. Indeed, that is just what occurred here. EPA Br. at 54–55 ("Following the expiration of

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[15] EPA's argument that registration changes would have to occur before tolerance decisions is contrary to the Ninth Circuit's order. It also ignores the central issue decided by the Ninth Circuit against EPA in *LULAC II*: EPA cannot require that tolerance decisions under FFDCA in response to a petition be "synchronize[d]" with FIFRA processes. 996 F.3d at 696.

chlorpyrifos tolerances, EPA received several requests for voluntary cancellation of chlorpyrifos registrations and published a notice regarding the 16 voluntary cancellations.") (citing 87 Fed. Reg. 25,256 (Apr. 28, 2022)). ***After*** revoking all chlorpyrifos tolerances, EPA sent a letter to registrants setting a deadline for registrants to submit cancellation requests and label amendments removing all food uses.[16] It would have been a simple matter for EPA to respond to *LULAC II* by issuing a final rule revoking all tolerances other than those associated with the Safe Uses, then issue a similar letter requiring registrants to make the necessary label amendments or cancel the registrations. Although EPA says additional geographic and application restrictions would need to be incorporated into the revised labels to conform to its safety finding, that is easily done. EPA had all the necessary information, including the geographic restrictions, A.R. 40 at 40; Pet.

[16] EPA posted some of the cancellation request letters to a public docket, available here: https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0223; *see, e.g.,* EPA-HQ-OPP-2022-0223-0017 (registrant letter referencing EPA March 3, 2022 letter). EPA omitted from this docket the voluntary cancellation request Gharda submitted, agreeing to voluntary cancellation for all but the Safe Uses. Pending the outcome of this litigation, Gharda also agreed not to sell any chlorpyrifos products labeled for food use.

App. 405, and application rates, A.R. 38 at 33–34; Pet. App. 34-35. Similar to other use changes, these modifications can be accomplished by amendments to the label through EPA's standardized Fast Track amendment process, through which EPA approves over a thousand amendments each year.

Ignoring these facts, EPA claims it would have a "reasonable basis" to anticipate narrowing of the uses only if it has cancellation and label amendment requests in hand to amend the underlying registrations to incorporate the PID's description of the Safe Uses. EPA Br. at 39–40, 51. In other words, EPA does not stop with asking the Court to insert an additional phrase ("reasonable basis") into the FFDCA—it then immediately asks the Court to translate that insertion into an "cancellation/amendments in hand" requirement. Without having those cancellation and label amendment requests in hand when the deadline arrived for a decision, EPA claims, it could do nothing other than declare everything unsafe. *Id.* Of course, EPA cites no statute, no regulation, and no case law for this proposition. Nor can EPA cite any example in which a Court countenanced such exponential rewriting of clear statutory text.

If the "cancellation/amendments in hand" requirement actually existed, one would think EPA could find some legal authority for it. One would also think EPA would have noted the existence of this requirement in its discussions with Gharda and specified the deadline. That never happened. Rather than telling Gharda what was required and setting a deadline for its submission, EPA mysteriously stopped communicating with Gharda entirely. Pet. App. 1611–25. No clearer evidence could exist that EPA's "cancellation/amendments in hand" requirement is a made up litigation position.

EPA's problems with its argument for a "cancellation/amendments in hand" requirement go beyond its dubious origin and lack of legal foundation. Even if it were credible, this argument runs headlong into the FFDCA's plain text, which places ***upon EPA*** the statutory duty to obtain from registrants the information necessary to determine whether existing tolerances can continue. The FFDCA requires EPA to take affirmative steps to request any "information" from registrants necessary to support continuation of an existing tolerance. "If the Administrator determines that additional data ***or information*** are reasonably required to support the continuation of a tolerance . . . . the

Administrator ***shall*** – [inter alia] (A) issue a notice requiring the [registrant] to submit the data or information . . . ." 21 U.S.C. § 346a(f)(1) (emphases added). This provision plainly applies to the decision EPA was making here—whether any existing chlorpyrifos tolerances could continue. The "information" EPA may demand from registrants in this circumstance includes information concerning the product label. *See* 40 C.F.R. § 156.10 (EPA regulation referring to label contents as "information"); 7 U.S.C. § 136(q)(1)(E) (FIFRA provision specifying label contents as "information"). If registrants do not provide EPA with the information required—which may include label amendments—the tolerances will be revoked. 21 U.S.C. §346a(f)(2). EPA's claim that it lacked the "tools" in the FFDCA necessary to get the information that would provide it a "reasonable basis" to reduce the number of approved uses, EPA Br. at 39, is false.

Not only did EPA have the tools to obtain the necessary information from registrants—it had the statutory obligation to use them as necessary to make its decision on continuing existing tolerances. 21 U.S.C. § 346a(f)(1) (EPA "shall" take one of the enumerated steps to obtain information "reasonably required").[17] But EPA did no such thing. Thus, even if it was true that the record lacked information concerning label amendments "reasonably required" for EPA to make a decision on tolerances, as EPA now contends, that would be due to EPA's violation of the FFDCA—not the fault of Gharda or any registrant.

The record evidence makes this clear. EPA and Gharda communicated for months about potential narrowing of uses, EPA's issuance of a safety finding on those narrowed uses consistent with the PID, and EPA's promulgation of an existing stocks order to cover the revoked uses. These negotiations were drawn out and complicated by EPA, not by Gharda. Pet'rs' Br. at 52–53. Throughout all these discussions, EPA never set a deadline for Gharda to submit a voluntary cancellation request, and never notified Gharda this was the only way EPA would be able to "anticipate" narrowing of uses in making a safety finding. EPA implies Gharda made an informed decision not to submit

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[17] Congress sensibly provided EPA the tools to obtain information and obligated the Agency to use them when necessary to support continuation of a tolerance. This protects the reliance interests of third parties such as Grower Petitioners, and the public at large, in a reliable and safe food supply.

a voluntary cancellation decision at its peril. EPA Br. at 51. Not true. The parties were nearing the final stages of months of negotiations on an agreement to retain a subset of uses—consistent with the PID—when EPA abruptly stopped communicating with Gharda about the process and what was required. Pet. App. 1611–25.[18] EPA advised Gharda to standby until EPA requested a voluntary cancellation letter memorializing the agreed terms, Pet. App. 1622–25; then EPA revoked all tolerances, claiming it had to do so in the absence of additional information from the registrants. That is contrary to what Congress commanded EPA do. *See* 21 U.S.C. § 346a(f)(1). And that is not the "fair" harmonization of the FFDCA and FIFRA Congress intended. H.R. Rep. No. 104-669(II), 104th Cong. at 51 (1996). Not only did EPA's unlawful actions harm Gharda; its actions unfairly deprived Grower

[18] EPA acknowledges these types of informal discussions with registrants are customary and how registrations are often amended to conform to tolerance determinations. *See* EPA Br. at 46. The Agency is not without authority to act on its own, however, if it genuinely believes it needs additional information to support its action. *Supra* at pp. 26–28.

Petitioners of a critical crop protection tool upon which Grower Petitioners depend.[19]

CONCLUSION

EPA's Final Rule violated the FFDCA and the APA. EPA's attempts to defend it have no support in the FFDCA, the regulations, or the case law—including *LULAC II*. In fact, EPA violated the remand instructions of *LULAC II* by refusing to act on the available evidence, and continues to ignore *LULAC II*'s central holding by arguing that FIFRA registration proceedings should conclude before making tolerance safety decisions.

Petitioners respectfully request that the Court grant Petitioners' request to vacate the Final Rule and Denial Order and remand with instructions that EPA issue a final rule conforming to the FFDCA and its mandate to consider the "available" scientific evidence and the "anticipated" exposures from the "proposed" uses identified in the PID.

[19] EPA's suggestion that Gharda is not without a remedy because it can simply petition for new tolerances is not reasonable. First, this ignores the time and expense involved for Gharda. *See* Pet. App. 1795 ¶¶5–6. Second, that would do nothing for the Grower Petitioners whose crops will be severely damaged by pests without the immediate use of chlorpyrifos.

Contrary to EPA's claim, those instructions would not require EPA to retain all tolerances. EPA Br. at 22, 56. Instead, Petitioners request that the Court direct EPA to act consistent with its safety finding and retain the tolerances for the Safe Uses. Consistent with the Ninth Circuit's remand instructions, this Court should order EPA to do so immediately and without further notice and comment, under 21 U.S.C. § 346a(d)(4)(A)(i).

September 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply Brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 6380 words.

I further certify that Petitioners' Brief complies with the typeface and type style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), as it was prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Pursuant to Eighth Circuit Rule 28A(h)(2), I certify that the electronic version of this Brief has been scanned for viruses and is virus-free.

September 2, 2022

s/ Nash E. Long
Nash E. Long

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 2, 2022, a true and accurate copy of the foregoing Reply Brief was electronically filed with the United States Court of Appeals for the Eighth Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, Petitioners will serve each party separately represented with a paper copy of the brief.

I further certify that ten (10) paper copies of the foregoing Brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Rule 28A(d).

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September 2, 2022

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EXHIBIT 13

October 29, 2021

Via EPA E-Filing System and Federal eRulemaking Portal

U.S. Environmental Protection Agency
Office of Administrative Law Judges
Mail Code 1900R
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: Objections to Decision Revoking All Chlorpyrifos Tolerances (EPA-HQ-OPP-2021-0523)

To Whom It May Concern:

Under Section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(g), the American Sugarbeet Growers Association (ASGA) and the U.S. Beet Sugar Association (USBSA) (collectively, the "Associations") hereby submit their objections to the U.S. Environmental Protection Agency's (EPA or the "Agency") August 30, 2021 decision to revoke all tolerances for the insecticide chlorpyrifos (the "Final Rule").[1] The Final Rule is inconsistent with the Agency's own scientific record on chlorpyrifos with respect to the safety of certain uses. It is also inconsistent with the requirements of applicable statutes and regulations, as well as a court order. This arbitrary decision causes unnecessary and irreparable harm to the Associations' members, the growers and manufacturers of beet sugar. Based on our objections, we request that the Final Rule be immediately reversed, or, at the very least, amended to reflect modification of the tolerances for sugarbeets consistent with the Agency's safety findings. We also request a stay of the effective date of the Final Rule to allow EPA time to respond to these objections, including consideration of maintaining the tolerances for sugarbeets,[2] without unduly and irreparably harming our members.[3]

I. INTRODUCTION

A. The American Sugarbeet Growers Association and the U.S. Beet Sugar Association

[1] Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021).

[2] There are four beet sugar tolerances; we request EPA retain each of them: (1) Beet, sugar, dried pulp, 5.0 parts per million (ppm); (2) Beet, sugar, molasses, 15 ppm; (3) Beet, sugar, roots, 1.0 ppm; and (4) Beet, sugar, tops, 8.0. 40 C.F.R. § 180.342(a)(1).

[3] *See* American Sugarbeet Growers Association and U.S. Beet Sugar Association, *Request for a Stay of Decision Revoking All Chlorpyrifos Tolerances* (EPA-HQ-OPP-2021-0523) (filed concurrently with these objections, requesting, at a minimum, a stay as to the 11 safe uses identified in the EPA's December 2020 Proposed Interim Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0971).

The American Sugarbeet Growers Association and the U.S. Beet Sugar Association represent farmer-owners and manufacturers that both grow and process over 56 percent of all sugar produced in the United States. ASGA's members associations represent 10,000 family farmers. And USBSA's nine manufacturing firms operate 21 factories that process refined white sugar, molasses, and dried beet pulp from sugarbeets. Together, we account for 1.2 million acres grown in 11 states: California, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming. Our farmers and farmer-owned processing facilities account for over 100,000 rural jobs, and contribute over $10.6 billion annually to the U.S. economy. The U.S. beet sugar industry has become a global leader in environmental sustainability as we have invested in significant programs that preserve our natural resources, family farms, unionized workforces, and rural communities for future generations. As a result, our industry now produces 29 percent more sugar on 8 percent less land than 20 years ago, and sugarbeets now require significantly less land, water, fuel and fewer pesticide inputs to grow.

Our industry depends significantly on chlorpyrifos as a critical, and in certain circumstances the only, crop protection tool available to fight pests and to meet the sugar demands of the U.S. food economy. In 2020, EPA recognized the high total benefits of chlorpyrifos use, estimating high-end benefits to be up to $32.2 million per year for sugarbeets.[4] This estimate is likely an underestimate.[5] According to EPA's own estimates, the per acre benefits of chlorpyrifos could be as high as $500 in parts of Minnesota and North Dakota, leading to Agency-estimated high-end benefits over $30 million overall.[6] And EPA acknowledges the lack of alternatives leading to potential yield loss in sugarbeet crops in Minnesota and North Dakota.[7] Losing chlorpyrifos as a critical tool would be devastating to our growers. As another example, Oregon seed production growers estimate that without chlorpyrifos they would suffer between $251,000 and $753,000 in revenue losses just from loss of seed production due to symphylan (garden centipede) damage.[8]
One of the primary pest targets for chlorpyrifos use in sugarbeets is the sugarbeet root maggot (SBRM). Chlorpyrifos is the most effective post-emergence liquid insecticide available for the control of SBRM flies. Registered alternatives to chlorpyrifos can only suppress SBRM, not

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[4] U.S. EPA, Memorandum, Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101), EPA-HQ-OPP-2008-0850-0969, at 49 (Nov. 18, 2020) [hereinafter, "Benefits Analysis"], https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969. For all agricultural uses of chlorpyrifos, EPA estimated the "total annual economic benefit of chlorpyrifos to crop production is estimated to be $19 - $130 million." U.S. EPA, Proposed Interim Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0971, at 39 (Dec. 3, 2020) [hereinafter, "PID"], https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971.
[5] We believe EPA has underestimated the percent crops treated with chlorpyrifos in their underlying benefits analysis, thus leading to an underestimate of benefits of chlorpyrifos in the PID. The Benefits Analysis notes that in states other than MN and ND, the percent crop treated (PCT) is 9%. Benefits Analysis at 10. Kynetec data for 2014–2018, however, show that for Idaho the PCT is 40–80%. U.S. EPA, Memorandum, Chlorpyrifos (059101) National and State Use and Usage Summary, EPA-HQ-OPP-2008-0850-0968, at 10 (Apr. 1, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0968. It is not clear that EPA appropriately accounted for this when averaging Idaho with other states. We also note the importance of an accurate tally of all states in which sugarbeets are grown. *Compare* PID at 41 (listing IL, LA, and WI as states that grow sugarbeets, and omitting WY), *with* Use Summary at 5, 10 (not listing IL, IA, and WI, but including WY).
[6] PID at 42.
[7] Benefits Analysis at 5.
[8] Chlorpyrifos is the only fully registered rescue option available in early spring to control symphylans and is typically applied on 25% to 33% of total sugarbeet seed production acres.

control it, or are only registered for use on adult flies, not larvae.[9] It is important to note, however, that not all sugarbeet acres are treated with chlorpyrifos each crop year. Chlorpyrifos applications for SBRM fly control are made only after determining there is a need,[10] and are targeted to specific areas of need based on monitoring of the sugarbeet growing geography.

B. Statutory Authority

i. FFDCA Tolerance Revocations

The FFDCA requires EPA to set food safety "tolerances," the maximum levels of pesticide residue allowed in or on food.[11] EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe."[12] When establishing, modifying, or revoking a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue."[13]

The Food Quality Protection Act (FQPA) amended the FFDCA to establish, among other things, a safety standard for pesticide tolerances pertaining to pesticide residues in or on raw agricultural commodities, such as sugarbeets. Such a tolerance is deemed "safe" if "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[14] This provision contemplates exposures from food, drinking water, and in residential settings, but *not* occupational exposure. When assessing "reasonable certainty of no harm," EPA applies an additional tenfold ("10x") margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[15] The Agency may, however, apply a different margin of safety—for instance, a 1x safety factor—if there is "reliable data" to support doing so.[16]

ii. Tolerance Revocation and FIFRA

When revoking a tolerance "for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA]."[17] That related action may be canceling that pesticide's registration and entering an "existing stocks" order under which

[9] David Franzen, et al., North Dakota State University, 2021 Sugarbeet Production Guide (Jan. 2021), https://www.ag.ndsu.edu/publications/crops/sugarbeet-production-guide.
[10] *See Comment submitted by Joe Hastings, General Agronomist, American Crystal Sugar Company*, EPA-HQ-OPP-2008-0850-0978), https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-0978 (comment submitted on EPA's Notice of Proposed Interim Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0964).
[11] 21 U.S.C. § 346a.
[12] *Id.* § 346a(b)(2)(A)(i).
[13] *Id.* § 346a(b)(2)(D)(i).
[14] *Id.* § 346a(b)(2)(A)(ii).
[15] *Id.* § 346a(b)(2)(C)(ii)(II).
[16] *Id.*
[17] *Id.* § 346a(l)(1).

EPA may "permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled."[18]

C. The Agency's Decision to Revoke All Chlorpyrifos Tolerances

On August 30, 2021, EPA issued a Final Rule revoking *all* tolerances for chlorpyrifos.[19] EPA stated that "given the currently registered uses of chlorpyrifos, EPA cannot determine that there is a reasonable certainty that no harm will result from aggregate exposure to residues, including all dietary (food and drinking water) exposures and all other exposures for which there is reliable information," notwithstanding the FQPA 10x safety factor to address "uncertainties" in relevant epidemiology studies.[20] At the same time, however, EPA re-acknowledged or confirmed findings from its December 2020 Proposed Interim Decision (PID). For instance, regarding aggregate exposure, EPA confirmed that "exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern,"[21] and only the combination of drinking water exposures with food and non-occupational exposures would raise the risk of concern.[22] Consistent with the PID, the Agency acknowledged that drinking water exposures associated with use on only 11 enumerated crops in specific regions do not exceed levels of concern.[23] EPA even admitted that "there may be limited combinations of uses that could be safe."[24]

As described in the Final Rule, EPA's action was against the backdrop of many years of administrative process and litigation surrounding chlorpyrifos. In 2007, several nongovernmental organizations (NGOs) petitioned EPA to revoke all chlorpyrifos tolerances. After years of delay, EPA issued an order denying that petition (2017) and subsequently denied the NGOs' objections made to that order (2019).[25] After additional litigation, on April 29, 2021, the U.S. Court of Appeals for the Ninth Circuit vacated both denials. On remand, the Court ordered the Agency to:

> [I]ssue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information," including for "infants and children"; and . . . 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).[26]

[18] 7 U.S.C. § 136d(a), (b).
[19] 86 Fed. Reg. at 48,315.
[20] *Id.* at 48,317.
[21] *Id.* at 48,333.
[22] *Id.*
[23] *Id.* The 11 uses that EPA determined to be high-benefit, critical crop uses are alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, **sugarbeet**, strawberry, and wheat. PID at 15–17.
[24] 86 Fed. Reg. at 48,333.
[25] *See League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 680–90 (9th Cir. 2021) ("*LULAC*") (detailing procedural history beginning with 2007 petition).
[26] *Id.* at 703–04.

The Court's order made clear that EPA could "choose to modify chlorpyrifos tolerances, rather than to revoke them," if the decision included the required safety determination.[27] In issuing its decision, the Court was aware of EPA's PID for chlorpyrifos, which had identified 11 uses of chlorpyrifos, including for sugarbeets, that could continue even if the Agency applied the 10x FQPA safety factor. The Court explained:

> [D]uring the pendency of this proceeding, in December 2020, the EPA issued a Proposed Interim Registration Review Decision proposing to modify certain chlorpyrifos tolerances. The EPA also convened another [Scientific Advisory Panel] in 2020. If, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them.[28]

Four months later, EPA published its Final Rule in response to the Court's order. Yet, rather than modify tolerances consistent with its own preliminary findings that 11 crop uses in select regions were safe,[29] the Agency chose to revoke *all* chlorpyrifos tolerances. EPA set tolerances to expire on February 28, 2022, a mere six months from publication of the Final Rule.

II. OBJECTIONS

The Associations object to EPA's flawed decision on multiple grounds. The Agency turned a blind eye to scientific data and safety findings in its own PID, improperly canceling tolerance uses that the Administrator can and should leave in effect under the requirements of the FFDCA. The Agency also failed to comply with the FFDCA and the Ninth Circuit's order by failing to harmonize its revocation decision with FIFRA. In addition, EPA abused its discretion by taking an overly cautious risk assessment approach based on hedging for uncertainty. The Agency also failed to consider other relevant scientific information and comments entirely, thus depriving stakeholders of due process. In addition to these flaws, EPA did not address the implications of its decision on existing stocks of chlorpyrifos products. Further, the Agency failed to undertake proper interagency review of the Final Rule before it was issued.

For these reasons, and because of the unnecessary, significant, imminent, and irreparable harm the Associations' members will suffer because of EPA's decision to revoke *all* tolerances,[30] the Final Rule should immediately be reversed, or, at the very least, amended to leave in effect the tolerances for sugarbeets consistent with the Agency's safety findings.

A. EPA's Failure to Rely on Its Own Prior Safety Findings for Eleven High-Benefit Crop Uses and to Harmonize those Findings with the FIFRA Registrations is Arbitrary and Capricious.

EPA's stated rationale for the revocation of *all* tolerances was that it could not make a safety finding for all current chlorpyrifos registered uses. As discussed further below, the Associations

[27] *Id.* at 702.
[28] *Id.* at 703.
[29] *See* PID at 40.
[30] As set out in detail in the Associations' accompanying stay request. *See* note 3*, supra*.

object generally on the grounds that EPA failed to base its decision on best available science for all uses and tolerances, for example by relying on the 2016 Drinking Water Assessment instead of the refined 2020 Drinking Water Assessment. But the Agency's decision to revoke *all* tolerances—including 11 high-benefit crop uses in specific regions that it previously identified in its PID as safe, such as sugarbeets—is arbitrary and capricious and otherwise not in accordance with the FFDCA. The PID carefully considered 11 crop uses in specific regions and determined that those uses "will not pose potential risks of concern with an FQPA safety factor 10x."[31] But even after reaffirming the PID's safety findings in the Final Rule, EPA simply refused to apply those findings when it determined to revoke the tolerances for the safe high-benefit crop uses. EPA clearly has the necessary data, the ability, and the authority to preserve the tolerances for these 11 uses. Not leaving the tolerances in effect for these 11 uses when the record supports doing so is arbitrary and capricious.[32]

EPA justified its decision by assuming that all currently registered uses are the baseline against which it must make its FFDCA safety evaluation. The Final Rule states that "the Agency's analysis indicates that aggregate exposures (i.e., exposures from food, drinking water, and residential exposures), ***which stem from currently registered uses***, exceed safe levels, when relying on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment . . . ."[33] But nothing in the FFDCA or the Ninth Circuit's order directs that approach; in fact they encourage the opposite. Section 408(b)(2) of the FFDCA directs that EPA may "leave in effect a tolerance . . . if the Administrator determines that the tolerance is safe."[34] And "[t]he Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe."[35] In making this finding, EPA must consider the "result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[36]

The Final Rule's conclusion that EPA cannot make the required safety finding is premised on a faulty baseline of *all* chlorpyrifos tolerances and *all* chlorpyrifos registrations remaining in place. EPA is fully capable of cancelling the tolerances where it cannot make the FFDCA safety finding and leaving in place the tolerances for the 11 safe uses, including sugarbeets. To fail to leave in effect the 11 tolerances for which the PID's science-based conclusions have already supported a safety finding runs afoul of the express direction in Section 408(b)(2). And nowhere in the Final Rule does EPA claim that this approach is unavailable to it. Accordingly, if EPA has the authority and necessary scientific support to lawfully leave in effect the tolerances for the 11 uses, yet it chooses to revoke these tolerances on the false premise that it cannot tailor its decision appropriately under FFDCA and FIFRA, it has significantly misapprehended its legal authority.

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[31] PID at 40. We also object to EPA's specific application of the 10x FQPA safety factor "to account for uncertainties" in relevant epidemiological studies. EPA improperly inserted data from studies that, by its own admission, were incomplete and unreliable, to support application of the 10x safety factor. EPA is authorized to make decisions based on valid, complete, and reliable data in its safety analysis. *See* 21 U.S.C. § 346a(b)(2)(D)(i). The Agency's misapplication of that authority is an abuse of discretion.

[32] The Associations request an evidentiary hearing under 21 U.S.C. § 346a(g)(2)(B) to demonstrate that the best available science, including EPA's 2020 PID, supports a finding that the tolerances for sugarbeets can remain in effect.

[33] 86 Fed. Reg. at 48,333 (emphasis added).

[34] 21 U.S.C. § 346a(b)(2)(A)(i).

[35] *Id.*

[36] 86 Fed. Reg. at 48,333 (quoting 21 U.S.C. § 346a(b)(2)).

This conclusion also sets a very negative precedent that the Agency could broadly revoke all tolerances, regardless of whether registrants, users, or EPA's own career scientists, have demonstrated the safety of the continued food use of a pesticide under the proper set of conditions on specific crops. EPA's all or nothing approach could be very damaging to pesticide programs in the future if it is allowed to stand.

Beyond EPA's clear ability to leave in effect a subset of chlorpyrifos tolerances for the 11 safe uses, EPA's faulty baseline also ignores its legal obligations under FFDCA to harmonize a tolerance revocation with FIFRA—that is, where the Agency revokes a tolerance, it must take corresponding action under FIFRA regarding the relevant registration. The FFDCA states in relevant part:

> (1)Coordination with FIFRA
>
> To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, ***the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act*** [7 U.S.C. 136 et seq.].[37]

This is a statutory duty. The statutory scheme for food uses of pesticides obviously contemplates tolerances and registrations to work in concert. The Final Rule offers no explanation why it is not "practicable" to cancel the FIFRA registrations and the tolerances for the food uses where EPA cannot make a safety finding,[38] while maintaining the registrations and tolerances that the 2020 PID found to be safe.[39] By not proposing this alternative or offering any discussion of this more tailored approach EPA disregarded its statutory duty to coordinate its tolerance revocation decisions with FIFRA. Moreover, nothing prevented EPA from using a baseline in its revocation decision that assumes the continued registration for only the 11 uses. The failure to even analyze an alternative baseline in the Final Rule, which is safe yet less burdensome to the agriculture sector, demonstrates that EPA has not considered all aspects of the problem, and is therefore arbitrary and capricious.

What is more, the Ninth Circuit expressly ordered the Agency on remand to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion" when issuing a final decision to revoke or modify the chlorpyrifos tolerances.[40] The Court recognized that the PID

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[37] 21 U.S.C. § 346a(l)(1) (emphasis added).

[38] *See* Gharda Chem. Int'l, Inc., Objections to the Final Rule Revoking All Tolerances for Chlorpyrifos, EPA-HQ-OPP-2021-0523, at 30 (noting that registrant voluntarily agreed with EPA to cancel unsafe registrations). *See generally* Part III.I, *infra* (incorporating by reference Gharda's comments, among others).

[39] The Final Rule provides for no corresponding action regarding chlorpyrifos registrations. Nor do the answers on EPA's Final Rule FAQ webpage, launched after the Final Rule was issued, provide any guidance. There, at most, the Agency paid mere lip service to its duty to take action on registrations by stating, without any elaboration on process or timing, that it "intends to cancel registered food uses of chlorpyrifos associated with the revoked tolerances under FIFRA, as appropriate." U.S. EPA, Frequent Questions About the Chlorpyrifos 2021 Final Rule, Question 9, https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-9.

[40] *LULAC*, 996 F.3d at 678, 703–04.

contemplated modifying certain tolerances and that it was possible for EPA to do so if it made the safety determination based on the PID's findings.[41] Thus, EPA's failure to harmonize its decision with FIFRA is not only a failure to uphold a statutory duty but also is inconsistent with a Court order.

EPA's communications with the Associations after issuing the Final Rule demonstrate that EPA has no concern that the sugarbeet tolerances can be safely retained. EPA invited stakeholders to submit questions regarding its revocation decision, and the Associations submitted questions, including asking about sugarbeet residue data. In answering, the Agency reminded the Associations that "chlorpyrifos risks from food, including sugar from sugar beets and all other foods, is very low *and not of concern*; sugar beets are not expected to contribute significant risk to the total dietary exposure. The primary contribution to overall chlorpyrifos risks is from residues in drinking water."[42] Consistent with this communication, the Agency could easily make a safety finding for sugarbeets based on the PID and thereby leave in effect the existing tolerances for sugarbeets (as well as the 10 other safe uses). Yet, EPA has decided to subject the Associations to additional administrative processes by leaving them no recourse but to seek new use tolerances for sugarbeets. The burden on the Associations to establish new use tolerances for sugarbeets would be incredibly heavy both procedurally and because of the preventable crop losses that will occur in the interim while EPA considers setting a new tolerance.[43] It makes no sense to subject the Associations to that protracted, costly endeavor where, based on all the information it has available to it, EPA could easily leave in place the tolerances (and registrations) for a food use—sugarbeets—that it has deemed safe.

The Associations object to the unnecessary manner in which EPA erects all of the existing registered chlorpyrifos uses as an impediment that allegedly forces EPA to cancel the tolerances for the 11 uses found safe in the PID along with all other uses of chlorpyrifos. This approach is pretextual, not supported by sound science, and fails to adhere to the FFDCA and the Court's order.[44] EPA should at a minimum preserve the tolerances for the 11 uses and harmonize any modifications needed (if any) on the registrations for those uses, and it should stay the effective date of the Final Rule to allow for this work if necessary. Sugarbeet growers will suffer severe economic harm when the revocation takes effect if EPA fails to address these issues.

B. In Issuing an Unnecessary and Overbroad Revocation of the Tolerances EPA Failed to Adequately Consider the Beet Sugar Industry's Reliance Interests.

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[41] *Id.* at 703.

[42] Letter from Mr. Ed Messina, EPA, to Ms. Cassie Bladow and Mr. Luther Markwart, 5 (Oct. 12, 2021) [hereinafter, "Messina Letter"] (emphasis added) (attached hereto as "Attachment A").

[43] *See* U.S. EPA, PRIA Fee Category Table - Registration Division - New Uses, https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-new-uses (last visited Oct. 28, 2021) (for action code R150, new food use, listing the decision time as 21 months and an application fee of $349,608; and, for action code R170, additional food use, listing the decision time as 15 months and an application of $87,483).

[44] *See LULAC*, 996 F.3d at 678, 703–04 (instructing that EPA "may modify chlorpyrifos registrations rather than cancelling them," "[i]f, based upon the EPA's further research," namely the 2020 PID as well as a 2020 Scientific Advisory Panel, "EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe"; and expressly ordering EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion" when issuing a final decision to revoke or modify the chlorpyrifos tolerances).

"When an agency changes course, . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'"[45] The agency is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns."[46]

EPA's overbroad revocation upends decades of Agency-approved chlorpyrifos use, where EPA otherwise could lawfully and based on sound science leave in effect the tolerances for the 11 high-benefit crops—including sugarbeets. The Final Rule fails to consider the sugarbeet growers' and processors' reliance interests in applying safe and effective pesticides. Had EPA properly weighed those significant interests, it would have left the tolerances in effect for which it could have made a safety finding under the FFDCA, while revoking the tolerances where it could not. By this failure, EPA improperly minimized the interests of a multi-billion dollar industry that is responsible for over 100,000 jobs, and that has relied on chlorpyrifos for decades to grow and process over half of all sugar produced in the United States. "It w[as] arbitrary and capricious to ignore such matters."[47]

C. EPA's Decision is Highly Conservative and Overly Protective.

The Associations also object because the scientific record is highly conservative and unnecessarily protective. We focus on two main areas in EPA's general risk evaluation approach, which includes compounded conservative assumptions.

i. EPA Misapplies the 10x FQPA Factor.

The weight of the evidence does not support the use of epidemiology data to apply a Food Quality Protection Act (FQPA) 10x safety factor for chlorpyrifos. In the Final Rule, EPA applies the 10x safety factor to address the "uncertainties surrounding the potential for adverse neurodevelopmental outcomes."[48] This is a highly conservative approach. EPA has been unable to establish any plausible biological explanation for the reported neurodevelopmental associations. For 10 years EPA has sought to address neurodevelopmental effects of chlorpyrifos and as stated in the Final Rule "these efforts ultimately concluded with the lack of a suitable regulatory endpoint based on these potential effects."[49] EPA determined that the most appropriate toxicological endpoint for assessing chlorpyrifos risks is to continue to use cholinesterase inhibition.[50] The 10x FQPA safety factor is admittedly applied by EPA as a "presumption" and is not based on reliable or sufficiently valid evidence. The concerns with the epidemiology data have been repeatedly presented to EPA, including most recently by the OP Coalition.[51] In fact, EPA has never been able to verify the conclusions of the epidemiology studies, and due to EPA's inability to receive the underlying data from the researchers, EPA likely will never be able to verify the conclusions of these studies. Yet these unsupported and unreliable data are inappropriately used by EPA to

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[45] *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)).
[46] *Id.* at 1915.
[47] *Id.* at 1913 (quoting *Encino*, 136 S. Ct. at 2126).
[48] 86 Fed. Reg. at 48,325.
[49] *Id.* at 48,322.
[50] *Id.* at 48,325.
[51] *See generally* Part III.I, *infra* (incorporating by reference OP Coalition's comments, among others).

support application of the 10x safety factor. While the FQPA provides that a different safety factor may be used if based on "reliable data," EPA takes a highly conservative approach by choosing to keep the 10x safety factor based on these unreliable data. If these unreliable epidemiological studies were removed from consideration, there would be no justification for maintaining the 10x safety factor as the rest of the scientific record clearly supports a safety factor of 1x.

ii. EPA's Use of the 2016 Drinking Water Assessment is Highly Conservative and Inaccurate.

The Final Rule acknowledges that the 2016 Drinking Water Assessment was refined to better account for variability and to better estimate regional and watershed drinking water concentrations.[52] These refinements underwent peer review, as described in the Final Rule and resulted in the release of a September 2020 refined drinking water assessment.[53] The refinements included incorporating new surface water modeling scenarios, the quantitative use of surface water monitoring data, new methods for considering the entire distribution of community water systems percent cropped area and integration of state level crop treated data using percent crop treated factors. However, in deciding to revoke all chlorpyrifos tolerances, EPA simply ignored the 2020 highly-refined assessment and used the less-refined 2016 Drinking Water Assessment.

On March 23, 2021, EPA Administrator Regan reaffirmed scientific integrity as a core value at EPA and noted that EPA's "ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies."[54] By relying on an admittedly outdated water assessment in a final regulatory action, when a more robust assessment exists and is available, EPA is failing to meet its own standards of scientific integrity and excellence. The 2020 refined drinking water assessment represents the best available science, yet EPA arbitrarily and capriciously opted to rely on the earlier 2016 assessment. EPA explained:

> While the 2020 DWA produced estimated drinking water concentrations that were below the DWLOC of 4.0 ppb, those EDWCs were contingent upon a limited subset of chlorpyrifos use. When assessing different combinations of only those 11 uses in specific geographic regions, the modeling assumed that chlorpyrifos would not be labeled for use on any other crops and would not otherwise be used in those geographic regions. At this time, however, the currently registered chlorpyrifos uses go well beyond the 11 uses in the specific regions assessed in the 2020 DWA. Because the Agency is required to assess aggregate exposure from all anticipated dietary, including food and drinking water, as well as residential exposures, the Agency cannot rely on the 2020 DWA to support currently labeled uses.[55]

EPA's explanation does not address the primary issue. The 2020 DWA, a robust, refined study, clearly supported a safety finding for the 11 enumerated uses in specific geographic regions. But

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[52] *Id.* at 48,332.

[53] *See generally* U.S. EPA, Memorandum, Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-2008-0850-0941 (Sept. 15, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.

[54] *See* Michael S. Regan, Message from the Administrator (Mar. 23, 2021), https://www.epa.gov/sites/default/files/2021-03/documents/regan-messageonscientificintegrity-march232021.pdf.

[55] 86 Fed. Reg. at 48,333.

EPA maintained that it could not use the regionally focused 2020 DWA to support all currently labeled uses. But the Ninth Circuit ordered EPA to *modify* tolerances if the data and information supported a safety finding, *and* to accordingly modify or cancel registrations. EPA had the ability and all the information it needed to modify registrations for these 11 uses. There is no adequate explanation in the Final Rule for rejecting this more tailored approach.

iii. EPA Failed to Adequately Consider Relevant Scientific Data and Information.

Because of EPA's excessive delays in this matter, the Ninth Circuit specifically chose not to remand to the Agency for further fact finding, but rather directly ordered the Agency to revoke or modify the chlorpyrifos tolerances based on the abundant data and information the Agency had on hand.[56] The Court believed that EPA could make its final decision based on that information. Yet, the Agency managed to ignore substantial pieces of information and data, including in comments and studies challenging EPA's 2016 DWA, among other things. The Agency's refusal to properly consider them resulted in a decision based on incomplete analysis, which affects all stakeholders, including the Associations and the growers and processors they represent.

D. EPA Has Failed to Respond to Comments Throughout this Process, thus Depriving the Stakeholders of Due Process.

EPA has failed to respond to comments throughout the history of this matter, namely, the over 90,000 comments the Agency received on its 2015 proposed rule to revoke tolerances. The Agency's failure to consider pertinent information and respond to comments deprives all stakeholders of their due process rights and renders the Final Rule arbitrary and capricious.

E. EPA Failed to Adequately Address the Revocation's Implications for Existing Stocks of Chlorpyrifos Products.

Related to its failure to perform its statutory and court-ordered duty to take action on chlorpyrifos registrations, EPA also failed to adequately address its broad revocation's implications for existing stocks of chlorpyrifos products. Again, on this issue, the Final Rule says nothing. And the FAQ webpage offers no workable guidance. There, the Agency has reasoned that because it "has not cancelled any chlorpyrifos products as a result of the final tolerance rule," "there are no existing stocks at this time."[57] That statement simply ignores that end-users like sugarbeet growers may have large inventories of chlorpyrifos products, the proper handling of which will be unclear once the tolerance revocation takes effect.

FIFRA authorizes EPA not only to cancel or suspend pesticide registrations[58] but also to issue existing stock orders, which allows for "the continued sale and use of existing stocks of a pesticide

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[56] *LULAC*, 996 F.3d at 702–03.

[57] U.S. EPA, Frequent Questions About the Chlorpyrifos 2021 Final Rule, Question 9, https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-9.

[58] 7.U.S.C. § 136d(a), (b).

whose registration is suspended or cancelled."[59] These orders are imperative to ensuring the safe handling of pesticide products that can no longer be used. Here, EPA has revoked all chlorpyrifos tolerances and has stated that once that revocation takes effect, "sale and distribution of chlorpyrifos products labeled for use on food crops would be considered misbranded; therefore, it would be a violation of FIFRA to sell and distribute those products."[60] But EPA fails to fulfill its duty under FIFRA to facilitate proper handling of existing stocks. As a result, sugarbeet growers have no clear path for handling existing stocks, which would cause nothing but undue confusion, increased risk of legal liability, and excess costs incurred as they attempt to navigate these waters without agency guidance.

F. EPA's Final Rule Failed to Comply with the Interagency Review Process, Thereby Denying Stakeholders an Opportunity to Participate in the Process.

In effect since 1993, Executive Order 12866, sought "to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public."[61] These important goals have been respected by all Presidents and administrations since 1993. Executive Order 12866 requires that significant regulatory actions go to the Office of Management and Budget (OMB) for coordinated interagency review. Significant regulatory actions are defined to include regulatory actions that "[h]ave an annual effect on the economy of $100 million or more or adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities."[62] Further, in 1993 guidance, OMB clarified that while some actions regarding tolerances were exempt from OMB review, an OMB review was still required for actions "that make an existing tolerance more stringent."[63]

EPA's Final Rule clearly meets the significant regulatory action criteria in Executive Order 12866 and as a rulemaking which makes a tolerance more stringent (by effectively revoking it to make the tolerance equivalent to zero), this rulemaking clearly should have undergone interagency review as directed by the Executive Order. In responding to questions about the bypassed review process, EPA has stated that "[t]he court-ordered deadline that the Agency was subject to comply with for this action resulted in the rapid timeline for this final rule."[64] EPA did not deny that the Final Rule should have gone to OMB for review. However, there are no exceptions in Executive Order 12866 for rapid timelines, and OMB has a history of accommodating reviews that are shorter than the typical 90 day review. While the OMB review process is limited to 90 days in the Executive Order, there is no minimum period for review. As such, EPA should have submitted this rule to OMB. Such a review not only would have afforded EPA the benefit of valuable feedback from other agencies, including the United States Department of Agriculture (USDA), but also it would have allowed our greatly impacted industry to voice our concerns with EPA and other agencies, including White House officials. As EPA noted in the PID and Benefits Analysis, our

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[59] *Id.* § 136d(a)(1).
[60] *Id.*
[61] Exec. Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993).
[62] *Id.* § 3(f)(1).
[63] OMB, Memorandum for Heads of Executive Departments and Agencies and Independent Regulatory Agencies on Guidance for Implementing E.O. 12866, M-94-3, app. C at 15 (Oct. 12, 1993), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/eo12866_implementation_guidance.pdf.
[64] Messina Letter at 10.

industry is highly impacted by EPA's revocation of the tolerances for sugarbeets and had we been afforded the opportunity, we believe our compelling facts would have altered the outcome of the Final Rule which ignored EPA's own science and arbitrarily and capriciously revoked the chlorpyrifos tolerances for all food uses.

G. Publicly Available Data Show No Residues of Chlorpyrifos on Sugarbeets and Sugarbeet Products.

While tolerances exist for sugarbeet roots, sugarbeet tops, dried beet pulp, and sugarbeet molasses, the record shows that no residues have ever been detected. As such, analyses conducted by EPA using the tolerance level as an exposure level are highly conservative. The data do not support the need for tolerances for sugarbeets and sugarbeet products. FDA's own Total Diet Study[65] shows no chlorpyrifos in processed sugar. In addition, residue data tests conducted by American Crystal Sugar Company, which has been testing products since 2016, have found no residues on sugarbeet products, including on crystallized sugar, molasses, and dried pulp.[66] EPA's own Pesticide Monitoring Program Fiscal Year 2016 Pesticide Report does not mention any findings of residues of chlorpyrifos on sugarbeets, sugarbeet tops, or any sugarbeet products (beet sugar, dried pulp, or molasses).[67] The Associations object to the extent that EPA assumed in the Final Rule that sugarbeets are a source of chlorpyrifos in the food supply.

H. EPA Appears to Have Considered Factors that it Could Not Lawfully Consider Under the FFDCA.

The safety standard for pesticide tolerances under the FQPA is whether "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."[68] This standard contemplates exposures from food, drinking water, and in residential settings. It does not contemplate occupational exposure.

On August 18, 2021, EPA issued a press release leading up to publication of the Final Rule.[69] There, EPA suggested that there are harmful and unnecessary exposures to farmworkers due to chlorpyrifos use.[70] Not only is that simply inconsistent with the scientific record in this administrative matter but also it speaks to occupational exposure, which EPA does not have authority to consider under the FFDCA safety standard.

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[65] *See* U.S. Food & Drug Admin., Analytical Results of the Total Diet Study, https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study (last updated Aug. 25, 2021).

[66] Tests were conducted using the CFDA multiresidue method (2016) and more recently using the PQAOE Pesticide Quenchers test method. Results are available upon request.

[67] *See* U.S. Food & Drug Admin, Pesticide Residue Monitoring Program Fiscal Year 2016 Pesticide Report, https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-2016-report-and-data.

[68] 21 U.S.C. § 346a(b)(2)(A)(ii).

[69] U.S. EPA, Press Release, EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health (Aug. 18, 2021), https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.

[70] *See id.*

The health and safety of the growers we represent, as well as the farmworkers who support our industry, are paramount. We importantly note that chlorpyrifos is applied by licensed certified applicators who are trained to safely handle pesticides. In addition, our growers take significant steps to ensure that chlorpyrifos is used only when needed and in the amounts that are needed. FIFRA is the statute that addresses concerns regarding pesticide application and occupational safety, whereas the FFDCA and FQPA address dietary and residential safety.

I. Other Objections

The Associations hereby incorporate by reference and set forth the objections to the Final Rule filed by Gharda Chemical International, Inc., CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE); Agricultural Retailers Association, et al.; the Coalition of Organophosphate (OP) Registrants; the American Crystal Sugar Company; and other individual members of ASGA and USBSA.

III. CONCLUSION

For these reasons, and because of the significant, imminent, and irreparable harm the Associations will suffer because of EPA's decision to revoke all tolerances, the Final Rule should immediately be reversed, or, at the very least, amended to reflect modification of the tolerances for sugarbeets consistent with the Agency's safety findings. We also request a stay of the effective date of the Final Rule to allow EPA time to revisit its decision, including consideration of maintaining the tolerances for sugarbeets, without unduly and irreparably harming our members.

Respectfully submitted,

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American Sugarbeet Growers Association
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Washington, DC 20005

ATTACHMENT A

October 12, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Cassie Bladow
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Washington, D.C., 20001

Mr. Luther Markwart
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Dear Ms. Bladow and Mr. Markwart:

Thank you for your letter of September 7, 2021, to the U.S. Environmental Protection Agency (EPA) regarding chlorpyrifos. Below are the questions that you posed to the Agency and the Agency's responses to those questions. At the end of this response, we have also provided the questions sent on September 9, via email, from Scott Herndon, the Vice President and General Counsel of the American Sugarbeet Growers Association, and the Agency's responses to those questions.

Historical Categorization/Technical Correction:
1) Could you help us understand the process and timing surrounding the upcoming chlorpyrifos cancellation order, guidance and Q&A?

Agency Response: Q&A were available on EPA's website at: https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule beginning on September 20, 2021.

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of the final rule and may also request a hearing on those objections. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 29, 2021. Please see Section I.C of the final rule for instructions on providing feedback. EPA will review any objections and hearing requests in accordance with 40 CFR 178.30, and will publish its determination with respect to each in the Federal Register.

Any registrant, including those who hold registrations of chlorpyrifos, can cancel the registration of a pesticide product or use at any time by voluntarily submitting a request to the Agency. If no requests are submitted, the Agency can issue a Notice of Intent to Cancel (NOIC) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to cancel registered food uses of chlorpyrifos associated with the revoked tolerances. When EPA issues an NOIC, it will be published in the Federal Register. For more information on the NOIC process, visit EPA's website: https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative.

(continuation of question #1): The final rule that was published in the Federal Register on 8/30/21 states, "In this final rule, EPA is revoking all tolerances for chlorpyrifos contained in 40 CFR 180.341." However, in EPA's 8/18/21 stakeholder briefing and in press reports, EPA indicated some uses will remain (namely for cotton, cow tags and golf courses). How will these and other commodities be able to retain uses?

Specifically:

a. Will any tolerances contained in 40 CFR 180.342, other than cotton, be preserved outside of the 8/18 announced final rule, and then potentially undergo reregistration in the final Interim Decision for Chlorpyrifos, which is statutorily required in 2022? Will EPA consider data that may allow other commodities to be considered in this process to retain uses?

b. If not, will cotton and other uses set to be preserved, be revoked, and then potentially reregistered through either: 1) a new registration process; or 2) an alternative means of registration RUP and/or Sec. 18 Emergency Exemption under FIFRA?

<u>Agency Response:</u> During the stakeholder meeting, we did state that the final rule does not impact non-food uses of chlorpyrifos. The Agency referenced cattle ear tags, public health uses for mosquito control, and USDA quarantine use for fire ant control. However, ear tags should not have been included in this list. Use on cattle ear tags is considered a food use because residues have been detected in cattle milk and fat, which are considered human food and/or animal feed. In addition, use on commodities such as cotton is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. Application after the tolerances expire would render these products to be adulterated, and distribution in interstate commerce would be a violation of the FFDCA. Products in the channels of trade that contain chlorpyrifos residues and were treated prior to the expiration of the tolerances would be governed by section 408(l)(5) of the FFDCA, which describes conditions that must be met in order for such food to be distributed. EPA has been working closely with FDA on guidance for treated commodities in the channels of trade that is expected to be published by the date the tolerances expire on February 28, 2022.

Per the Revised Human Health Risk Assessment for Registration Review, residential post-application exposures can occur for adults and children golfing on chlorpyrifos-treated golf course turf and from contacting treated turf following a mosquitocide application. There are no residential post-application risk estimates of concern for adults or children from chlorpyrifos use on golf course turf or as a mosquitocide on the day of application. EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, which is expected to be completed by October 2022.

2) Should sugar beets have originally been considered "non-food uses," given our data demonstrates zero residues on our end food and feed products and FDA studies from 2002-2017 (most recent) demonstrate no chlorpyrifos residues on sugar?

a. Could you provide us with an initial understanding of why EPA has set the tolerances for sugar beets as "food-uses" in 40 CFR § 180.342 and in the updated 2020 Proposed Interim Registration Review (PID)?

b. Should sugar beets originally have been considered "non-food uses" under 40 CFR § 180.2003 (Subpart E – Pesticide Chemicals Not Requiring a Tolerance or an Exemption From a Tolerance) which is defined as:

"(b) Non-food uses are those uses that are not likely to yield residues in food or feed crops, meat, milk, poultry or egg." Our data confirms there are no residues in our end products (see below information on lack of residues on sugar beets)."

Furthermore, the most recently published FDA Total Diet Studies from 2014-2017 tested sugar for traces of chlorpyrifos and found none.

c. The Pesticide Residue Monitoring Program Fiscal Year 2016 Pesticide Report examined residues in food and feeds and did not mention any findings of residues of chlorpyrifos in food or animal foods. Can EPA explain why they believe that residues for chlorpyrifos exist on sugarbeet products?

Agency Response: *The sugar beet use of chlorpyrifos is and should be considered a food use. In addition to the residues in sugar beet roots (1 ppm tolerance), residues concentrate in the processed commodities of molasses (15 ppm tolerance) and dried pulp (5 ppm tolerance), both of which are livestock feedstuffs and may contribute to residues in meat and milk. Also, Codex established an MRL for sugar beets at 0.05 ppm for chlorpyrifos. Since we established tolerances previously with the available data, any reconsideration of status as a food use would have to come in through the PRIA process.*

d. Is EPA aware our data demonstrates no residues on our end products such as crystallized sugar, molasses, dried pulp? As you may know, sugar beet co-ops do significant testing on our products for quality control. Our data indicates zero chlorpyrifos residues remain on our end products sold into commerce—which are crystallized sugar, dried pulp, and molasses. This contradicts the definition of "food-uses," which are defined as:
"(a) food uses are the uses of a pesticide chemical that are likely to yield residues in food or feed crops, meat, milk, poultry or egg."
What is the best way to provide you our data to update your analysis?

Agency Response: *The study numbers (MRIDs) would need to be provided to confirm whether the Agency has these data or not; however, these data will likely not change our conclusions since they appear to be monitoring data rather than field trial data which are used to set tolerances. Tolerances are established based on residues "at the farm gate". Monitoring data could be collected at any point in the chain of commerce and would likely not be acceptable for establishing tolerances or determining food-use status. Since the Agency established tolerances previously with the available data, any reconsideration of status as a food use would have to come in through the PRIA process.*

3) Could you provide us with an understanding of how EPA has set the tolerances for sugar beets in 40 CFR § 180.342 and in the updated 2020 Proposed Interim Registration Review (PID)? Both are mentioned in your final rule.

Agency Response: *Field trial data are used to set tolerances. Tolerances are established based on residues "at the farm gate". For more information about how we set tolerances, please see the following link: https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety. Tolerances are set on the processed commodities of sugar beets based on processing studies. For more information describing all of the processed commodities from sugar beets which we consider (e.g., molasses), please see the following link: https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0155-0002.*

a. When considering dietary risk, does the data factor in that sugar beets are not consumed raw nor are they sold into interstate commerce to be consumed raw? In fact, the user agreement that growers must sign to utilize the seed technology, states that the grower agrees that sugarbeet seeds, and the resulting crop, are solely for the processed sugar, energy production, or animal feed.

Agency Response: *Use on commodities such as sugar beet is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. For sugar beets (consumed as the processed blended commodities sugar and molasses), a processing factor of 0.02 was applied to the sugar beet (Raw Agricultural Commodity (RAC)) tolerance of 1 ppm and corrected for 20% crop treated to come up with a residue of 0.004 ppm. For more information about how we set tolerances, please see the following link: https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety. For more information describing all of the processed commodities from sugar beets which we consider (e.g., molasses), please see the following link: https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0155-0002.*

b. Chlorpyrifos is a contact insecticide that is not absorbed by or translocated within a plant which would explain the lack of residue in sugar beet and its related products.

c. Similar to EPA's PDP, a US Market Basket Analysis found 90% of all products tested were absent of chlorpyrifos and the remaining 10% well below legal tolerances.

d. Although Eaton et al. recognize consumptive exposure as the greatest non-occupational exposure they concluded: "Based on the weight of the scientific evidence, it is highly unlikely that current levels of chlorpyrifos exposure in the United States would have any adverse neurodevelopmental effects in infants exposed in utero to chlorpyrifos through the diet." These authors applied extensive scientific rigor in comparing studies from Columbia, Mount Sanai, and Berkley. Although two showed correlative effects between chlorpyrifos levels there was zero consistency between cohorts when analyzed by meta-analysis suggesting no causal relationship between chlorpyrifos levels and neurological issues. The authors concluded up to 10 ppb per day of exposure resulted in no adverse effects.

e. Given the aspects in points why would there need to be a tolerance for tops, and leaves for food or feed? Page 50 of the final rule states: "EPA has determined that the metabolite chlorpyrifos oxon is not a residue of concern in food or feed, based on available field trial data and metabolism studies that indicate that the oxon is not present in the edible portions of the crops. In addition, the chlorpyrifos oxon is not found on samples in the USDA PDP monitoring data. Furthermore, the oxon metabolite was not found in milk or livestock tissues"

Agency Response: *There are chlorpyrifos residues found in sugar beet tops as indicated by the established tolerances. The fact that residues of the metabolite, chlorpyrifos-oxon, are not present does not change the conclusion that tolerances for these commodities are required.*

4) Where did EPA's existing residue data for sugar beet originate? As noted in your rule, "Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed." The PDP data base does not list sugar or sugar beets as a commodity.

a. Given this omission, and given that our data shows no residues, is the field data being used to determine residue, despite the fact that no raw sugar beet enter commerce for human consumption?

b. If EPA retains such field data, can we work with the agency to retroactively correct it so that the agency's science is more accurate?

Agency Response: *For sugar beets (consumed as the processed blended commodities sugar and molasses), a processing factor of 0.02 was applied to the sugar beet (Raw Agricultural Commodity (RAC)) tolerance of 1 ppm and corrected for 20% crop treated to come up with a residue of 0.004 ppm.*

As a reminder, chlorpyrifos risks from food, including sugar from sugar beets and all other foods, is very low and not of concern; sugar beets are not expected to contribute significant risk to the total dietary exposure. The primary contribution to overall chlorpyrifos risks is from residues in drinking water. In setting tolerances, EPA must consider aggregate exposure, which consists of food, drinking water, and any residential exposure. Regardless, use on sugar beets remains a food use requiring tolerances. Since the Agency established tolerances previously with the available field trial data, any reconsideration of status as a food use would have to come in through the PRIA process. Additionally, field trial data are used to establish tolerance levels reflective of residues likely to be found "at the farm gate". Field trial data generally represent unwashed, whole commodities rather than the washed, edible portion of a commodity represented by monitoring data such as that generated by the Pesticide Data Program (PDP) which is used for dietary risk assessment.

5) As stated in your rule, "Without a tolerance or exemption, pesticide residues in or on food is considered unsafe, 21 U.S.C. 346a(a)(1), and such food, which is then rendered "adulterated" under FFDCA section 402(a), 21 U.S.C. 342(a), may not be distributed in interstate commerce, 21 U.S.C. 331(a)." Assuming that no residues exist in or on food, does it need a tolerance or exemption to enter interstate commerce?

a. In sum, while sugar beets may be treated with chlorpyrifos, none of the products (crystallized sugar, dried pulp, molasses) sold into commerce have residues, so may they be distributed via interstate commerce?

b. Is EPA aware of any other commodities that also fall in this distinct category?

Agency Response: *The FFDCA prohibits the introduction of adulterated food into interstate commerce. Adulterated food includes any food that contains pesticide residues not covered by a tolerance. If there are no pesticide residues, then the food would not be adulterated. The Agency's available data indicate that sugar beets treated with chlorpyrifos will have pesticide residues "at the farm gate" and thus need a tolerance.*

6) In the event sugar beets continue to be considered by EPA as "food-uses," uncertainty still rests in that classification.

a. Has EPA considered that sugar beets are unique in that they are not consumable as "foods" in raw form, and zero commerce takes place between harvest and processing? This is unique from other "food uses" subject to the final rule.

b. Objectively, should an input that is never intended to be consumed or enter commerce really be classified as a food?

Agency Response: *Use on sugar beets is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. For more information, please see above response to question #2.*

Current Crop:

7) While our products do not contain residues, given that EPA has historically assigned tolerances we have an interest to ensure any forthcoming guidance with EPA and FDA provides clear understanding of what may or may not be considered adulterated. EPA's rule states that "any residues of these pesticides

in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food."

a. For example, sugar beets grown in 2021 and that are set to be processed from this growing season, and from past growing season, will have been treated lawfully with chlorpyrifos will be processed well into 2022. Assuming there is no allowable future use of chlorpyrifos, will FDA provide guidance that these products do not need to be segregated while awaiting processing? Given the millions of tons of sugarbeets affected, segregation would be virtually impossible. Will EPA and FDA work to clarify this language to ensure it provides certainty for both food and feed uses and so that sugarbeet products have the presumption of satisfying the requirements of FDA outline above? For example, could EPA and FDA provide guidance that such foods may be processed in the ordinary course by producers and/or third-party processors and any resulting food or feed products shall likewise not be considered adulterated? Could EPA and FDA provide blanket guidance that commodities harvested under a lawful manner under FIFRA be processed and not be considered adulterated without the need for new record keeping requirements?

<u>Agency Response:</u> *It is the timing of application that determines whether food treated with chlorpyrifos is adulterated. Until the date the tolerances expire, chlorpyrifos may be used on food commodities in accordance with label directions and the existing tolerances. Residues of chlorpyrifos in or on the food after the tolerances expire would not render the food adulterated as long as those conditions are met. After the tolerances are revoked, application of chlorpyrifos will render any food so treated adulterated and unable to be distributed in interstate commerce. Food in the channels of trade that was treated prior to the expiration of the tolerances would be governed by section 408(l)(5) of the FFDCA, which describes conditions that must be met in order for such food to be distributed. EPA has been working closely with FDA on a guidance for treated commodities in the channels of trade.*

b. How is EPA coordinating with your sister agencies at the Association of American of Pesticide Control Officials to ensure that enforcement will be consistent with federal intent and will not create new record keeping requirements?

<u>Agency Response:</u> *EPA met with representatives from AAPCO on Wednesday, August 18, 2021, the day of pre-publication of the final tolerance rule, to discuss the rule and answer questions. EPA representatives also presented at the SFIREG Joint Meeting of the Environmental Quality Issues (EQI) and Pesticide Operations and Management (POM) Committees on Monday, September 20, 2021, to discuss the final tolerance rule and answer questions.*

<u>**Existing Stocks:**</u>

8) After the tolerance revocation takes effect in 6 months, would EPA consider continued use of chlorpyrifos via an "Order Governing Existing Stocks to be used in conjunction with the tolerance revocation?"— either for sugar beets until the aforementioned arguments are resolved or for growers more broadly?

Agency Response: Existing stocks is a term under FIFRA generally used in connection with the pesticide products that have been released for shipment as of the date a product registration is cancelled. EPA has not cancelled any chlorpyrifos products as a result of the final tolerance rule; therefore, there are no existing stocks at this time.

The tolerance rule issued on August 30, 2021, does not prohibit sale and distribution of registered pesticide products. However, once the tolerances expire and are revoked in six months, sale and distribution of chlorpyrifos products labeled for use on food crops would be considered misbranded; therefore, it would be a violation of FIFRA to sell and distribute those products. Once the tolerances are revoked, there is no provision for continued use of product.

EPA intends to cancel registered food uses of chlorpyrifos associated with the revoked tolerances under FIFRA, as appropriate. That cancellation action would only address the registered food uses of chlorpyrifos; it would not impact nonfood uses of chlorpyrifos, including public health uses for mosquito control and USDA quarantine use for fire ant control. EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos. Following the cancellation of food uses, there may be some products that have label instructions for both food and non-food uses. Those labels would need to be amended to remove any food-uses that were cancelled.

Additionally, a registrant, including those of chlorpyrifos, can cancel the registration of a pesticide product or use at any time by voluntarily submitting a request to the Agency.

Drinking Water Analysis:

9) EPA's assessment discusses impacts on drinking water for determining risk (i.e., drinking water exceeds 4 ppb (DWLOC) which is the exposure level determined safe for children)

一 a. EPA does not explain how you reached that 4 ppb as a safe standard. Could you elaborate on how you reached that number?

Agency Response: Please see Section 7.0 Aggregate Exposure/Risk Characterization of the 2020 Human Health Risk Assessment, which starts on page 44, which covers the specifics of deriving the drinking water level of comparison (DWLOCs) (calculations are in the footnotes of the tables). The 2020 Human Health Risk Assessment can be found at the following link:https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944.

一 b. This document cites "Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (Ref 28) to justify revocation of tolerance as it demonstrates the DWLOC exceeds 4 ppb. In this document EPA states:

一 i. The EPA acknowledges in the body of Ref 28 that the models used overestimate water contamination (e.g., assume highest label rates and lowest application intervals) and further explain the actual exposure is more sporadic as well as spatially and temporally variable.

一 ii. Although the document concludes chlorpyrifos concentrations "could be greater than 100 ppb (100 ug/L)" those assumptions are "based off of peak values from models derived from the highest label rate crops (tart cherries)." Looking at the model averages for more representative crops (bulb onions) the concentration drops to 0.8 ppb (0.8 ug/L) far below the DWLOC.

一 iii. The document (Ref 28) shows extensive data collected measuring actual presence of chlorpyrifos in surface water. The highest number collected was 2.1 ppb (half of the DWLOC), but most were under 0.3 ppb. These numbers dropped significantly following filtration (standard practice in water treatment) since chlorpyrifos can adsorb to particulate.

一 iv. The document (Ref 28) also states "…there were no detections of chlorpyrifos-oxon in paired finished water samples from the PDP monitoring program. Tierney et al., 200394 also did not detect chlorpyrifos in finished water at community water systems."

c. If EPA uses PDP monitoring to justify the lack of threat from food residue, why does it ignore the PDP data to justify a lack of risk from drinking water?

Agency Response: *EPA has considered available PDP monitoring data for chlorpyrifos in drinking water. Evaluation of PDP data is described in the 2016 DWA, which can be found at the following link: https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437. In summary, samples from raw intake water (source water) as well as finished drinking water are analyzed as part of the PDP, typically on a bimonthly basis. Samples have been collected from 82 locations in 28 states and the District of Columbia; however, only a subset of these sampling locations are sampled each year. Furthermore, although sampling sites fall within pesticide use areas, sample collection was not designed to specifically coincide with pesticide applications.*

EPA acknowledges that the highly censored nature, i.e., many non-detects, of the monitoring data available for chlorpyrifos and chlorpyrifos-oxon make it difficult to interpret the data. Non-detects could be the result of an inadequate sampling frequency, lack of use in the watershed, local meteorological conditions not conducive to runoff prior to sample collection, or sampling did not coincide with the chlorpyrifos application window. The limited number of site-years and limited sample frequency limits the utility of the PDP data for estimating concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water. Consistent with the 2019 FIFRA SAP on the Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments, EPA addressed sampling frequency with sampling bias factors and SEAWAVE-QEX in the 2020 DWA, *which can be found at the following link: https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.*

d. Is EPA aware biological monitoring reported in the peer-reviewed literature shows infants and small children only routinely being exposed to 0.5 ppb chlorpyrifos through nonoccupational exposure and concluded "exposure has been overstated by more than 1000-fold"?

Agency Response: *The Agency completed an extensive review of the literature for chlorpyrifos. All pertinent data that would affect our risk assessment were incorporated into our assessment. Without knowing what specific data is being referred to here, the Agency cannot comment further.*

Future Uses:

10) Does EPA plan to start a new registration process that may provide new restrictions on chlorpyrifos use?

a. Will this use the current decision documents including the 2020 PID, or will EPA be altering course in light of the 9th Circuit's decision?

Agency Response: *EPA does not initiate registration actions in general and does not plan to start a new registration process for the food uses of chlorpyrifos.*

b. Will EPA be reproposing for comment the Chlorpyrifos Proposed Interim Registration Review Decision from December 2020, especially in light of all the changes in the August 18, 2021, pre-published final rule on Chlorpyrifos; Tolerance Revocations?

Agency Response: *EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, with the Interim Decision expected to be completed by October 2022. EPA does not intend to release a revised PID for comment.*

11) Further, is EPA considering registering the pesticide as Restricted Use Products with increased restrictions?

Agency Response: *EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, which is expected to be completed by October 2022. If the Agency determines that the pesticide, when applied in accordance with the label's directions for use, warning and cautions, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. FIFRA 3(D)(1)(c). The Agency did not make that determination at the time of the PID, but if comments are received relevant to consideration of changes to the proposed mitigation, they will be addressed in the interim decision.*

12) If chlorpyrifos is no longer an option for insect control, we are limited to just two labeled post-emergence liquid insecticide options that are both pyrethroids for sugarbeet root maggot control. These pyrethroids are not as effective and do not perform well in warmer temperatures above 80 degrees F. Only using and having available the one mode of action can lead to insect resistance to the pyrethroid chemistry as well.

Has EPA considered whether there are viable alternatives for chlorpyrifos in different crops and, if so, does the agency plan to provide the public with that analysis?

a. Has EPA considered that losing more and more pesticides with different mode of actions will complicate Integrated Pest Management, complicate proper rotation of different modes of action, and with that increase the likeliness of insecticide resistance?

b. Has EPA considered the effects on sustainability, carbon footprint and farm economics? Soft chemistries (pyrethroids) would require more frequent applications, with that an increase in fuel consumption, soil compaction, and a potential decline of beneficial insects (based on more frequent applications)?

Agency Response: *Under the revisions mandated by the FQPA, EPA cannot consider benefits in FFDCA decisions. However, as part of the registration review process under FIFRA, the Agency did evaluate the benefits of chlorpyrifos to growers by crop. The economic benefits to growers are equivalent to the losses they face without chlorpyrifos. This analysis is available in a supporting memorandum in the chlorpyrifos regulatory docket, which is available at the following link: https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969. Sugarbeets was one of several crops discussed in some detail in this document, and EPA acknowledges that it concluded that until suitable alternatives can be adapted to replace chlorpyrifos, sugarbeet yields in production areas of the upper Midwest Red River Valley region could be reduced due to increased problems with the sugarbeet root maggot. EPA is aware that IPM and resistance management are critical pest management benefits of many pesticides, and where benefits considerations are permitted by law, the Agency takes these aspects into serious consideration.*

13) Would EPA consider honoring future Section 18 Emergency Exemption Requests for chlorpyrifos—either for sugar beets or for growers more broadly?

Agency Response: Section 18 of FIFRA allows EPA, when emergency conditions exist, to exempt states and federal agencies from the provisions of FIFRA, including the requirement that pesticides must be registered to be sold or distributed. Since at this time, registrations of chlorpyrifos have not been cancelled, no section 18 exemption would be necessary to allow sale and distribution. An emergency exemption cannot reinstate the tolerances under the FFDCA; emergency exemptions only address the sale, distribution, and use of a pesticide under FIFRA. Should EPA receive a request for a section 18 emergency exemption after the food uses for chlorpyrifos are cancelled under FIFRA, EPA would need to establish a time-limited tolerance under FFDCA 408(l)(6). EPA can only establish such a tolerance to cover residues of the pesticide applied under a section 18 emergency exemption if it can determine that the tolerance is safe, as defined by the FFDCA. If EPA cannot determine the tolerances would be safe, EPA cannot establish the tolerances and thus, EPA would not be able to grant a section 18 emergency exemption request.

OMB Process Issues:

14) The final rule states, "The Office of Management and Budget (OMB) has exempted tolerance regulations from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866 (EO 12866), this final rule is not subject to Executive Order 13563 (76 FR 3821, January 21, 2011). B. Paperwork Reduction Act (PRA)."

EPA's posted final rule renders food tolerances more stringent than the status quo and according to previous USDA estimates, and EPA's December 2020 PID, chlorpyrifos has an economic impact over $100 million. Revoking chlorpyrifos tolerances seems to fit the requirements of EO 12866.

a. Why wasn't this rule considered a "significant regulatory action," that should have been subject to interagency review?
b. When will EPA put this rule back out for public comment to comply with the EO?
c. When will EPA be sending the final rule back to OMB for interagency review?

Agency Response: The Agency published a benefits memo from late 2020 that estimated the benefits of chlorpyrifos in agriculture, which is how the Agency would estimate the cost of revoking the tolerances. These estimates reflect significant uncertainty. The court-ordered deadline that the Agency was subject to comply with for this action resulted in the rapid timeline for this final rule. At this time, the Agency intends to proceed in accordance with the process laid out in FFDCA section 408(g).

Follow up questions:

1. Where should we send information on our non-residue data to EPA?

Agency Response: The non-residue data to support reconsideration of status would be subject to review under PRIA. Please find more information on how to submit as a PRIA action at the following link: https://www.epa.gov/pria-fees/fy-2020-2021-fee-schedule-registration-applications and/or please contact the Registration Division.

2. We are also reaching out to USDA for their data too. Please confirm that the below is the appropriate contact at USDA.
    a. **Julie A. Chao, M.A., MSPH**
    Regulatory Risk Assessor
    julie.chao@usda.gov

Agency Response: Julie Chao is the correct contact at USDA.

3. Can you provide a timeline for responding to the questions addressed in the letter sent on Tuesday evening (attached again for convenience)?

   Agency Response: This document provides the responses to the questions in the letter.

4. Can you provide us with the list of contacts you are in discussions with at FDA so we can also engage with them?

   Agency Response:
   Center for Food Safety and Applied Nutrition at the US FDA (CFSANTradepress@fda.hhs.gov)
   Alice Chen (alice.chen@fda.hhs.gov)
   Charlotte Liang (Charlotte.Liang@fda.hhs.gov)
   Lauren Robin (Lauren.Robin@fda.hhs.gov)
   Carie Jasperse (carie.jasperse@fda.hhs.gov) (Counsel)

5. Can you point us to where the 4ppb tolerance in the water model came from? As mentioned on the call yesterday, a couple of our scientists wanted to understand that issue better and couldn't find it in the document referenced on the call.

   Agency Response: Please see Section 7.0 Aggregate Exposure/Risk Characterization of the 2020 Human Health Risk Assessment, which starts on page 44, which covers the specifics of deriving the drinking water level of comparison (DWLOCs) (calculations are in the footnotes of the tables). The 2020 Human Health Risk Assessment can be found at the following link:https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944. Please refer to table 7.2.2 in revised draft human health assessment. In the footnote, the formula provided for the calculation is:
   DWLOC: DWLOC ppb= PoDwater (ppb; from Table 4.2.2.1.2) /MOEwater

If you have further questions regarding this matter, please contact Alexandra (Alex) Feitel at feitel.alexandra@epa.gov or 703-347-8631, or Melissa Grable at grable.melissa@epa.gov or 703-308-3953.

Sincerely,

Edward Messina, Esq.
Director

Cc: Loni Cortez Russell, Office of Public Engagement and Environmental Education

EXHIBIT 14

October 19, 2021

Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted electronically via Office of the Administrative Law Judges E-Filing System and Federal eRulemaking Portal

RE: Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos (EPA-HQ-OPP-2021-0523)

To Whom It May Concern:

We represent growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders. We write concerning EPA's final rule issued on August 30, 2021, to revoke all tolerances for the insecticide chlorpyrifos (EPA-HQ-OPP-2021-0523). Pursuant to the Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(g) (21 U.S.C. 346a) we are writing to file formal objections regarding this action, as we believe it is inconsistent with federal statute, the Agency's own record on chlorpyrifos, and sound, science-based and risk-based regulatory practices. Based on these objections, we urge EPA to rescind the final rule revoking tolerances and consider continued agricultural uses of chlorpyrifos under its ongoing, normal-order registration review of chlorpyrifos. Furthermore, because this rule will cause significant and irreparable harm to food and agricultural stakeholders, we request the Agency stay implementation of the rule until these objections can be formally addressed and responded to by EPA.

Harm to Food & Agricultural Stakeholders, the Environment

As many of our organizations have commented regarding the ongoing registration review for chlorpyrifos (EPA-HQ-OPP-2008-0850), this chemistry holds a unique and significant value for many agricultural producers. Chlorpyrifos has more than 50 registered agricultural uses on numerous crops, many of which are high-benefit uses to protect against economically significant pests. We object to the tolerance revocation of all uses, as EPA's own risk assessments show some uses meet the legal standard under FFDCA. Additionally, this action will leave thousands of growers across the country defenseless to devastating pests, which is why we also request that EPA stay implementation of this rule until the Agency can thoroughly consider and respond to objections. To lose the ability to use chlorpyrifos, as would occur through implementation of the rule, would unnecessarily result in significant and immediate economic and environmental damage.

For example, Michigan cherry producers currently have no other effective control options besides chlorpyrifos for American Plum Borers and Peachtree Borers. These insect pests can bore into trunks of cherry trees ultimately leading to the tree's death.[1] What is worse, since fruit trees take years to reach maturity, growers who lose trees will be harmed for not just one growing season, but many years to come. Michigan State University (MSU) Economists estimated that a grower who loses a tree to borers would spend $180 replacing it, as well as $42 per year in lost income for the average of seven years it takes a tree to begin producing marketable fruit, ultimately costing the producer $474 in lost revenue

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[1] *Tart Cherry Pest Management in the Future: Development of a Strategic Plan*. June 2011. 23-24. https://ipmdata.ipmcenters.org/documents/pmsps/MITartCherryPMSP.pdf

and replacement costs for every deceased tree.[2] Given that USDA estimates Michigan has more than 4.7 million cherry trees planted,[3,4] this action would expose Michigan cherry producers to potentially tens to hundreds of millions of dollars in irreparable damage through the loss of chlorpyrifos.

U.S. sugarbeet growers will also face significant damages from this rule. These growers contend with sugarbeet root maggots (SBRM) – flies that lay their eggs at the base of sugarbeets, whose larvae then hatch, burrow into the plant, and feed on the sugarbeet. Chlorpyrifos is the most effective product available for treating emerged SBRM. The few other products registered can only suppress SBRM, not control it, or are only registered for use on adult flies, not larvae.[5] Without chlorpyrifos, sugarbeet growers will be exposed to this damaging pest which can inflict up to 45 percent yield loss and $500 in damages per acre.[6] When considering more than 140,000 acres of sugarbeets are at risk of from SBRM,[7] U.S. sugarbeet growers could be looking at tens of millions of dollars in irreparable damages annually should this rule take effect.

It is important to note that it is not just farmers, but also our environment that will be impacted should this rule take effect. For example, soybean growers use chlorpyrifos to control both two-spotted spider mites (TSM) and soybean aphid populations that have developed resistance to other insecticides, such as pyrethroids. These pests can inflict yield losses as high as 60 percent if left unchecked.[8] For growers who face these pests, there is no one-to-one replacement for chlorpyrifos – it is the only option that will control both pests.[9] Should this rule take effect, soybean growers who face TSM and pyrethroid-resistant aphids will now have to choose between applying twice as much pesticide active ingredient (which will also significantly increase their operational costs) or face serious crop damage. This results in an increase in pesticides used in the environment and additional sprays which unnecessarily increase the use of water and fuel.

These are just a few examples out of many where agricultural producers, supply chains, and our environment will face irreparable harm should this rule take effect. Wheat, asparagus, peach, apple, alfalfa, citrus, peanut, onion, and other producers will experience similar costly adverse impacts. We object to the rule on the basis that it will inflict significant economic damage to the tune of hundreds of millions of dollars to these farmers and many others. To ensure that this irreparable harm does not occur from this rule, which the Agency may yet modify or rescind based on public comment, we request

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[2] Gordon, Julie and Kyle Harris. *Comments submitted by Cherry Marketing Institute to Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (EPA-HQ-OPP-2008-0850)*. February 26, 2021.

[3]United States Department of Agriculture. National Agriculture Statistics Service. 2019. *2018-2019 Michigan Fruit Inventory: Tart Cherries*. https://www.nass.usda.gov/Statistics_by_State/Michigan/Publications/Michigan_Rotational_Surveys/mi_fruit18/Tart%20Cherries.pdf

[4]U.S. Department of Agriculture. National Agriculture Statistics Service. 2019. *2018-2019 Michigan Fruit Inventory: Sweet Cherries*. https://www.nass.usda.gov/Statistics_by_State/Michigan/Publications/Michigan_Rotational_Surveys/mi_fruit18/Sweet%20Cherries.pdf

[5] Franzen, David, Mark Boetel, Ashok Chanda, Albert Sims, and Thomas Peters. North Dakota State University. January 2021. "2021 Sugarbeet Production Guide." https://www.ag.ndsu.edu/publications/crops/sugarbeet-production-guide

[6] Boetel, Mark. North Dakota State University. June 10, 2021. "NDSU Helping Control Sugarbeet Root Maggot." *Newsletter.* https://www.ndsu.edu/vpag/newsletter/ndsu_helping_control_sugarbeet_root_maggot/

[7] Ibid.

[8] Hodgson, Erin. Iowa State University Extension and Outreach. July 6, 2016. "Spider Mite Injury Confirmed in Soybean." *Integrated Crop Management*. https://crops.extension.iastate.edu/cropnews/2016/07/spider-mite-injury-confirmed-soybean

[9] Koch, Robert, Theresa Cira, Raj Mann, Bruce Potter, Anthony Hanson. University of Minnesota Extension. August 19, 2021. "Environmental Protection Agency's Cancellation of Chlorpyrifos Tolerances: Alternatives for Management of Key Crop Pests." *Minnesota Crop News.* https://blog- crop- news.extension.umn.edu/2021/08/environmental-protection-agencys.html

that EPA stay implementation of this rule until it considers and formally responds to additional objections raised below and by other stakeholders.

Harm to Holders of Safe, Otherwise-Legal Foods

We also object to this rule on the grounds that its implementation will likely force the disposal of significant volumes of safe, legal food and feed products. EPA has indicated that detectable food and feed residues of chlorpyrifos after the February 28, 2022 implementation date will be subject to section 408(l)(5) of FFDCA and FDA's channels of trade guidance. Under these provisions, FDA requires that:

> *"In order to avoid possible regulatory action against a food containing a residue of a pesticide chemical that is subject to the channels of trade provision, the party responsible for the food must, under section 408(l)(5) of the FFDCA, demonstrate that the residue is present as a result of a lawful application or use of the pesticide chemical and that the residue does not exceed a level that was authorized at the time of that application or use."*[10]

While this will not be an immediate issue, this provision is likely to become a significant concern once the rule takes full effect in February 2022. Since many finished food and feed products have extended shelf lives, there are almost certainly already foods in commerce with detectable residues from applications made prior to EPA's revocation rule and before applicators knew special channels of trade application records would be retroactively required. Without these special records, products could be unnecessarily found adulterated and subsequently destroyed despite applications being made legally and residues not exceeding legal levels at time of application. This will potentially result in millions of dollars of additional food waste losses and further irreparable harm to agricultural supply chains. These significant food and feed losses do not seem to have been considered by the Agency in its issuance of the rule. We also object to the rule on this basis and, due to these additional economic harms that would occur should the rule take effect, request that EPA stay the rule's implementation until it can fully consider and respond to these objections.

Lack of Clarity on Continued Use, Existing Stocks

We are also greatly concerned with and object to EPA's approach to existing stocks of chlorpyrifos under the rule and in additional clarification guidance.[11] The Agency has effectively not taken a position on the matter or how it expects to responsibly wind-down use of the product. As very few growers are using chlorpyrifos this late into the 2021 growing season, millions of gallons remain in storage across the country and are unlikely to be used ahead of the rule's February 2022 implementation date. Most users will be effectively prohibited from using the product even if the registration has not been formally cancelled at that point, placing the financial and logistical burden on users and retailers to determine how to responsibly dispose of product. Without additional clarification from EPA on what to do with these existing stocks, it could inadvertently lead to inappropriate or mass disposal of product which would have significant environmental consequences.

Significant Regulatory Action Subject to OIRA Review

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[10] United States Food & Drug Administration. *Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations*. Jeffrey Shuren. Federal Register 70, No. 95. (May 18, 2005): 28544. https://www.federalregister.gov/documents/2005/05/18/05-9811/guidance-for-industry-on-channels-of-trade-policy-for-commodities-with-residues-of-pesticide

[11] United States Environmental Protection Agency. Last Updated September 20, 2021. *Frequent Questions about the Chlorpyrifos 2021 Final Rule*. Accessed October 8, 2021. https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule

We also take objection with EPA's determination that this rule is not an economically significant regulatory action as defined by section 3(f)(1) of Executive Order (E.O.) 12866, subject to review by the Office of Information and Regulatory Analysis (OIRA). By EPA's own analysis, the December 2020 proposed interim decision (PID) suggests this rule is likely to trigger the impacts threshold of an economically significant action. In the benefits section of the PID, EPA attests that the annual economic benefit of chlorpyrifos could be as high as $130 million.[12] Many of our organizations provided comment to the PID in a letter dated March 6, 2021 demonstrating how we believe this assessment drastically undervalues chlorpyrifos' annual economic benefit, and that the actual value is likely to be much higher. The grower harm scenarios provided above for cherries and sugarbeets alone offer scenarios where harm might occur to individual crop groups in excess of the $100 million threshold of an economically significant regulatory action, to say nothing of the dozens of other crop producer groups who also will be economically impacted by the loss of chlorpyrifos resulting from this action.

And this is only the impact on growers. As previously discussed, the economic damage from this action is likely to ripple across the agricultural supply chain as food holders may be required to discard millions of dollars in food and feed due to special retroactive channels of trade document challenges. It also does not factor in the costly paperwork burdens for stakeholders who may be capable of meeting the arduous channels of trade requirement, nor does it account for millions of gallons of existing stocks that may need to be discarded after the rule takes effect, and so on. When these factors are all considered, this rule will vastly exceed the $100 million economically significant threshold.

If there continues to be any doubt that this rule is economically significant, the $100 million threshold is only one factor of several that can trigger this status under section (3)(f)(1). If a rule is also likely to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities,"[13] it is also considered economically significant. We have provided numerous examples how this rule is likely to adversely affect the entire agricultural economy, jobs, productivity, and our environment. At this point, there should be no doubt to the Agency that this action is in fact economically significant.

As an economically significant action, EPA should have provided OIRA with a copy of this draft regulatory action, required cost and benefit assessments, and other documents enumerated in sections (a)(3)(B) and (C) of E.O. 12866. However, the Agency conducted none of these requirements for this action. While we appreciate the Ninth Circuit Court of Appeals gave EPA a swift deadline for considering its order, E.O. 12866 also provides a mechanism for managing just such a scenario. Section (a)(3)(D) stipulates "for those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review…." We object to this action on the grounds that EPA had an obligation to conduct an OIRA review of this rule – a review which may have resulted in a significantly different regulatory outcome. However, EPA neglected to carry out this essential review function directed by E.O. 12866 and as a result our organizations will be subject to significant harm from this rule. EPA should rescind the rule and, should it seek to advance it or another economically significant rule again, do so through appropriate regulatory review processes.

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[12] United States Environmental Protection Agency. December 3, 2020. *Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100*. (EPA-HQ-OPP-2008-0850-0971). 39. https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971

[13] *Executive Order 12866 of September 30, 1993: Regulatory Planning and Review*. Clinton, William J. Federal Register 50, No. 98. (October 4, 1993). https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf, https://www.epa.gov/laws-regulations/summary-executive-order-12866-regulatory-planning-and-review.

Revocation of Tolerances for High-Benefit Uses, Even with FQPA 10X Safety Factor

We also object to EPA's revocation of uses that the Agency describes as high-benefit and which EPA's record for chlorpyrifos, as established by EPA's career scientists, indicates would be safe for continued use. In its April 29, 2021 decision which precipitated this rule, the Ninth Circuit ordered EPA to "issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA 'has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information' including for 'infants and children.'"[14]

Importantly, the Agency has ample evidence instructing this matter from its ongoing registration review of chlorpyrifos. In the December 2020 chlorpyrifos PID, EPA identified 11 high-benefit agricultural uses that "the agency has determined will not pose potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X and may be considered for retention."[15] These uses include or are similar to the ones described above where growers or the environment would be significantly harmed if access to chlorpyrifos were lost. The PID is clear that these 11 agricultural uses meet the FFDCA safety standard when EPA evaluated the aggregate exposure for both food residues and drinking water concentrations. While we do not believe this 10X FQPA safety factor is necessary for the Agency to adopt and EPA's water estimates significantly overstate potential drinking water exposures, which we further discuss in our below objections, these uses clearly satisfy FFDCA standards and the criteria the Court gave to EPA.

Despite that EPA was given the option by the Court to modify chlorpyrifos tolerances, the Agency instead opted to arbitrarily revoke all tolerances in this rule, even those that EPA's own record supported as meeting FFDCA safety standards to protect human health. EPA supposes in the rule that it must consider "all currently registered uses" when determining aggregate exposure risks and whether tolerances can be maintained, but this is simply not true. The Court permitted EPA to modify tolerances in response to the ruling and the law permits EPA to modify or revoke individual tolerances (21 U.S.C. 346(b)). We object to this rule in that it unnecessarily revokes tolerances for these 11 high-benefit agricultural uses that EPA's own assessments establish are safe, will protect human health from aggregate exposures, satisfies the orders given to EPA by the Court, and would otherwise help to minimize the rule's environmental and economic impact on stakeholders.

Import Tolerance Concerns

It is also concerning, and we take objection that the rule makes no accommodation for retaining import tolerances. Food residues are the only potential domestic exposure source from imports with chlorpyrifos residues, and the Agency has clearly stated those are not of concern. Since the Agency clarifies in the rule that "exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern," and since there are no domestic drinking water or environmental risks that could arise from foreign chlorpyrifos applications, there is no science-based reason for EPA to revoke these tolerances.
U.S. producers regularly face prejudice in export markets that impose restrictions on pesticide residues that are not aligned with CODEX standards or are otherwise scientifically unsupported. U.S. trade representatives constantly struggle convincing foreign governments to align their import tolerances with

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[14] *League of United Latin American Citizens, et al. v. Michael S. Regan*, 996 F.3d 673. 67. (9th Cir. 2021).
[15] United States Environmental Protection Agency. *Chlorpyrifos Proposed Interim Decision*. 40.

these international standards. However, when EPA takes steps mirroring the unscientific actions of foreign governments, it erodes the ability of U.S. trade negotiators and producers to seek appropriate regulatory treatment abroad. This is yet another reason why the Agency should have sought OIRA review of this rule, to ensure EPA's action would not undermine the mission of other federal agencies.

Finally, our trade partners have expressed concern at previous EPA proposals to revoke chlorpyrifos tolerances, suggesting that "the EPA's revocation on all tolerances for this product may unfairly impact Canadian products exported to the U.S. market."[16] Given that EPA does not seem to have consulted with the U.S. Trade Representative on this action, we are concerned the Agency has not sufficiently ensured it is compliant with U.S. trade obligations which has great potential to disrupt international trade. We object to the rule on the basis that it does not permit import tolerances that are important to the U.S. agricultural trade strategy, as these residues pose no domestic dietary or environmental risks.

Uses on Non-Food Crops, Foods Not Resulting in Residues

Similar to our concerns with import tolerances, there are numerous domestic uses that are not intended for food purposes or will not result in food or feed residues, and thus pose little to no risk. Regardless, EPA has indicated it plans to revoke tolerances and will soon move to cancel these uses. We object to this aspect of the rule as well. For example, applications to fruit tree trunks where product is not directly applied to fruit will not result in residues and should not be cancelled. Sugarbeets are not sold as a raw commodity, but are highly refined, resulting in no residues in finished product. This use also should not be cancelled. Although EPA may have concerns with drinking water exposures resulting from these uses based on very conservative water modeling estimates, we would point the Agency to additional comments below on new drinking water data that should be considered which EPA did not use in developing this rule. The Agency should carefully review these uses and not unnecessarily revoke tolerances or cancel uses that truly do not pose a dietary exposure risk and will only result in burdening producers.

Epidemiological, Drinking Water Data Concerns

Finally, as suggested above, we have numerous concerns with the underlying data and methodologies EPA has used to establish a 10X FQPA safety factor and ultimately reach the revocation decision in this rule. We continue to believe EPA's record on chlorpyrifos strongly supports use of a 1X FQPA safety factor. The primary driver of the Agency's decision to use the 10X safety factor is three epidemiological cohorts that supposedly identified links between chlorpyrifos or organophosphates generally and alleged neurodevelopmental effects from a potentially unknown mode of action (MOA) beyond the known acetylcholinesterase (AChE)-inhibition.

We object to EPA's use of this data for establishing the use of a 10X FQPA safety factor for numerous reasons. First, these cohorts – and most notably the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies, which was specific to chlorpyrifos – have not to date provided raw study data to EPA, despite numerous requests from the Agency. Without this underlying data, it is impossible for the Agency to determine alleged exposure sources, exposure levels, and actual causes of neurodevelopmental effects. For these limitations and others, EPA's expert FIFRA Scientific Advisory

[16] Panday, Chris. *Comments submitted by Agriculture and Agri-Food Canada to Tolerance Revocation: Chlorpyrifos (EPA-HQ-OPP-2015-0653)*. December 22, 2015.

Panel (SAP) on several occasions in recent years has cautioned the Agency against using these three cohorts as the basis for regulatory decisions.[17]

The weight the Agency should place on these studies is further diminished by other factors. In the years since these cohorts were released, several other epidemiological studies (which EPA has as part of its record) have been released finding no link between organophosphates and alleged neurodevelopmental effects beyond known AChE-inhibition, to say nothing of decades of animal and other tests that also do not support the findings of these three cohorts. The results of these three studies have not been reproducible to date. Moreover, an additional, unknown MOA beyond the commonly-accepted AChE-inhibition that could have potentially caused neurodevelopmental effects to date has never been identified, for chlorpyrifos or any other organophosphate. Finally, even if an unknown MOA does exist, EPA's own career scientists at the Office of Research and Development (ORD) have developed data that indicates the mitigations the Agency has put in place to protect against AChE-inhibition would also be protective against the effects alleged in the epidemiological cohorts regardless of any unknown MOA.

In the rule itself EPA acknowledges that food residues and non-occupational exposures are not a concern, only ultimately raising concern with modeled estimates of drinking water exposure risks. We believe these concerns can also be addressed, as in the rule EPA states of its 2020 drinking water assessment (DWA) that it "applied the new methods for considering the entire distribution of community water systems PCA [percent cropped area] adjustment factors, integrated state level PCT [percent crop treated] data, incorporated refined usage and application data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information" relative to its previous 2016 DWA. Using this improved DWA in its 2020 human health risk assessments for the registration review of chlorpyrifos, EPA sought to determine drinking water risks on the subset of 11 critical, high-benefit crop uses (the uses that the PID recommended retaining under the FQPA 10X scenario). The Agency found under the improved 2020 DWA none of the assessed uses exceeded drinking water levels of concern. It should also be noted that the 2016 DWA EPA reported there were no detections of chlorpyrifos-oxon degradates in any finished drinking water samples that people actually consume[18] – another sign of how inappropriately conservative the Agency's drinking water assessments are in this rule.

Confoundingly, the Agency contends it cannot use the 2020 DWA because it is not comprehensive across all currently registered uses. This is an inappropriate determination. In this rule, EPA has instead opted to revert to its cruder 2016 DWA for all uses, concluding it should throw out every use even when it has better data it could utilize. EPA has the opportunity and obligation to use the best available science where it can and can explore the appropriateness of modeling or extrapolation where there may be gaps. We strongly encourage EPA to reconsider its decision in this rule using the improved, best-available science in the 2020 DWA.

Conclusion

To summarize our concerns, FIFRA is a risk-benefit statute which directs the Agency to identify hazards of a pesticide use, determine the risks caused by that hazard, weigh those risks against the benefits of uses, and assuming they can be mitigated, reasonably mitigate those risks so the benefits of use

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[17] United States Environmental Protection Agency. FIFRA Scientific Advisory Panel. "Meeting on Chlorpyrifos: Biomonitoring Data." (Meeting transcript: Arlington, VA; April 19-21, 2016). 644-646. https://www.epa.gov/sites/default/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf

[18] United States Environmental Protection Agency. Office of Chemical Safety and Pollution Prevention. *Chlorpyrifos Refined Drinking Water Assessment for Registration Review.* April 14, 2016. 104.

outweigh the risks. This process is done in concert with FFDCA, incorporating a stringent safety standard to protect the safety of the food supply. However, in this instance EPA has not even identified a hazard. The Agency has three limited, inconclusive studies which suggest a *potential* hazard, to say nothing of possible risks, the findings for which have never been confirmed or reproduced. There is also an abundance of additional human epidemiological and other evidence refuting the existence of this potential hazard. Even if a hazard exists and it presents a risk, EPA's own experts believe that risk can be mitigated using existing controls.

Despite all this, to mitigate the potential risks that may be posed by the alleged hazard, through this rule EPA is opting to eliminate hundreds of millions of dollars in agricultural benefits and inflict tens to hundreds of millions of dollars in additional costs to supply chains and the environment. We are very concerned about the precautionary precedent this rule poses to EPA's pesticide program and object on the grounds that it is fundamentally averse to the processes by which Congress directed the Agency to regulate pesticides, as well as commonly-accepted principles of modern science and risk-based regulation. We urge EPA to rescind this rule based on the above objections and to stay the rule's implementation to avoid these irreparable harms from taking effect until the Agency can thoroughly review and respond to these concerns.

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EXHIBIT 15

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October 28, 2021

Environmental Protection Agency
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RE: Docket Number EPA-HQ-OPP-2021-0523

To Whom it May Concern:

The National Association of Wheat Growers (NAWG) appreciates the opportunity to comment on the recent chlorpyrifos decision (Docket Number EPA-HQ-OPP-2021-0523). NAWG is a federation of 20 state wheat grower associations that works to represent the needs and interests of wheat producers before Congress and federal agencies. Based in Washington, D.C., NAWG is grower-governed and grower-funded, and works in areas as diverse as federal farm policy, trade, environmental regulation, agricultural research, and sustainability.

Chlorpyrifos is an important pest management tool that wheat growers use to address insect outbreaks arising during favorable weather conditions. The action taken by the EPA to cancel all tolerances for chlorpyrifos is concerning to NAWG members. It is critical for growers to have access to a variety of tools with different modes of action to control such insect pressures. There also must be a continued development and approval of new crop protection tools that are reviewed on a predicable schedule. New products must be made available to growers, especially considering the action EPA is taking under this announcement to eliminate the use of a product that allow wheat growers to protect their crop from insect infestations.

When the EPA announced the action to cancel chlorpyrifos tolerances prior to altering the registration and product labels, it was done in a manner that is contrary to normal procedure under FIFRA and contrary to agency’s own data under the registration review of chlorpyrifos. Today, chlorpyrifos is registered for use on wheat and meets the EPA and FDA safety standards. To proceed outside the approved regulatory process that allows for a transparent public input of data, comments and decision making sets a dangerous precedent for other crop protection products. Growers rely on EPA and FDA to establish requirements for the safe use of crop protection products and the current regulatory framework provides for those reviews.

The agency action to terminate tolerances prior to altering the label uses of the product can cause market disruptions in the wheat supply chains. Wheat is often stored on farm or processed into flour and further to baked goods that can be stored anywhere along the supply chain, including in an individual's home. The food products can be on the shelf or in the freezer, resulting in different storage timelines that must be taken into consideration by the agencies when they address the future of products in the supply chain. Additionally, wheat can be used as animal feed. To date, both the EPA and FDA have failed to provide sufficient guidance on the safety of these products and the how of protect channels of trade and ensure that wheat growers are not adversely impacted by this agency action.

We urge both EPA and FDA to quickly address the channels of trade specifically for the chlorpyrifos residues and the unique situation that the EPA's action to cancel tolerances has created. The agencies should take an action that does not result in destruction of these food products that are in the supply chain and allows sufficient time for supplies to move through the channels of trade for both food and animal feed.

Thank you for the opportunity to comment on this agency action. There must be more information provided to growers that have wheat that may have been treated with Chlorpyrifos during the growing season. We look forward to working with both EPA and FDA to ensure that wheat growers are able to continue to market their wheat produced in accordance with EPA requirements at the time it was grown and maintain the safety of products made with that wheat.

Sincerely,

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EXHIBIT 16

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October 29, 2021

Environmental Protection Agency
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Submitted electronically via Office of the Administrative Law Judges E-Filing System and Federal eRulemaking Portal

RE: Formal Written Objections, Request for Evidentiary Hearing, and Request to Stay Tolerance Revocations: Chlorpyrifos (EPA-HQ-OPP-2021-0523)

To Whom It May Concern:

On behalf of the American Soybean Association (ASA), pursuant to the Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(g) (21 U.S.C. 346a), I am writing to file formal objections regarding EPA's final rule issued on August 30, 2021, to revoke all tolerances for the insecticide chlorpyrifos (EPA-HQ-OPP-2021-0523). ASA represents more than 500,000 U.S. soybean farmers on domestic and international policy issues important to the soybean industry and has 26 affiliated state associations representing 30 soybean-producing states.

ASA has numerous concerns with the final rule as published. We believe it is inconsistent with federal statute, the Agency's own record on chlorpyrifos, and sound, science-based and risk-based regulatory practices. We also believe EPA has assumed certain factual errors in the rule that require an evidentiary hearing, which we request below. As a result of these issues and factual errors, we are concerned this rule will result in significant, irreparable harm to soybean growers. To prevent the unavoidable harm that will occur should the rule take effect, we further request EPA stay implementation of the rule until the Agency can formally review and respond to objections raised, including the factual errors ASA is seeking to address in our requested evidentiary hearing.

We would also like to point out that we view the objections listed below as supplemental to those ASA has already raised with other agricultural stakeholders in an objections letter posted to this docket and filed with the Office of the Administrative Law Judges (OALJ) dated October 19, 2021. ASA stands by and reaffirms the objections and stay request raised in that letter and seeks to raise additional concerns with the rule and highlight soybean-specific impacts in this objections letter.

Irreparable Harm to Soybean Producers, the Environment

We are greatly concerned this rule will cause significant, irreparable harm to soybean growers and the environment. Soybean growers rely on chlorpyrifos to control numerous insect pests, but some of the highest-benefit and most critical uses are to control soybean aphids and two-spotted spider mites (TSM) in the Upper Midwest. If left unchecked, these pests can cause up to 60 percent yield loss,[1] and in some cases transmit secondary viruses that can cause further crop damage. Soybean aphids and TSM pose a

[1] Hodgson, Erin. Iowa State University–Extension and Outreach. July 6, 2016. *Spider Mite Injury Confirmed in Soybean*. https://crops.extension.iastate.edu/cropnews/2016/07/spider-mite-injury-confirmed-soybean

serious threat to crops and are notoriously difficult to control. Aphid populations in the Upper Midwest have largely developed resistance to the pyrethroid class of insecticides, and very few control options exist for TSM. Chlorpyrifos is the only chemistry that reliably controls both aphids and TSM. If growers lose access to chlorpyrifos, as would occur from this rule, there is no one-to-one replacement scenario – growers will have to at a minimum spray two active ingredients to control these pests. This rule will increase growers' operational costs by requiring them to purchase more pest control products and will reduce their ability to be good environmental stewards by requiring the application of greater volumes of pesticides in the environment.

In our analysis, the most plausible replacement scenario is the use of dimethoate to control TSM and an application of a 4A mode of action (MOA) chemistry, such as imidacloprid, to control aphids. While dimethoate is registered for use on aphids, its record at controlling this pest is unreliable, therefore we do not believe growers will rely on it for this purpose.[2] While slightly outdated, for the sake of convenience we will use a 2017 analysis on the cost of insect control products to provide a conservative replacement scenario.[3]

Based on this 2017 estimate, a gallon of a chlorpyrifos product would cost a grower $55.00. When assuming a standard application rate of one pint per acre, this results in a cost of $6.88/acre treated. Under this analysis, a common dimethoate product will cost a grower $47.00/gallon. When again assuming a common application rate of one pint per acre, the cost to the grower is $5.88/acre treated. A common imidacloprid product in this analysis will cost a grower $120.00/gallon. When assuming a label-directed application rate of 1.5 ounces/acre, the cost is approximately $1.41/acre treated. Combining the costs of the dimethoate and imidacloprid treatments, a grower could expect to pay $7.29/acre to control these two pests under a scenario without chlorpyrifos – a $0.41 increase per crop acre treated than under the status quo with chlorpyrifos.

Considering EPA estimated in its November 2020 *Revised Benefits of Agricultural Uses of Chlorpyrifos* that U.S. soybean producers use chlorpyrifos on an estimated 3.08 million acres of soybeans annually, this cost is rapidly amplified.[4] When extrapolated, U.S. soybean farmers in this conservative replacement scenario could expect see a $1.26 million annual cost increase to protect their crops. Producers in states like Minnesota, North Dakota, and South Dakota, where these specific pest pressures are higher, will be disproportionally burdened by this impact.

And this scenario would only account for immediate replacement product costs. Growers use a variety of insecticides with multiple biochemical modes of action (MOA) to prevent insect pests from developing resistance to any one chemistry or MOA. By losing access to chlorpyrifos, as would result from this rule, growers will suffer the loss of a vital, effective pest management tool. As a result, growers will have to increasingly rely on the few other remaining chemistries, expediting insect resistance to those other tools and, over time, ultimately resulting in greater crop damage.

Finally, we are very concerned with requirements in the rule that would likely cause growers to lose significant volumes of food and feed product. The rule, after it takes full effect on February 28, 2022, will

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[2] Potter, Bruce, Robert Koch, Phil Glogoza, Ian MacRae, Janet Knodel. University of Minnesota-Extension. July 31, 2017. "Pyrethroid resistant soybean aphids: What are your control options?" *Minnesota Crop News.* https://blog-crop-news.extension.umn.edu/2017/07/pyrethroid-resistant-soybean-aphids.html

[3] University of Nebraska-Lincoln. N.D. *2017 Approximate Retail Price ($) per Unit of Selected Insecticides for Field Crops.* Accessed October 27, 2021. https://cropwatch.unl.edu/2017-CW-News/2017-documents/insect-management/UNL-EC130-Insecticide-Prices-2017.pdf

[4] Mallampalli, Nikhil, Rebeccah Waterworth, and Derek Berwald. United States Environmental Protection Agency. Office of Chemical Safety and Pollution Prevention. November 18, 2020. *Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101)*.

require holders of food to provide special channels of trade documents verifying any chlorpyrifos residues detected after that date were legal at the time of application and fall below the legal limit under the previously established tolerances. Foods that do not meet these requirements may be found adulterated. However, many soybean producers made chlorpyrifos applications prior to EPA's announcement of this action in August 2020, from which there will be detectable residues. Soybean growers and other producers could not have known at that time that special channels of trade documents would be required, and thus this retroactive requirement may force them to lose otherwise legal food and feed products.

Due to recent supply chain disruptions, many growers are finding themselves unable to ship harvested soybeans, which they are having to store in grain bins until shipments can be arranged in the months to come. Many of these shipments will likely go to market after the rule fully takes effect. If shipments occur after February 2022, residues are detected, and retroactively-required channels of trade documents are not available, growers could have significant volumes of produce seized by the Food and Drug Administration (FDA). A reasonably average-sized grain bin 36 feet in diameter and 18 feet high can hold approximately 58,600 bushels of soybeans.[5] At the current market rate of approximately $12.20/bushel, if these soybeans were found to be adulterated due to residue presence, an individual grower could suffer nearly $715,000 in losses. Apply this experience to potentially hundreds or thousands of growers across the supply chain, and U.S. producers could be facing tens to hundreds of millions of dollars in losses of safe and otherwise legal food product, all because they fail to possess retroactively-required documents they could have had no way of knowing they would need at the time of application.

In summary, the soybean grower community stands to suffer immense, irreparable harm should this rule take effect. We object to the rule on these grounds, and request that EPA stay the rule's implementation to prevent these harms from occurring until the Agency can fully review and formally respond to objections.

Due Process Concerns

We are also greatly concerned growers and other stakeholders may have been denied sufficient opportunity to comment and object to this rule and on continued agricultural uses of chlorpyrifos. On October 12, 2021 – nearly six weeks after the rule had been published, and approximately three-quarters of the way through the legally required 60-day objection period – ASA staff discovered this docket on the Federal eRulemaking Portal was not open to accept comments. We immediately notified EPA of this finding, but it is unclear how long the Portal had not been open. The rule is very clear that objectors must file with both the Federal eRulemaking Portal and with EPA's Office of Administrative Law Judges (OALJ) e-filing system, but individuals seeking to object may not have had that opportunity.

The months of September and October, which was the window for filing objections to this rule, happen to be the primary harvest season and one of the busiest times of the year for U.S. soybean growers. If individual growers spared some of their very limited time to go online to the eRulemaking Portal and found the comment function disabled, they may not have had another opportunity to log on during this demanding season. If the Portal truly was disabled for several weeks, it is entirely possible numerous individuals would have been denied their legal right to object to this rule.

Moreover, ASA is concerned agricultural stakeholders will not have an opportunity to advocate for continued agricultural uses of chlorpyrifos during the registration review process. By issuing a final rule

[5] Dorn, Tom. University of Nebraska-Lincoln. March 26, 2012. "How to Estimate Bushels in a Round Grain Bin." *CropWatch.* https://cropwatch.unl.edu/how-estimate-bushels-round-grain-bin

to revoke tolerances and the Agency indicating that it will not further consider agricultural uses as part of the ongoing registration review process,[6] stakeholders have no mechanism to contend for continued agricultural uses. Behind closed doors without public input, EPA unilaterally and inappropriately decided to revoke all tolerances and has indicated it will cancel all agricultural uses. This is not how Congress intended the standard notice and comment process to occur when it enacted the Administrative Procedure Act. We object to the rule on the basis that we do not believe EPA has followed legal due process requirements to allow stakeholders sufficient time to object to this rule or advocate for continued agricultural uses of this pesticide.

Finding that Soybean Uses Pose Dietary Risk – Request for Evidentiary Hearing

We further object to this rule based on EPA's errant finding that the Agency cannot with reasonable certainty be confident that chlorpyrifos residues resulting from soybean uses do not pose an aggregate dietary risk warranting revocation. Pursuant to 40 CFR 178.27, we request EPA grant an evidentiary hearing to review this factual matter.

Through this rule, EPA is revoking all tolerances, including those for soybeans, citing as its justification for this action that the Agency "cannot determine that there is a reasonable certainty that no harm will result from aggregate exposure to residues, including all anticipated dietary (food and drinking water) exposures and all other exposures for which there is reliable information." Further, EPA has indicated it will formally cancel these uses in a separate rulemaking in the near future.[7] We contend this underlying finding that soybean uses of chlorpyrifos might pose a potential dietary risk of concern – the very claim prompting the revocation action of this tolerance – is a factually inaccurate determination by EPA.

As part of its ongoing registration review process, EPA published a proposed interim decision (PID) for the re-registration of chlorpyrifos in December 2020. Under one scenario in the PID, EPA used a heightened 10X Food Quality Protection Act (FQPA) safety standard to ascertain uses that were reasonably certain not to result in harm under a new registration. In that scenario, EPA identified 11 high-benefit crop uses of chlorpyrifos, including soybeans, that "the agency has determined will not pose potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X and may be considered for retention."[8] The Agency considered both food residue and drinking water risks in making this determination. As demonstrated, EPA's own career scientists have established elsewhere in its administrative record that they are reasonably certain soybean uses will not pose harm from aggregate dietary exposures. EPA's determination in this rule that soybean uses might pose an aggregate dietary risk and warrant revocation is factually inaccurate based on the Agency's own recent registration review determinations.

As ASA and others contend in our coalition objection letter dated October 19, 2021, the Court allowed EPA to retain uses of chlorpyrifos it was reasonably certain would not pose harm from aggregate dietary exposure. EPA also clearly has the legal authority to take that very action. ASA seeks an evidentiary hearing to dispute this underlying factual inaccuracy, from which our preferred remedy would be to rescind this rule in its entirety, or at a minimum have the rule modified to preserve soybean chlorpyrifos tolerances. Pursuant to 40 CFR 178.27(c), we will not be including a copy of EPA's December 2020 PID on chlorpyrifos, as we believe this document is an EPA document that is routinely available to any member of the public.

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[6] United States Environmental Protection Agency. Last Updated September 20, 2021. *Frequent Questions about the Chlorpyrifos 2021 Final Rule*. Accessed October 28, 2021. https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule

[7] Ibid.

[8] United States Environmental Protection Agency. December 3, 2020. *Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100*. 40.

Conclusion

While we have previously filed objections with other agricultural stakeholder groups citing some concerns, the irreparable harms that this rule uniquely pose to soybean producers and our ability to be good environmental stewards compels us to file these supplemental objections. Also, because we believe significant factual errors contributed to determinations in this rulemaking that will result in harm to soybean growers, we request an evidentiary hearing to dispute these matters. We are also concerned that other growers and stakeholders, who may have their own objections with this rule, have not been given sufficient opportunity to state their objections or appeal for continued agricultural uses of chlorpyrifos. These are rights guaranteed by federal statutes. Until EPA can review and formally respond to these objections, including the underlying factual concerns ASA has raised for which we request an evidentiary hearing, we urge the Agency to stay this rule to prevent from occurring the significant, irreparable harms that it otherwise will inflict on U.S. soybean producers.

Sincerely yours,

Kevin Scott
President

EXHIBIT 17

CHERRY MARKETING INSTITUTE

MONTMORENCY
U.S. TART CHERRIES™

October 29, 2021

Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

RE: Formal Written Objections and Request for Evidentiary Hearing for Chlorpyrifos Tolerance Revocation (EPA-HQ-OPP-2021-0523)

To Whom It May Concern,

Cherry Marketing Institute (CMI) would like to further object to and request an evidentiary hearing regarding the misrepresentation and disregarding factual statements as it pertains to the revocation of tolerances for Chlorpyrifos. CMI is a non-profit national organization representing U.S. tart cherry growers and Michigan sweet cherry growers. The total U.S. tart cherry crop has the capacity to produce 275-360 million pounds annually, contributing more than $1.4 billion to the economy this past year. Environmental Protection Agency's (EPA) decision on one of the most effective tools in cherry growers' toolbox will cause irreparable harm to cherry growers and the economy.

In a memorandum published in 2020, EPA reviewed 11 different geographical regions and the crops grown there, determining that if a prescribed set of parameters are followed, the amount of residue would below levels of concern.[1] The Michigan tart cherry industry is one of those 11 industries that EPA has determined to receive a "high benefit" from the use of Chlorpyrifos and does not pose a dietary risk. EPA states in Sec. 5(a)(1) of the Proposed Interim Registration Review Decision (PID) (Docket Number EPA-HQ-OPP-2008-0850) that, "Table 10 provides a list of the high-benefit agricultural uses that the agency has determined will not pose potential risk of concerns…"[2].

Furthermore, as stated in the Federal Register, "Considering food exposure alone, the Agency did not identify risks of concern for either acute or steady state exposure."[3] As well, the Michigan tart cherry industry uses this "high-benefit" chemistry as a trunk spray to treat for peachtree borer, lesser peachtree borer, and American plum borer control where the "high benefit signifies that there are no alternative pesticides available or the alternatives are expensive or not as efficacious for a pest on a specific crop."[4]

CMI's concern is that the Michigan tart cherry industry can, as has been proven by EPA, use this resource to produce a nutritional crop in a safe manner. Again, it has been proven by a drinking water assessment and a dietary assessment that our industry's use meets Federal Food, Drug, and Cosmetic Act safety standards. Therefore, by EPA revoking the tolerances for use of Chlorpyrifos

[1] Bohaty, Ph.D., Rochelle et. al, Memorandum: Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review | September 15, 2020 | https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941
[2] Chlorpyrifos, Proposed Interim Registration Review Decision, Case Number 100, December 2020 | https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971
[3] Federal Register, Vol. 86, No. 165, published on Monday, August 30, 2021 https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0001
[4] Bohaty, Ph.D., Rochelle et. al, Memorandum: Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review | September 15, 2020 | https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941

in the Michigan tart cherry industry due to a dietary risk of concern is factually inaccurate, based on EPA's own findings.

In conclusion, Cherry Marketing Institute respectfully request an evidentiary hearing to further convey our concerns with EPA's determination. The Agency has shown that Chlorpyrifos can be used with no risk of harm in the Michigan tart cherry industry, yet revokes the tolerance anyways, a move that could cause irreparable harm.

We appreciate your understanding and consideration in this request.

Sincerely,

Kyle Harris
Director, Grower Relations
Cherry Marketing Institute
12800 Escanaba Drive, Suite A
DeWitt, MI 48820

EXHIBIT 18

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 21, 2020

SUBJECT: Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review.

PC Code: 059101	**DP Barcode:** D456427
Decision No.: 559846	**Registration No.:** NA
Petition No.: NA	**Regulatory Action:** Registration Review
Risk Assessment Type: Single Chemical Aggregate	**Case No.:** NA
TXR No.: NA	**CAS No.:** 2921-88-2
MRID No.: NA	**40 CFR:** §180.342

FROM: Danette Drew, Chemist
Risk Assessment Branch V/VII (RAB V/VII)

John Liccione, Ph.D., Toxicologist, RAB V/VII
David Nadrchal, Chemist, RAB V/VII
Cecilia Tan, Ph.D., Immediate Office
Elizabeth Mendez, Ph.D., Immediate Office
Health Effects Division (HED) (7509P)
Office of Pesticide Programs (OPP)

And

Anna Lowit, Ph.D., Senior Science Advisor
Immediate Office
OPP

THROUGH: Michael S. Metzger, Chief
RAB V/VII
HED (7509P)
OPP

TO: Patricia Biggio, Chemical Review Manager
Risk Management and Implementation Branch I (RMIB I)

Pesticide Re-evaluation Division (PRD) (7508P)

As part of Registration Review, the Pesticide Re-evaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that Health Effects Division (HED) evaluate the hazard and exposure data and conduct dietary (food and drinking water), residential, aggregate, and occupational exposure assessments to estimate the risk to human health that will result from the currently registered uses of pesticides. This memorandum serves as HED's draft human health risk assessment (DRA) for chlorpyrifos to support Registration Review.

The most recent human health risk assessment for chlorpyrifos was completed in 2016 (W. Britton *et al*, D436317, 11/03/2016). The following revisions have been included in the current risk assessment:

- The toxicological points of departure (PODs) are derived from 10% red blood cell (RBC) acetyl cholinesterase (AChE) inhibition using a physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) model, as reported in the 2014 revised chlorpyrifos Human Health Risk Assessment (HHRA) (2014 (D. Drew *et al.*, D424485, 12/29/2014);
- Because the science addressing neurodevelopmental effects remains unresolved, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

As part of an international effort, the EPA's Office of Research and Development (ORD) has been developing a battery of new approach methodologies (NAMs)[1] for evaluating developmental neurotoxicity (DNT). The suite of *in vitro* assays developed by ORD evaluates the majority, but not all, of the critical processes of neurodevelopment. The ORD assays will be presented, using the organophosphates (OPs) as a case study, to the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Scientific Advisory Panel (SAP) in September 2020.[2] Additional assays that evaluate processes not covered by the ORD assays are currently under development by researchers funded by the Europen Food Safey Authority (EFSA). Once data are available from these additional assays, any OP data may be considered in combination with the results of the ORD assays in the future as part of an overall weight of evidence evaluation of the DNT potential for individual OPs, including chlorpyrifos.

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[1] The term NAM has been adopted as a broadly descriptive reference to any non-animal technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment.
[2] https://www.epa.gov/sap/use-new-approach-methodologies-nams-derive-extrapolation-factors-and-evaluate-developmental

Table of Contents

1.0 Executive Summary

This document presents the third revision to the human health risk assessment for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Registration Review of the organophosphate (OP) insecticide chlorpyrifos.

Background
A preliminary human health risk assessment (HHRA) for chlorpyrifos was completed on June 30, 2011 (D. Drew *et al.*, D388070, 06/30/2011) as part of the FIFRA Section 3(g) Registration Review program. A revised HHRA was completed in 2014 (D. Drew *et al.*, D424485, 12/29/2014) to address comments received on the preliminary HHRA and to incorporate new information and new approaches that became available since the June 2011 risk assessment. Most notably, the 2014 revised HHRA incorporated the following: (1) a physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) model for deriving toxicological points of departure (PODs) based on 10% red blood cell (RBC) acetyl cholinesterase (AChE) inhibition; and (2) evidence on neurodevelopmental effects in fetuses and children resulting from chlorpyrifos exposure as reported in epidemiological studies, particularly the results from the Columbia Center for Children's Environmental Health (CCCEH) study on pregnant women which reported an association between fetal cord blood levels of chlorpyrifos and neurodevelopmental outcomes. The 2014 HHRA retained the 10X Food Quality Protection Act (FQPA) Safety Factor (SF) because of the uncertainties around doses that may cause neurodevelopmental effects.

Based on the aggregate risks identified in 2014 (D. Drew *et al.*, D424485, 12/29/2014), a proposed rule (PR) for revoking all tolerances of chlorpyrifos was published in the Federal Register on November 6, 2015 (80 FR 69079). At that time, the EPA had not completed a refined drinking water assessment or an additional analysis of the hazard of chlorpyrifos that was suggested by several commenters to the EPA's 2014 revised HHRA. Those commenters raised the concern that the use of 10% RBC AChE inhibition for deriving PODs for chlorpyrifos may not provide a sufficiently health protective human health risk assessment given the potential for neurodevelopmental outcomes. Accordingly, following the issuance of the proposed rule, the EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood (reported by the CCCEH study investigators) as the source for PODs for the 2016 risk assessment (W. Britton *et al.*, D436317, 11/03/2016). In the 2016 assessment, the 10X FQPA SF was retained.

In the current risk assessment, EPA is utilizing the same endpoint and points of departure as those used in the 2014 HHRA (i.e., the PBPK-PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon). Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

This 2020 human health risk assessment substantially relies on the previous documents developed for chlorpyrifos, along with an updated animal toxicity literature review, and an updated drinking water assessment. Those primary documents include the following:

- D. Drew *et al.,* Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, December 29, 2014, D424485;
- U.S. Environmental Protection Agency, Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides, September 15, 2015, D331251;
- R. Bohaty, Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, September 15, 2020, D459269.
- R. Bohaty, Evaluating the Impact of Removal of the 10x FQPA Safety Factor on Chlorpyrifos, September 15, 2020, D459270.
- U.S. Environmental Protection Agency, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies, March 11, 2016 and supporting analyses presented to the FIFRA Scientific Advisory Panel's (SAP) meeting on April 19-21, 2016, (EPA-HQ-OPP-2016-0062).
- W. Britton *et al*., Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, November 3, 2016, D436317.
- E. Méndez, Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Lifestage Exposure, June 1, 2020, D457378.

Hazard Characterization

The hazard characterization for chlorpyrifos and its oxon is based on adverse health effects in animals and humans related to two different endpoints - AChE inhibition and potential for neurodevelopmental effects. A weight-of-the-evidence (WOE) analysis on the potential for neurodevelopmental effects following chlorpyrifos exposure has been completed using OPP's *Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment* (USEPA, 2010; FIFRA SAP 2010). The Agency is using a robust PBPK-PD model to estimate human PODs for chlorpyrifos and/or its oxon for multiple exposure pathways (e.g., food, water, occupational, non-occupational, and residential) and using the PBPK-PD model to replace default inter- and intra-species factors for risk assessment.

The key issues considered in the WOE are 1) whether chlorpyrifos causes long-term effects from prenatal and/or early lifestage exposure and 2) whether adverse effects can be attributed to doses lower than those which elicit 10% inhibition of RBC AChE. Evidence from 1) the experimental toxicology studies evaluating adverse outcomes such as behavior and cognitive function; 2) mechanistic data on possible modes of action/ adverse outcome pathways (MOAs/AOPs); and 3) epidemiologic and biomonitoring studies, must be considered in making these determinations.

Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with and without retention of the 10X FQPA safety factor; the occupational risk assessments have been conducted both with and without retention of a 10X UF_{DB}.

EPA has applied the Data-Derived Extrapolation Factor (DDEF) guidance (USEPA, 2014), in its use of the PBPK-PD model; the human model replaces the use of default intra-species uncertainty factor for some populations. The PBPK-PD model simulates human RBC AChE inhibition from exposures via oral, dermal, and inhalation routes and thus obviates the need for a default inter-species uncertainty factor to convert an animal POD to a human POD. In addition, the PBPK-PD model incorporates inter-individual variation in response to chlorpyrifos to estimate a distribution of administered doses that could have resulted in 10% RBC AChE inhibition in humans. The DDEF for intra-species extrapolation can then be estimated as the ratio between the mean dose and a dose at the tail of the distribution representing sensitive individuals. For this risk assessment, the 99th percentile of the distribution is being used to account for variation of sensitivity; the intra-species DDEF is 4X for chlorpyrifos and 5X for the oxon for all groups except women who are pregnant or may become pregnant for whom the 10X intra-species factor was retained (Dow, 2014b). While the current PBPK-PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, this model does not include any descriptions on physiological, anatomical and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women of childbearing age, the Agency is applying the standard 10X intra-species extrapolation factor for women of childbearing age.

In addition to DDEF, the PBPK-PD model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following acute (single day, 24 hours) and steady state (21-day) exposures for a variety of exposure scenarios for chlorpyrifos and/or chlorpyrifos oxon. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute studies. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with OPs show a consistent pattern of inhibition reaching steady state at or around 2-3 weeks of exposure in adult laboratory animals (U.S. EPA, 2002). This pattern observed with repeated dosing is a result of the amount of inhibition coming to equilibrium (or steady state) with the production of new enzyme. As such, AChE studies of 2-3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.*, up to 2 years of exposure), so the model simulates a 21-day exposure as a steady-state condition.

Separate PODs have been calculated for dietary (food, drinking water), residential, non-occupational, and occupational exposures by varying inputs on exposure routes (dermal, oral, inhalation), exposure duration and frequency (such as 2 hours per day), and populations exposed based on body weights at different life stages (such as infants or adults).

Use Profile

Chlorpyrifos is a broad-spectrum, chlorinated OP insecticide. Registered use sites include a large variety of food crops and non-food use settings. Public health uses include aerial and ground-based fogger adulticide treatments to control mosquitoes. There is a wide range of registered formulations, application rates, and application methods. Registered labels generally require that handlers use normal work clothing (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. Also, some products are marketed in engineering controls such as water-soluble packets. The restricted entry intervals (REIs) on the registered chlorpyrifos labels range from 24 hours to 5 days. The pre-harvest intervals (PHIs) range from 0 days (Christmas trees) to 365 days (ginseng).

Dietary Risk Assessment

The acute and steady state dietary (food only) exposure analyses are highly refined. The majority of food residues used were based upon U.S. Department of Agriculture's (USDA's) Pesticide Data Program (PDP) monitoring data. Percent crop treated information and food processing factors were included, where available. All commodities with U.S. tolerances for residues of chlorpyrifos are included in the assessment.

Acute dietary (food only) risk estimates are all <100 % of the acute population adjusted dose for food ($aPAD_{food}$) at the 99.9^{th} percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is females (13-49 years old) at 3.2 % $aPAD_{food}$. With the FQPA SF reduced to 1X, the acute dietary risk estimates are <1% of the $aPAD_{food}$ for all populations.

Steady state dietary (food only) risk estimates are all <100 % of the steady state PAD for food ($ssPAD_{food}$) at the 99.9^{th} percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is children (1-2 years old) at 9.7 % $ssPAD_{food}$. With the FQPA SF reduced to 1X, the steady state dietary risk estimates are <1% of the $ssPAD_{food}$ for all populations.

The total dietary exposure to chlorpyrifos is through both food and drinking water. The acute and steady state dietary exposure analyses discussed above only include food and do not include drinking water; the drinking water exposure and risk assessment is discussed in the aggregate exposure/risk characterization portion of this document (Section 7).

Residential (Non-occupational) Risk Assessment

Based upon review of all chlorpyrifos registered uses, only the registered roach bait products may be applied by a homeowner in a residential setting. Residential handler exposure from applying roach bait products has not been quantitatively assessed because these exposures are considered negligible. Residential post-application exposures can occur for adults and children golfing on chlorpyrifos-treated golf course turf and from contacting treated turf following a mosquitocide application. The residential post-application assessment considered and incorporated all relevant populations and chemical-specific turf transferable residue (TTR) data. The residential post-application risk assessment results incorporate PODs derived from 10% RBC AChE inhibition using the PBPK-PD model and assuming both that the FQPA SF is retained at 10X and reduced to 1X.

There are no residential post-application risk estimates of concern for adults or children from chlorpyrifos use on golf course turf or as a mosquitocide on the day of application assuming either the FQPA SF is retained at 10X or reduced to 1X.

Non-Occupational Spray Drift Exposure and Risk Assessment

An updated quantitative non-occupational spray drift (from treatment of agricultural fields) assessment was conducted to assess the potential for residential bystander (who live on, work in, or frequent areas adjacent to chlorpyrifos-treated agricultural fields) exposures. The potential risks from spray drift and the impact of potential risk reduction measures were assessed in a July 2012[3] memorandum. To increase protection for children and other bystanders, chlorpyrifos technical registrants voluntarily agreed to lower application rates and adopt other spray drift mitigation measures such as buffer zones.[4] The spray drift risk assessment results incorporate PODs derived from 10% RBC AChE inhibition using the PBPK-PD model and assuming both that the FQPA SF is retained at 10X and reduced to 1X. There are no risk estimates of concern incorporating the agreed-upon buffer distances[5] and droplet sizes/nozzle types by the EPA and the technical registrants in 2012 if the FQPA SF FQPA SF is retained at 10X or reduced to 1X.

Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Assessment
In January 2013, a preliminary assessment of the potential risks from chlorpyrifos volatilization was conducted.[6] However, this assessment was revised in June 2014[7] following submission of two high-quality vapor phase nose-only inhalation toxicity studies for chlorpyrifos and chlorpyrifos oxon[8]. The studies were conducted to address the uncertainty surrounding exposure to aerosol versus vapor phase chlorpyrifos. At the saturation concentration there was no statistically significant inhibition of AChE activity in RBC, plasma, lung, or brain at any time after the six-hour exposure period in either study. Under actual field conditions, exposures are likely to be much lower to vapor phase chlorpyrifos and its oxon as discussed in the January 2013 preliminary volatilization assessment. Because these studies demonstrated that no toxicity occurred even at the saturation concentration, which is the highest physically achievable concentration, there are no anticipated risks of concern from exposure through volatilization of either chlorpyrifos or chlorpyrifos oxon.

Aggregate Risk Assessment
The Agency has considered aggregate exposures and risks from combined food, drinking water, and residential exposures to chlorpyrifos and chlorpyrifos oxon. The acute aggregate assessment includes only food and drinking water. The steady state aggregate assessment includes exposures from food, drinking water, and residential uses. Exposure to the parent compound chlorpyrifos is

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[3] J. Dawson, W. Britton, R. Bohaty, N. Mallampalli, and A. Grube. Chlorpyrifos: Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures. 7/13/12. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399483, D399485.
[4] R. Keigwin. Spray Drift Mitigation Decision for Chlorpyrifos (059101). 7/2012. U.S. EPA Office of Chemical Safety and Pollution Prevention. EPA-HQ-OPP-2008-0850-0103.
[5] The 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of 80 feet are required for coarse or very coarse droplets and buffer distances of 100 feet are required for medium droplets for aerial applications for application rates ≥ 2.3 lb ai/A. In addition, the 2012 agreement requires buffer distances of ≥ 25 feet and medium to coarse drops for airblast applications at rates >3.76 lb ai/A.
[6] R. Bohaty, C. Peck, A. Lowit, W. Britton, N. Mallampalli, A. Grube. Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization. 1/31/13. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399484, D400781.
[7] W. Britton. W. Irwin. J. Dawson. A. Lowit. E. Mendez. Chlorpyrifos: Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies. 6/25/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D417105.
[8] W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D411959. TXR# 0056694. EPA MRID# 49119501.

expected for food and residential uses. Exposure to either chlorpyrifos or chlorpyrifos oxon may be expected from drinking water sources. The drinking water assessment assumed 100% conversion of chlorpyrifos to the more toxic chlorpyrifos oxon (the predominant chlorpyrifos transformation product formed during drinking water treatment (*e.g.*, chlorination)).

For acute and steady state aggregate assessments, EPA has used a drinking water level of comparison (DWLOC) approach to calculate the amount of exposure available in the total "risk cup" for chlorpyrifos in drinking water after accounting for any chlorpyrifos exposures from food and residential uses. This DWLOC can be compared to the estimated drinking water concentrations (EDWCs) of chlorpyrifos oxon to determine if there is an aggregate risk of concern. The EDWCs are presented in the Environmental Fate and Effects Division's (EFED) updated drinking water assessment (DWA) (see R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

The acute aggregate assessment includes only food and drinking water. Acute DWLOCs were calculated for infants, children, youths, and adult females. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb. With the FQPA SF reduced to 1X, the lowest acute DWLOC calculated was for infants (<1 year old) at 230 ppb.

The steady state aggregate assessment includes dietary exposures from food and drinking water and dermal exposures from residential uses (dermal exposures represent the highest residential exposures). Steady state DWLOCs were calculated for infants, children, youths, and adult females. With the 10X FQPA SF retained, the lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb. With the FQPA SF reduced to 1X, the lowest steady state DWLOC calculated was for infants (<1 year old) at 43 ppb.

Occupational Handler Risk Assessment

In this assessment for the non-seed treatment scenarios, a total of 288 steady state occupational handler exposure scenarios were assessed. Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X database uncertainty factor has been retained (LOC = 100), 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Risks of concern for 45 additional exposure scenarios could potentially be mitigated if engineering controls are used. If the 10X database uncertainty factor is reduced to 1X (LOC = 10), 19 scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 10). Risks of concern for 15 additional scenarios could potentially be mitigated if engineering controls are used.

For the seed treatment scenarios, a total of 93 steady state scenarios were assessed. These scenarios are assessed using default amount handled assumptions for short-term and intermediate exposure durations. These assumptions are appropriate for the steady state exposures. Assuming the 10X database uncertainty factor has been retained (LOC = 100), 12 short-term exposure and 10 intermediate-term scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Assuming the 10X database uncertainty factor has been reduced to 1X (LOC = 10), there are no short- or intermediate-term risk estimates of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs > 10).

Occupational Post-Application Risk Assessment

Steady state occupational post-application exposures and risks were assessed for any crops where hand labor is anticipated following applications of chlorpyrifos. The assessment was completed using seven chlorpyrifos dislodgeable foliar residue (DFR) studies. Chlorpyrifos parent compound is the residue of concern for occupational post-application exposures that occur outdoors; however, it may be possible that the formation of chlorpyrifos oxon is greater and its degradation slower in greenhouses when compared to the outdoor environment. Occupational post-application assessments were performed for: 1) exposures to the parent compound chlorpyrifos in outdoor environments (uses other than greenhouse), 2) exposures to the parent chlorpyrifos (only) in greenhouses and 3) exposures to both the parent and chlorpyrifos oxon in greenhouses.

Current labels require a Restricted Entry Interval (REI) of 24 hours for most crops and activities, but in some cases such as tree fruit, REIs are up to 5 days after application. All post-application worker risks have been updated in the current assessment to incorporate PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the database uncertainty factor has been either retained at 10X and reduced to 1X. Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} of 10X has been retained, the majority of the post-applications scenarios are not of concern 1 day after application (REI = 24 hours). However, for some activities such as irrigation, hand harvesting, scouting, and thinning result in risks of concern up to as many as 10 days following application for the non-microencapsulated formulations and > 35 days for the microencapsulated formulation.
Using the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} has been reduced to 1X, the majority of the post-application risk estimates are not of concern 1 day after application (REI = 24 hours).

Due to uncertainty regarding the formation of chlorpyrifos oxon in greenhouses, HED also estimated risks for reentry into treated greenhouses (all 4 formulations) for the parent chlorpyrifos plus chlorpyrifos oxon using a total toxic residue approach. The total toxic residue approach[9] estimates the chlorpyrifos oxon equivalent residues by 1) assuming a specific fraction of the measured chlorpyrifos dislodgeable foliar residues are available as the oxon and 2) factoring in the relative potency of chlorpyrifos oxon with use of a TAF of 18. It was conservatively assumed that 5% (0.05) of the total chlorpyrifos present as DFR in greenhouses is available for worker contact during post-application activities. When the total toxic residue approach is used and with the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X UF_{DB} has been retained, MOEs are not of concern 0 to 6 days after treatment for non-microencapsulated formulations. For the microencapsulated formulation, MOEs are not of concern 3 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

When the total toxic residue approach is used and with the PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the 10X UF_{DB} has been reduced to 1X, there

[9] Total DFR ($\mu g/cm^2$) = [Chlorpyrifos DFR ($\mu g/cm^2$) * TAF] + [Chlorpyrifos DFR ($\mu g/cm^2$)]

are no risk estimates of concern with the current labeled REI (24 hours), except for the microencapsulated formulation. For the microencapsulated formulation, MOEs are of concern 0 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

2.0 Risk Assessment Conclusions

Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}). There are no acute or steady state dietary (food only) risks of concern with or without the retention of the 10X FQPA SF. There are no residential post-application risk estimates of concern for adults or children with or without the 10X FQPA SF. The aggregate risks are variable and can be determined by comparison of the calculated DWLOCs presented herein with the EDWCs presented in EFED's DWA. Many occupational handler scenarios are of concern with the retention of a 10X UF_{DB}. With the 10X UF_{DB} removed, there are still some handler scenarios of concern. For occupational post-application exposures, even with the 10X UF_{DB} removed, some scenarios are of concern one day after application.

2.1 Data Deficiencies

Toxicology
None.

Residue Chemistry

860.1500:
Separate magnitude of the residue studies for lemons are needed after application of Lorsban 4E and 75% WDG formulations in order to reevaluate the existing tolerance for chlorpyrifos for the citrus fruit crop group.

Magnitude of the residue studies are needed to establish a tolerance for residues of chlorpyrifos on wheat hay.

860.1520:
Processing studies are needed for soybean meal, hulls and refined oil.

Occupational/Residential

No new data requirements have been identified for chlorpyrifos; however, in the 2011 preliminary HHRA, additional studies to address the uncertainties regarding the formation and degradation of chlorpyrifos oxon in greenhouses were recommended. To date, those data have not been submitted. In the absence of the recommended data, and to account for the potential for oxon to form in greenhouses, EPA has used a conservative total toxic residue approach for parent chlorpyrifos plus the chlorpyrifos oxon.

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

The methods in the Pesticide Analytical Manual (PAM) Volume II are adequate to analyze the residue of concern for tolerance enforcement purposes, chlorpyrifos only. The limit of detection of these methods is adequate to cover the lowest tolerance level included in the 40 CFR 180.342 for detection of chlorpyrifos only, 0.01 ppm. In addition, chlorpyrifos is completely recovered using FDA multiresidue protocols D and E (nonfatty matrices) and partially recovered using multiresidue method protocol E (fatty matrices).

2.2.2 Recommended & Established Tolerances

According to HED's *Guidance on Tolerance Expressions* (S. Knizner, 05/27/2009), the tolerance expression for chlorpyrifos in the 40 CFR§180.342 should read as follows:

> "(a) General. (1) Tolerances are established for residues of chlorpyrifos, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorpyrifos (*O,O* -diethyl *O* -(3,5,6-trichloro-2-pyridyl) phosphorothioate."

The current tolerance expression reads "Tolerances are established for residues of the pesticide chlorpyrifos *per se* (*O,O*-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate) in or on the following food commodities."

Based on residue data, HED is recommending tolerances for chlorpyrifos on the following: cotton, gin byproducts (15 ppm); grain, aspirated fractions (30 ppm); corn, field, milled byproducts (0.1 ppm); and wheat, milled byproducts (1.5 ppm). These recommendations, along with recommendations for revisions to current tolerances based on the Organization for Economic Cooperation and Development (OECD) rounding class practice, commodity definition revisions, crop group conversions/revisions, and harmonizition with Codex, are presented in Tables 2.2.2.1 and 2.2.2.2.

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Alfalfa, forage	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Grain, aspirated fractions	--	22	Recommended tolerance based on submitted residue data.
Beet, sugar, dried pulp	5.0	5	Corrected values to be consistent with OECD Rounding Class Practice.
Beet, sugar, roots	1.0	1	Corrected values to be consistent with

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
			OECD Rounding Class Practice.
Beet, sugar, leaves [2]	--	8	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Beet, sugar, tops	8.0	remove	
Brassica, leafy greens, subgroup 4-16B	--	1	Crop group conversion/revision.[3,4]
Cherry, sweet	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Cherry, tart	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10-10, dried pulp	--	5	Crop group conversion/revision. Corrected values to be consistent with OECD Rounding Class Practice.
Citrus, dried pulp	5.0	remove	
Fruit, citrus, group 10-10, oil	--	20	Crop group conversion/revision.
Citrus, oil	20	remove	
Corn, field, forage	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, field, stover	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, milled byproducts	--	0.1	Recommended tolerance based on submitted residue data.
Corn, sweet, forage	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Corn, sweet, stover	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Cotton, gin byproducts	--	15	Recommended tolerance based on submitted residue data.
Cotton, undelinted seed	0.2	0.3	Harmonization with Codex.
Cranberry	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10-10	--	1	Crop group conversion/revision. Corrected values to be consistent with OECD Rounding Class Practice.
Fruit, citrus, group 10	1.0	remove	
Kohlrabi	--	1	Crop group conversion/revision.[3,4]
Kiwifruit, fuzzy	--	2	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Kiwifruit	2.0	remove	
Milk	--	0.01	Commodity definition revision.
Milk, fat	--	0.25	
Milk, fat (Reflecting 0.01 ppm in whole milk)	0.25	remove	
Pepper, bell	--	1	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice.
Pepper, nonbell	--	1	
Pepper	1.0	remove	
Peppermint, fresh leaves	--	0.8	Commodity definition revision.
Peppermint, tops	0.8	remove	
Peppermint, oil	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Radish, roots	--	2	Commodity definition revision. Corrected values to be consistent with OECD Rounding Class Practice
Radish	2.0	remove	

Table 2.2.2.1. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(a)).[1]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Rutabaga, roots	--	0.5	Commodity definition revision.
Rutabaga	0.5	remove	
Spearmint, fresh leaves	--	0.8	Commodity definition revision.
Spearmint, tops	0.8	remove	
Spearmint, oil	8.0	8	Corrected values to be consistent with OECD Rounding Class Practice.
Sorghum, grain, stover	2.0	2	Corrected values to be consistent with OECD Rounding Class Practice.
Strawberry	0.2	0.3	Harmonization with Codex.
Sweet potato, tuber	--	0.05	Commodity definition revision.
Sweet potato, roots	0.05	remove	
Turnip, roots	1.0	1	Corrected values to be consistent with OECD Rounding Class Practice.
Turnip, leaves	--	0.3	Commodity definition revision.
Turnip, tops	0.3	remove	
Vegetable, brassica, head and stem, group 5-16	--	1	Crop group conversion/revision.[3] Corrected values to be consistent with OECD Rounding Class Practice.
Vegetable, brassica, leafy, group 5	1.0	remove	
Wheat, forage	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Wheat, milled byproducts	--	1.5	Recommended tolerance based on submitted residue data.
Wheat, straw	6.0	6	Corrected values to be consistent with OECD Rounding Class Practice.

[1] This table only includes recommended revisions to established tolerances and recommended establishment of new tolerances. For a complete list of all established tolerances see the International Residue Level Summary (IRLS) in Appendix 4.
[2] Sugar beet leaves/tops are no longer considered a significant livestock feed item. Commodity/tolerance may be removed.
[3] The recommended conversion of existing tolerance in/on **Vegetable, brassica, leafy, group 5** is to the following: **Vegetable, brassica, head and stem, group 5-16; Brassica, leafy greens, subgroup 4-16B;** and **Kohlrabi ("**Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)" dated 11/3/2015).
[4] HED is recommending for individual tolerances of 1 ppm for Kohlrabi based on the currently established tolerance for this commodity as part of crop group 5 (Vegetable, brassica, leafy). Kohlrabi is displaced by the crop group conversion noted in the footnote 3 above.

Table 2.2.2.2. Summary of Tolerance Revisions for Chlorpyrifos (40 CFR §180.342(c))[1, 2]			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Asparagus	5.0	5	Corrected values to be consistent with OECD Rounding Class Practice.

[1] This table only includes recommended revisions to established tolerances. For a complete list of all established tolerances see the IRLS in Appendix 4.
[2] Regional registrations.

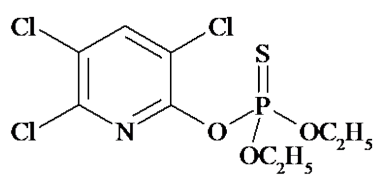
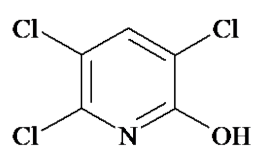
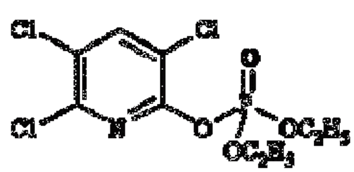
2.2.3 International Harmonization

The Codex Alimentarius Commission and Canada Pesticide Management Rgulatory Agency (PMRA) have established Maximum Residue Limits (MRLs) for chlorpyrifos. Mexico generally adopts U.S. tolerances and/or Codex MRLs for its export purposes. The residue definition for enforcemnt is harmonized for U.S. tolerances and Codex MRLs and includes parent compound chlorpyrifos only. However, Canada MRLs are for chlorpyrifos for a few commodities and for both parent chlorpyrifos and its metabolite TCP (3,5,6-trichloro-2-pyridinol) which is not a U.S. residue of concern, for other commodities.

Except for apple commodities, Canada MRLs are currently not harmonized with the U.S. tolerances because of the difference in residue definition. Codex MRLs are currently harmonized with U.S. tolerances for the following commodities: field corn grain; citrus; cranberry; egg; sorghum grain (and stover); wheat grain; and head and Chinese cabbage. HED is recommending that the current tolerances for strawberry and cotton, undelinted seed be increased to harmonize with the Codex MRLs. There are several U.S. tolerances that are not harmonized with Codex MRLs; harmonization is not currently being recommended for these commodities because the large difference in residue levels indicates that domestic and foreign use patterns are much different. A summary of the U.S. tolerances and international MRLs is included in Appendix 4.

3.0 Introduction

3.1 Chemical Identity

Table 3.1 Chlorpyrifos Degradate/ Residues of Concern Nomenclature.	
Chlorpyrifos	
IUPAC name	*O,O*-diethyl *O*-3,5,6-trichloro-2-pyridyl phosphorothioate
CAS name	*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridinyl) phosphorothioate
CAS registry number	2921-88-2
TCP Metabolite/Degradate (Residue of Concern for Canada) IUPAC Name 3,5,6 Trichloro-2-pyridinol	
Oxon Metabolite/Degradate Common Name Chlorpyrifos Oxon IUPAC Name O,O-diethyl. O-3,5,6-trichloro-2-pyridyl phosphate	

3.2 Physical/Chemical Characteristics

Technical chlorpyrifos is a white crystalline solid. Chlorpyrifos is stable in neutral and acidic aqueous solutions; however, stability decreases with increasing pH. Chlorpyrifos is practically insoluble in water, but is soluble in most organic solvents (i.e., acetone, xylene and methylene chloride). Chlorpyrifos is moderately volatile based on its vapor pressure of 1.87×10^{-5} mmHg at 25°C. See Appendix 3.

Laboratory studies show chlorpyrifos is susceptible to hydrolysis under alkaline conditions and that volatilization and photo-degradation are not likely to play a significant role in the dissipation of chlorpyrifos in the environment. Nonetheless, chlorpyrifos has been detected in air samples, and so volatilization may play more of a role in dissipation than laboratory studies indicate. The major route of dissipation appears to be aerobic and anaerobic metabolism, as well as partitioning to the soil (partition coefficient of 6040). The aerobic aquatic metabolism half-life is 30.4 days (~6% remaining in 4 months). The water peak half-lives were ~1 day in a monitoring study (MRID 44711601). Based on available data, chlorpyrifos degrades slowly in soil under both aerobic and anaerobic conditions. Degradation begins with cleavage of the phosphorus ester bond to yield 3,5,6-trichloro-2-pyridinol (TCP). Field dissipation studies show that chlorpyrifos is moderately persistent under field conditions—dissipation half-life less than 60 days. Chlorpyrifos is only slightly soluble in water (1400 ppb). However, if it reaches aquatic environments the Log K_{ow} (4.7) indicates that chlorpyrifos may bioaccumulate in fish and other aquatic organisms. A fish bioaccumulation study shows that chlorpyrifos is absorbed by fish; however, it rapidly depurates when exposure ceases.

Oxidation of chlorpyrifos to chlorpyrifos oxon could potentially occur through photolysis, aerobic metabolism, and chlorination as well as other oxidative processes. Chlorpyrifos oxon is expected to have similar fate characteristics as chlorpyrifos except chlorpyrifos oxon is more soluble in water and undergoes hydrolysis faster. The hydrolysis half-life of chlorpyrifos oxon is significantly shorter than that observed for chlorpyrifos (5 days vs 81 days). Chlorpyrifos oxon hydrolyses to form TCP. For chlorpyrifos, water purification (chlorination) has been shown to be a major route of chlorpyrifos oxon formation and degradation.

3.3 Pesticide Use Pattern

Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro -2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated OP insecticide. Registered use sites include a large variety of food crops (including fruit and nut trees, many types of fruits and vegetables, and grain crops), and non-food use settings (e.g., golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products). Public health uses include aerial and ground-based fogger adulticide treatments to control mosquitoes. There are also residential uses of roach bait products and ant mound treatments. Permanent tolerances are established (40 CFR§180.342) for the residues of chlorpyrifos in/on a variety of agricultural commodities, including meat, milk, poultry and eggs. There are also tolerances for use in food handling/service establishments (FHE or FSE). Chlorpyrifos is manufactured as granular, microencapsulated liquid, soluble concentrate liquid, water dispersible granular in water soluble packets (WSP), wettable powders in WSPs, impregnated paints, cattle ear tags, insect bait stations and total release foggers. There is a wide range of application rates and methods. Registered labels generally require that handlers use normal work clothing/baseline attire (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. The REIs on the registered chlorpyrifos labels range from 24 hours to 5 days. The master use table is provided in Appendix 5.

3.4 Anticipated Exposure Pathways

Chlorpyrifos applications may be made directly to growing crops (food and feedstuffs) which may result in human exposure to chlorpyrifos in food and to chlorpyrifos or chlorpyrifos oxon in drinking water (from surface and ground water sources). Registered uses that may result in residential (non-occupational) exposures to chlorpyrifos include aerial and ground-based fogger adult mosquitocide applications and golf course turf applications. There are also potential exposures for residential bystanders who live on, work in, or frequent areas adjacent to chlorpyrifos-treated agricultural fields from spray drift and volatilization. In occupational settings, exposure may occur while handling the pesticide prior to application, as well as during application. There is also a potential for post-application exposure for workers re-entering treated fields.

3.5 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf). As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age and ethnic group. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Spray drift can also potentially result in post-application exposure and it was considered in this analysis. Further considerations are also currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

4.0 Hazard Characterization and Dose-Response Assessment

The 2014 chlorpyrifos HHRA provided summary information and weight of evidence findings integrating multiple lines of evidence from experimental toxicology and epidemiology with respect to AChE/ChE inhibition (acetylcholinesterase/cholinesterase) and neurodevelopmental outcomes. The 2014 HHRA also describes the use of a robust PBPK-PD model for PODs and refined intra-species factors. Full details of the science and data analysis that support these conclusions can be found in the 2014 chlorpyrifos HHRA (D. Drew *et al.,* D424485, 12/29/2014).

4.1 Safety Factor for Infants and Children (FQPA Safety Factor)[10]

The dietary, residential, aggregate, and non-occupational assessments have been conducted both with and without the retention of the 10X FQPA Safety Factor based on the following considerations:

- The toxicology database for chlorpyrifos is complete for deriving risk assessment PODs based on cholinesterase inhibition.
- Despite several years of study, the science addressing neurodevelopmental effects remains unresolved. Regulatory history of the scientific evaluation is contained in Appendix 2.
- Chlorpyrifos is an OP insecticide with an established neurotoxic MOA; neurotoxicity is the most sensitive effect in all species, routes, and lifestages. AChE inhibition is being used to derive the PODs for risk assessment. These PODs are protective for neurotoxic effects related to AChE inhibition and potential downstream neurotoxic effects. Although the dose response relationship of AChE inhibition across different lifestages is established quantitatively, the MOAs/AOPs for postulated neurodevelopmental effects occurring at doses below those eliciting cholinesterase inhibition have not been established.
- A literature search identified epidemiological studies with results suggesting an association between neurodevelopmental effects and exposure to chlorpyrifos even in the absence of AChE inhibition.
- There are no residual uncertainties in the exposure database. The chlorpyrifos residue chemistry database is robust. The exposure assessment in drinking water provides a conservative approach for estimating chlorpyrifos parent and oxon concentrations in ground and surface water sources of drinking water and is unlikely to underestimate exposure. The dietary (food) exposure analyses, although highly refined, incorporate conservative assumptions that are unlikely to underestimate exposures. Residue levels are based on either monitoring data reflecting actual residues found in the food supply, or high-end residues in foods. Furthermore, processing factors used were either those measured in processing studies, or default high-end factors representing the maximum concentration in the processed commodity. Residential exposure assessments use data from surrogate and chemical-specific sources and rely on the 2012 Residential Standard Operating Procedures (SOPs). Although some refinements have been incorporated into the exposure assessments, the exposure assumptions will not underestimate risks.

As discussed above and in Appendix 2, despite several years of study, the science addressing neurodevelopmental effects remains unresolved, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted both with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF

[10] HED's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children).

(*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X Database Uncertainty Factor (UF_{DB}).

4.2 Dose Response Assessment

4.2.1 Durations of Exposure, Critical Windows of Exposure, & Temporality of Effects

In risk assessment, exposure is evaluated considering the toxicology profile. More specifically, a variety of toxicokinetic and toxicodynamic factors are considered when determining the appropriate exposure durations to assess for risk potential. In the case of chlorpyrifos, exposure can occur from a single event or on a single day (*e.g.*, eating a meal) or from repeated days of exposure (*e.g.*, worker, residential).

With respect to AChE inhibition, these effects can occur from a single exposure or from repeated exposures. For OPs, repeated exposures generally result in more AChE inhibition at a given administered dose compared to acute exposures. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with most OPs show a consistent pattern of inhibition reaching steady state at or around 2-3 weeks of exposure in adult laboratory animals (U.S. EPA, 2002). This pattern observed with repeated dosing is a result of the amount of inhibition comes at equilibrium with production of new enzyme. As such, AChE studies of 2-3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.*, up to 2 years of exposure). Thus, for most of the human health risk assessments for the OPs, the Agency is focusing on the critical durations ranging from a single day up to 21 days (*i.e.*, the approximate time to reach steady state for most OPs). As described below, PODs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations.

With respect to effects on the developing brain, very little is known about the duration of chlorpyrifos exposure needed to precipitate adverse effects in the developing brain. There are critical windows of vulnerability (Rice & Barone, 2000; Rodier, 2004) with regard to toxicant effects on brain development. This vulnerable period in humans spans early pregnancy to adolescence (Rice & Barone, 2000). In fact, evidence shows that synapse formation peaks quite late in human brain development at 4-8 years of age (Glantz *et al.,* 2007). Within these vulnerable periods there are key neurodevelopmental processes (*e.g.* cell division, migration, differentiation, synaptogenesis, and myelination) and each of these is region and stage specific. Consequently, the time of toxicant exposure will be a major determinate in the spectrum of neurotoxic effects. Because of the dynamic processes in the developing brain (*i.e.*, vulnerable windows) it is difficult to determine if the effect or differences in effects is due to duration of exposure or if different vulnerable windows were affected. As such, it is impossible at this time to rule out even a single day of high exposure to chlorpyrifos having a potential adverse neurodevelopmental effect in humans.

For the chlorpyrifos risk assessment, PODs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations.

4.2.2 Use of the PBPK-PD Model

Evaluation of PBPK-PD models intended for risk assessments includes a review of the model purpose, model structure, mathematical representation, parameter estimation (calibration), and computer implementation (USEPA, 2006b). The chlorpyrifos PBPK-PD model has been through several quality assurance reviews by various individuals or groups, including the Agency, and found that the model reasonably predicts both blood/urine dosimetry of chlorpyrifos and 3,5,6-trichloro-2-pyridinol (TCPy), and ChE inhibition in two controlled, deliberate oral human dosing studies (Nolan *et al.,* 1982; Kisicki *et al.,* 1999) and a dermal human study (Nolan *et al.,* 1984). The PBPK-PD model predictions for rats inhaled chlorpyrifos compare well with observed data (Hotchkiss *et al.,* 2013) with respect to chlorpyrifos, oxon, and TCPy concentrations in plasma, and ChE in plasma, RBC and brain (Poet *et al.,* 2014). Significant improvements have been made to the PBPK-PD model in response to the 2008, 2011, and 2012 SAPs, the Agency, and peer reviewers from academic journals. The Agency believes that the model is sufficiently robust for use in HHRA. Age-specific parameters are incorporated in the model to allow for lifestage-specific evaluations from infant through adulthood. Since the model accounts for human specific metabolism and physiology, using the human model obviates the need for the inter-species extrapolation factor. The deterministic model can be used to simulate an "average individual" for all age groups. As such, as described below, the Agency is using the PBPK-PD model to derive the scenario-specific PODs for all age groups (See Table 4.2.2.1.2 below).

At the 2011 SAP meeting, the Panel specifically noted the lack of maternal and fetal PK and PD compartments in the current PBPK-PD model to inform about tissue dosimetry and AChE inhibition during lactation (FIFRA SAP 2011). As described in detail below, the Agency has assessed exposure to bottle-feeding infants exposed to the oxon through water used with infant formula. With respect to chlorpyrifos or oxon exposure to infants through breast milk, any exposure to chlorpyrifos would be far lower than drinking water levels predicted by EFED. Thus, the Agency is already accounting for oral exposure to chlorpyrifos to infants via bottle-feeding and a lactation component in the PBPK-PD model is not necessary.

The SAP noted the lack of maternal and fetal PK and PD compartments in the PBPK-PD model to inform tissue dosimetry and AChE inhibition to pregnant women and their fetuses (FIFRA SAP 2011). With respect to exposure to the fetus during gestation, there are multiple studies on chlorpyrifos (Mattsson et al., 1998, 2000) and other OPs (U.S. EPA, 2006a) which show that the pregnant dam exhibits similar or more AChE inhibition than the fetus at a given dose to the dam. As such, for AChE inhibition, protecting against AChE inhibition in the pregnant female is expected to be protective for AChE inhibition in the fetus. Biomonitoring data from rats and humans support the findings of these AChE studies. Specifically, Whyatt *et al.* (2003) have shown that levels of chlorpyrifos in maternal blood are similar to the levels measured in human umbilical cord blood (Whyatt *et al.,* 2003). With respect to the pregnant dam during gestation, metabolic activities and physiological parameters can be altered during pregnancy (for citations, see Appendix 1 of D424485 (D. Drew *et al.,* 12/29/2014)). While the PBPK-PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, the model does not include any descriptions on physiological, anatomical and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women who may be pregnant, **the Agency is applying the standard 10X intra-species extrapolation factor for women of childbearing age.**

4.2.2.1 Derivation of Human Equivalent Doses/Concentrations

In typical risk assessments, PODs are derived directly from laboratory animal studies and inter- and intra-species extrapolations are accomplished by use of 10X factors. In the case of chlorpyrifos and its oxon, PBPK-PD modeling is being used as a data-derived approach to estimate PODs for all age groups and Data-Derived Extrapolation Factors (DDEF) for intra-species extrapolation for some groups (USEPA, 2014). The Agency typically uses a 10% response level for AChE inhibition in human health risk assessment. This response level is consistent with the 2006 OP cumulative risk assessment (USEPA, 2006a) and other single chemical OP risk assessments. As such, the model has been used to estimate exposure levels resulting in 10% RBC AChE inhibition following single day (acute; 24 hours) and 21-day exposures for a variety of exposure scenarios (see Table 4.2.2.1.2 below).

The PBPK-PD model accounts for PK and PD characteristics to derive age, duration, and route specific PODs (Table 4.2.2.1.2 below). Separate PODs have been calculated for dietary (food, drinking water), residential, and occupational exposures by varying inputs on types of exposures and populations exposed. Specifically, the following characteristics have been evaluated: duration [acute, 21 day (steady state)]; route (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency [events per day (eating, drinking)].

For each exposure scenario, the appropriate body weight for each age group or sex was modeled as identified from the Exposure Factors Handbook (USEPA, 2011) for occupational and residential exposures and from the NHANES/What We Eat in America (WWEIA) Survey[11] for dietary exposures. All body weights used are consistent with those assumed for dietary, occupational, and residential exposure assessments. The Agency assesses dietary exposures for children 6-12 years old, and children between 6-11 years old for residential exposures. For purpose of aggregate assessment, these age groups are combined. The Agency assesses dietary exposures for youths 13-19 years old, and youths between 11-16 years old for residential exposures. For purpose of aggregate assessment, these age groups are combined. The body weights used in the chlorpyrifos PBPK model are summarized in Table 4.2.2.1.1.

[11] http://www.ars.usda.gov/Services/docs.htm?docid=13793

Table 4.2.2.1.1 Body Weight Assumptions Incorporated into PBPK Model for Chlorpyrifos.						
			Population & Body Weight (kg)			
Exposure Scenario	**Exposure Pathway**	**Infants (<1 year old)**	**Young Children (<1 - 2 years old)**	**Children (Residential:6-11 years old; Dietary:6-12 years old)**	**Youths (Residential:11-16 years old; Dietary:13-19 years old)**	**Females (13 – 49 years old)**
Dietary	Food and Drinking Water	4.8[1]	12.6[2]	37.1[2]	67.3[2]	72.9[2]
Residential (Contact with Treated Turf from Mosquitocide Application)	Oral		11[3]			
	Dermal			32[5]	57[6]	69[4]
	Inhalation		11[3]			69[4]
Residential (Golfing)	Dermal			32[5]	57[6]	69[4]
Non-Occupational Spray Drift	Oral		11[3]			
	Dermal					69[4]
Occupational	Dermal, Inhalation					69[4]

1 For infants from birth to < 1 year old, the Agency has selected the body weight for the youngest age group, birth to < 1 month old, 4.8 kg (Exposure Factors Handbook, Table 8-3, mean body weight for the birth to < 1 month age group).
2 NHANES/WWEIA
3 Exposure Factors Handbook, Table 8-3, mean body weight for the 1 to < 2 year old age group.
4 Exposure Factors Handbook, Table 8-5, mean body weight for females 13 to < 49 years old.
5 Exposure Factors Handbook, Table 8-3, mean body weight for the 6 to < 11 year old age group.
6 (Exposure Factors Handbook, Table 8-3, mean body weight for the 11 to < 16 year old age group).

In order to derive the scenario specific PODs, assumptions were incorporated into the PBPK model on routes of exposure, surface area exposed, etc. The following scenarios were evaluated: dietary exposure to the oxon exposures via drinking water (24-hour and 21-day exposures for infants, children, youths, and female adults); exposure to chlorpyrifos exposures via food (24-hour and 21-day exposures for infants, children, youths, and female adults); 21-day residential exposures to chlorpyrifos via skin for children, youths, and female adults; 21-day residential exposures to chlorpyrifos via hand-to-mouth ingestion for children 1- 2 years old; 21-day residential exposures to chlorpyrifos via inhalation for children 1-2 years old and female adults.

Steady state dietary exposure was estimated daily for 21 days. For drinking water exposure, infants and young childrens (infants < 1 year old, children between 1-2 years old, and children between 6-12 years old) were assumed to consume water 6 times per day, with a total consumption volume of 0.69 L/day[12]. For youths and female adults, they were assumed to consume water 4 times per day, with a total consumption volume of 1.71 L/day[13].

[12] The daily volumes consumed and number of daily consumption events for all populations are mean values by age group based on USDA What We Eat in America, NHANES survey for dietary exposures. The mean daily water consumption values for children 1- 2 years old (0.35 L/day) and children 6-12 years old (0.58 L/day), were less than that for the infants (0.69 L/day); however, the infant daily water consumption volume was selected to be protective for PBPK-PD POD derivation for these age groups.
[13] For youths 13-19 years old, the mean daily water consumption (0.93 L/day), was less than that for the female adults (1.71 L/day); however, the adult daily water consumption was also selected to be protective.

All residential steady state exposures were set to be continuous for 21 days. For all residential dermal exposures to chlorpyrifos the dermal PODs were estimated assuming 50% of the skin's surface was exposed. Exposure times for dermal exposure assessment were consistent with those recommended in the 2012 Residential Standard Operating Procedures (SOPs)[14]. For residential inhalation exposures following public health mosquitocide application, the exposure duration was set to 1 hour per day for 21 days. The incidental oral PODs for children 1 to < 2 years old for other turf activities were estimated assuming that there were six events, 15 minutes apart, per day.

In addition to dietary and residential exposures, the PBPK-PD model was also used to estimate exposure levels resulting in 10% RBC AChE inhibition following steady state occupational exposures. For occupational handlers and post-application workers, the dermal PODs were estimated assuming a body weight of 69 kg (to represent a female aged 13-49), 100% of the skin's surface was exposed for 5 days/week and the exposure duration was 8 hours/day for 21 days. For occupational handlers, the inhalation PODs were estimated exposure for 8 hours/day, 5 days/week, for 21 days.

[14] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

Table 4.2.2.1.2. Chlorpyrifos PBPK Modeled Doses (PODs) Corresponding to 10% RBC AChE Inhibition.

RA Type	Exposure Pathway (all chlorpyrifos unless noted)	Infants (< 1 yr old)		Young Children (1 - 2 years old)		Children (Residential: 6-11 years old; Dietary: 6-12 years old)		Youths (Residential: 11-16 years old; Dietary: 13-19 years old)		Females (13 – 49 years old)	
		Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)	Acute	Steady State (21 day)
Dietary	Drinking Water (oxon conc, ppb)	1,183	217	3,004	548	7,700	1,358	4,988	878	5,285	932
	Food (mg/kg/day)	0.60	0.103	0.581	0.099	0.53	0.09	0.475	0.080	0.467	0.078
Residential (Golfers)	Dermal (mg/kg/day)						25.75		13.95		11.89
Residential (Mosquitocide Application) and Spray Drift	Dermal (mg/kg/day)				134.25						23.6
	Oral (mg/kg/day)				0.101						
	Inhalation (concn. in air mg/m^3)				2.37						6.15
Occupational	Dermal (mg/kg/day)										3.63
	Inhalation (mg/kg/day)										0.138

*PODs and exposure and risk estimates for females 13-49 yrs covers all youths >13 yrs

4.2.2.2 Intra-species Extrapolation

With respect to intra-species extrapolation, the PBPK-PD model can be run in 'variation' mode which allows for age-specific parameters to vary across a distribution of values. The model will not be described in detail here as it is described in multiple recent publications, including a detailed report reviewed by the FIFRA SAP in 2011; summary information is provided here. All model code for the PBPK-PD variation model are available to the public.

Significant improvements have been made to the PBPK-PD model in response to the 2008, 2011, and 2012 SAPs, the Agency, and peer reviewers from academic journals in addition to the input of new data. At the 2011 SAP, the panel was critical of some aspects of how the registrant proposed to assess intra-species extrapolation. The registrant made multiple changes, including the addition of a global sensitivity analysis, improvements to the quantitative approach to evaluate population variability across individuals at a given age, and an uncertainty analysis on metabolism data from human hepatic microsomes to address variation in metabolic capabilities. .

Of the more than 120 parameters in the PBPK-PD model, 16 parameters were selected for varying in the DDEF intra-species analysis. They were selected using local and global sensitivity analyses (MRID 49248201, Dow, 2014a,b). The distributions for these 16 parameters are provided in Table 4.2.2.2.1 below. Inter-individual variations for the 16 sensitive parameters (listed above) were assumed to follow a lognormal distribution. The distributions are truncated at far extreme values only to permit the model to compute but functionally not truncated with respect to assessing human variability. References cited in the table are listed in the report "Development of Chemical Specific Adjustment Factors for Chlorpyrifos and Chlorpyrifos Oxon" (MRID number 49248201) and also provided in Dow, 2014a,b,c.

Table 4.2.2.2.1. Sixteen parameters in variation model. Extracted from Dow, 2014c.				
Parameter	**Mean value**	**Standard Deviation**	**CV**	**Variability Reference**
Total Blood Volume (L/kg body	0.08	0.0022	0.027	P3M; Price *et al.,* 2003
Plasma PON1 (µmol/hr×L)	162,000	92,000	0.57	Smith et al., 2011
Hepatic Blood Flow (L/hr×kg tissue)	50	14	0.27	Materne et al., 2000
RBC ChE Inhibition Rate (l/µmol×hr)	100	17	0.17	Dimitriadis and Syrmos,
Hepatic PON1 (µmol/hr×kg tissue)	154,000	88,000	0.57	Smith et al., 2011
Hematocrit (%)	0.45	0.031	0.068	P3M; Price *et al.,* 2003
RBC ChE Degradation Rate (l/hr)	0.01	0.0014	0.14	Chapman *et al.,* 1968
Hepatic P450 Bioactivation to Oxon (µmol/hr×kg tissue)	690	410	0.59	Smith et al., 2011
Hepatic P450 Detoxification to TCPy (µmol/hr×kg tissue)	1500	800	0.53	Smith et al., 2011
RBC ChE Reactivation Rate (l/hr)	0.014	0.0050	0.36	Mason et al., 2000
Intestinal CYP Bioactivation to Oxon (µmol/hr×kg tissue)	82	43	0.52	Obach *et al.,* 2001
Intestinal CYP Detoxification to TCPy (µmol/hr×kg tissue)	53	28	0.52	Obach *et al.,* 2001
Transfer Rate to Intestine (hr-1)	0.31	0.081	0.26	Singh et al., 2006
Volume of the Liver (L/kg body weight)	0.032	0.0010	0.032	P3M; Price *et al.,* 2003
Hepatic Carboxyl Basal Activity Rate (l/hr/kg tissue)	1,270,000	460,000	0.36	Pope *et al.,* 2005
Hepatic Carboxyl Reactivation Rate (l/hr)	0.014	0.0050	0.36	Mason et al., 2000

Of these 16 parameters, four metabolism-related parameters (hepatic CYP450 activation of chlorpyrifos to chlorpyrifos oxon, hepatic CYP450 detoxification of chlorpyrifos oxon to TCPy, hepatic PON1 detoxification of chlorpyrifos oxon to TCPy, PON1 detoxification of chlorpyrifos oxon to TCPy in plasma) were found to drive more than 80% of the total variation in RBC AChE inhibition (Table 4.2.2.2.2). The human variability for these four parameters were assessed using *in vitro* data from 30 human hepatic microsome samples and 20 human plasma samples (Smith et al., 2011). Twenty of the hepatic microsome samples came from individuals < 12 years of age; and 10 of the samples came from adults > 17 years old. Ten of the plasma sample came from individuals < 2 years of age; and 10 of the samples came from adults. Because the findings from Smith et al (2011) account for more than 80% of the total variation in RBC AChE inhibition, it was determined that evaluating the uncertainty associated with the data (i.e., small number of samples compared to the large U.S. population) from this study was important to having confidence in the DDEFs derived from the variation model. Although some other *in vitro* studies shown in Table 4.2.2.2.1 also have small numbers of samples, these parameters make relatively small contributions to the overall variability. As such, additional quantitative uncertainty analysis on these *in vitro* studies is not needed.

Table 4.2.2.2.2. Four Metabolism Related Parameters in Variation Model. Extracted from Dow, 2014c.			
hepatic CYP450 activation of chlorpyrifos to chlorpyrifos oxon	total blood volume	RBC ChE degradation rate	transfer rate of chlorpyrifos or oxon from the stomach to the intestine
hepatic PON1 detoxification of chlorpyrifos oxon to TCPy	hepatic blood flow	RBC ChE reactivation rate	volume of the liver
PON1 detoxification of chlorpyrifos oxon to TCPy in plasma	RBC AChE inhibition rate	intestinal CYP bioactivation to chlorpyrifos oxon	hepatic carboxyl basal activity rate
hepatic PON1 detoxification of chlorpyrifos oxon to TCPy	hematocrit	intestinal CYP detoxification to TCPy	hepatic carboxyl reactivation rate

The uncertainty associated with these four critical parameters were incorporated in the subsequent Monte Carlo analysis by generating 50 sets of unbounded parametric distributions using the following approach. First, the parametric bootstrap approach was used to sample 1000 values, with replacement, from the *in vitro* data. Then, this process was repeated for 50 iterations, and the resulting 50 sets of distribution all have equally probable sets of means and coefficient of variation as the observed data, except for the coefficient of variation of the plasma PON1 metabolism rate. Since the liver is the origin of PON1 in plasma, the variation of the plasma PON1 metabolism rate was set to be the same as the hepatic PON1 metabolism rate. Even though the distributions have similar means and coefficient of variation as the observed data, they included values outside of the range of the observed data because the distributions were assumed to be unbounded. These 50 sets of distributions, for each of the four parameters, were found to cover the entire range of the observed data; and the ratios of maximum value to minimum value in the simulated distributions were at least three times the ratios of maximum value to minimum value in the observed data.

According to EPA's Data-Derived Extrapolation Factor guidance, when calculating a DDEF intra-species extrapolation (USEPA, 2014), administered doses leading to the response level of interest (10% change in RBC AChE inhibition) are compared between a measure of average response and response at the tail of the distribution representing sensitive individuals. Oral doses that cause 10% RBC AChE inhibition in both adults and 6-month old infants (example provided in Figure 1 a,b) were estimated using the model. The ratio of the adult ED_{10} to the infant ED_{10} was then used to derive intraspecies extrapolation factors. In the subsequent Monte Carlo simulations, the target age group is six-month-old individuals. Some model parameters are specific to this age group (e.g., PON1 metabolism in plasma), and some parameters are scaled by body weight that reflect this age group (e.g., tissue volume). Based on the 5th percentile of the distributions, the DDEF for intraspecies extrapolation is 2.8X for chlorpyrifos and 3.1X for the oxon (Dow, 2014b). Based on the 99th percentile of the distributions, the DDEF for intraspecies extrapolation is 4X for chlorpyrifos and 5X for the oxon (Dow, 2014b). For this revised HHRA, the 99th percentile is being used to account for sensitivities (i.e., the intra-species factor is 4X for chlorpyrifos and 5X for the oxon for all groups except women who are pregnant or may become pregnant). As shown in Figure 1b, at the 99th-ile, only 1% of infants will experience 10% or greater RBC AChE inhibition at the POD.

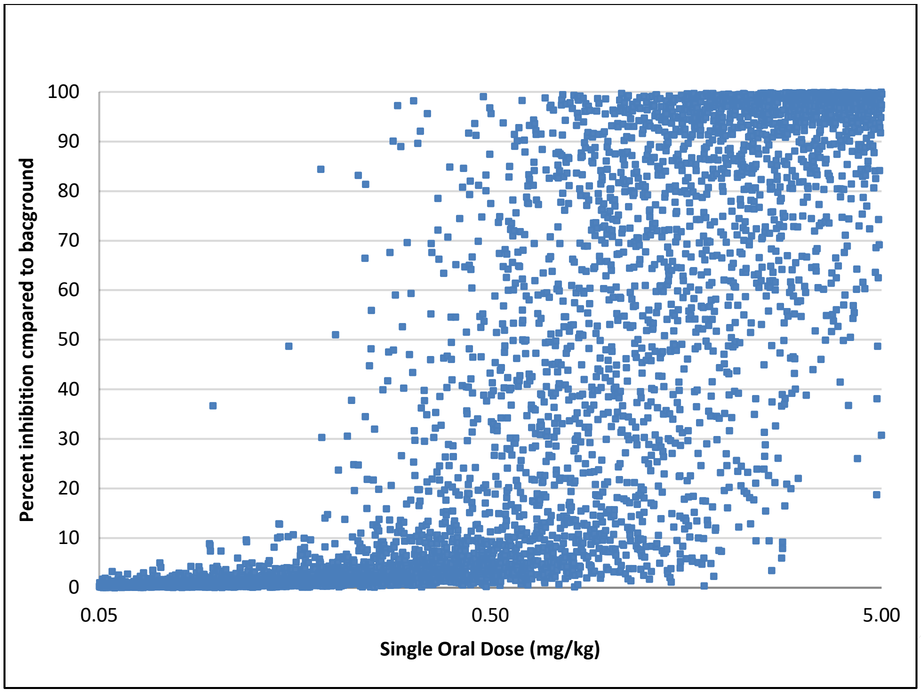


Figure 1a. Simulated population of 6 month olds for intra-species extrapolation DDEF derivation. Percent RBC AChE inhibition from exposure to single oral doses of chlorpyrifos ranging from 0.05 to 5.0 mg/kg/day (X and Y axes provided on the log scale).

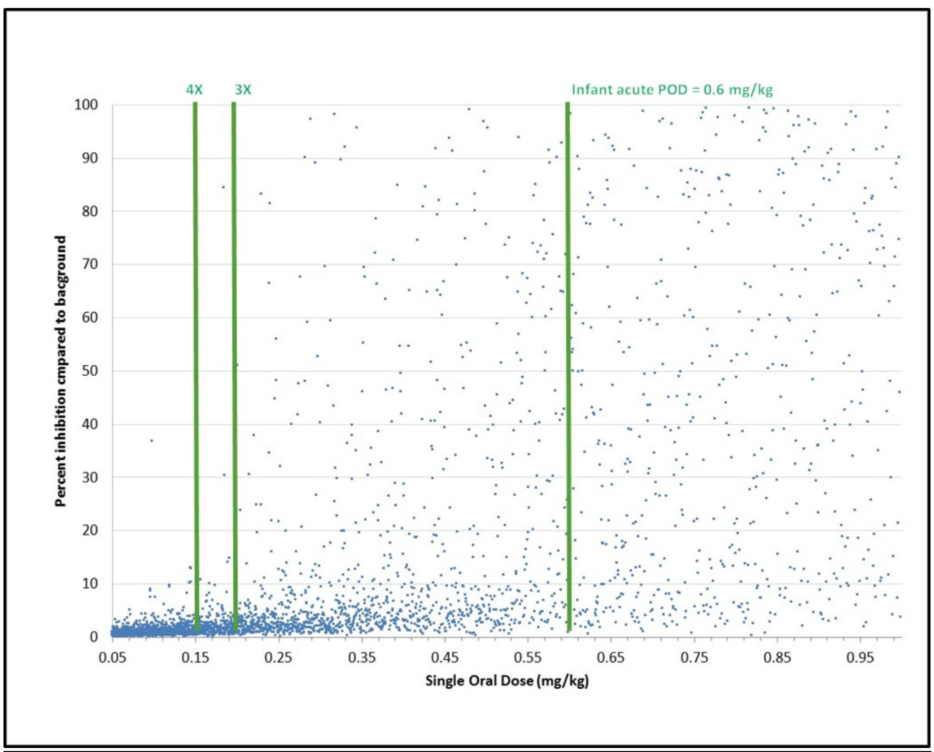


Figure 1b. Simulated population of 6 month olds for intra-species extrapolation DDEF derivation. Percent RBC AChE inhibition from exposure to single oral doses of chlorpyrifos ranging from 0.05 to 1.0 mg/kg/day. Green lines represent the infant acute POD for chlorpyrifos, the POD adjusted for the 3X and 4X intraspecies factors for the 95 and 99[th]-%ile, respectively.

In summary, for the chlorpyrifos HHRA, the human PBPK-PD model has been used to derive PODs for RBC AChE inhibition for various populations, durations, and routes (Table 4.2.2.1.2). As such, the interspecies factor is not needed. To account for variations in sensitivities, an intra-species factor of 4X for chlorpyrifos and 5X for the oxon is applied for all groups except women of childbearing age. For women of childbearing age, the typical 10X intra-species factor is being applied due the lack of appropriate information and algorithms to characterize physiological changes during pregnancy. Risks are being presented throughout the document assuming both the 10X FQPA SF is being retained for all subpopulations and reduced to 1X for all subpopulations. The individual and total uncertainty factors are summarized in Table 4.2.2.2.3.

Table 4.2.2.2.3 Uncertainty Factor Summary.

Uncertainty Factor	FQPA 10X Retained			FQPA 10X Reduced to 1X		
	Females	All other Subpopulations		Females	All other Subpopulations	
		Food (parent)	Drinking Water (oxon)		Food (parent)	Drinking Water (oxon)
Interspecies	1	1	1	1	1	1
Intraspecies	10	4	5	10	4	5
FQPA	10	10	10	1	1	1
Total	**100**	**40**	**50**	**10**	**4**	**5**

4.3 Endocrine Disruptor Screening Program

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision for chlorpyrifos, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), chlorpyrifos is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[15] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

Chlorpyrifos is on List 1 for which EPA has received all of the required Tier 1 assay data. The Agency has reviewed all of the assay data received for the appropriate List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets (see Docket # EPA-HQ-OPP-2008-0850 for chlorpyrifos)."For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[16]

5.0 Dietary Exposure and Risk Assessment

HED had previously conducted both acute and steady state dietary (food only) exposure analyses for chlorpyrifos using DEEM and Calendex software with the Food Commodity Intake Database (FCID) (D. Drew *et al.,* D424486, 11/18/2014), respectively.

For the current assessment, the resulting acute and steady state food exposure values are compared to the PBPK-derived aPAD or ssPAD. When the dietary exposure exceeds 100% of the aPAD or ssPAD there is a potential risk concern.

All details pertaining to the assumptions, data inputs, and exposure outputs for the dietary analysis may be found in the 2014 dietary assessment memorandum (D. Drew *et al.,* D425586, 11/18/2014).

[15] See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[16] https://www.epa.gov/endocrine-disruption

Table 5.0.1. Chlorpyrifos Population Adjusted Doses (PADs) Derived from PBPK Modeled Doses Corresponding to 10% RBC AChE Inhibition – FQPA SF 10X Retained[1].															
RA Type	**Infants (< 1 year old)**			**Children (1 – 2 Years old)**			**Children (6-12 Years Old)**			**Youths (13-19 Years Old)**			**Females (13-49 Years Old)**		
	LOC	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**
Drinking Water (oxon conc, ppb)	50	23.66	4.34	50	60.08	10.96	50	154	27.16	50	99.76	17.56	100	52.85	9.32
Food (µg/kg/day)	40	15	2.6	40	15	2.5	40	13	2.3	40	12	2.0	100	4.7	0.78

1. Population Adjusted Dose (PAD) = POD ÷ LOC (including all applicable uncertainty factors). PODs for each scenario and subpopulation are provided in Table 4.2.2.1.2.

Table 5.0.2. Chlorpyrifos Population Adjusted Doses (PADs) Derived from PBPK Modeled Doses Corresponding to 10% RBC AChE Inhibition – FQPA SF Reduced to 1X[1].															
RA Type	**Infants (< 1 year old)**			**Children (1 – 2 Years old)**			**Children (6-12 Years Old)**			**Youths (13-19 Years Old)**			**Females (13-49 Years Old)**		
	LOC	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**	**LOC**	**Acute**	**Steady State**
Drinking Water (oxon conc, ppb)	5	236	43.4	5	600.8	109.6	5	1540	271.6	5	997.6	175.6	10	528.5	93.2
Food (µg/kg/day)	4	150	26	4	150	25	4	130	23	4	120	20	10	47	7.8

1. Population Adjusted Dose (PAD) = POD ÷ LOC (including all applicable uncertainty factors). PODs for each scenario and subpopulation are provided in Table 4.2.2.1.2.

5.1 Residues of Concern Summary and Rationale

The qualitative nature of the residue in plants and livestock is adequately understood based on acceptable metabolism studies with cereal grain (corn), root and tuber vegetable (sugar beets), and poultry and ruminants. The residue of concern, for tolerance expression and risk assessment, in plants (food and feed) and livestock commodities is the parent compound chlorpyrifos.

Based on evidence (various crop field trials and metabolism studies) indicating that the metabolite chlorpyrifos oxon would be not be present in edible portions of the crops (particularly at periods longer than the currently registered PHIs), it is not a residue of concern in food or feed at this time. Also, the chlorpyrifos oxon is not found on samples in the U.S. Department of Agriculture's Pesticide Data Program (USDA PDP) monitoring data. In fact, from 2007 to 2012, out of several thousand samples of various commodities, only one sample of potato showed presence of the oxon at trace levels, 0.003 ppm where the LOD was 0.002 ppm, even though there are no registered uses of chlorpyrifos on potato in the U.S.

The oxon metabolite was not found in milk or livestock tissues in cattle and dairy cow feeding studies, at all feeding levels tested, and is not a residue of concern in livestock commodities.

Oxidation of chlorpyrifos to chlorpyrifos oxon could potentially occur through photolysis, aerobic metabolism, and chlorination as well as other oxidative processes. Because of the toxicity of the oxon and data indicating that chlorpyrifos rapidly converts to the oxon during typical drinking water treatment (chlorination), the drinking water risk assessment considers the oxon as the residue of concern in treated drinking water and assumes 100% conversion of chlorpyrifos to chlorpyrifos oxon (see DWA, R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

Table 5.1. Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression.

Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	Chlorpyrifos	Chlorpyrifos
	Rotational Crop	Chlorpyrifos	Chlorpyrifos
Livestock	Ruminant	Chlorpyrifos	Chlorpyrifos
	Poultry	Chlorpyrifos	Chlorpyrifos
Drinking Water		Chlorpyrifos Oxon	Not Applicable

5.2 Food Residue Profile

Acute and steady state dietary (food only) exposure analyses for chlorpyrifos were conducted using the Dietary Exposure Evaluation Model (DEEM) and Calendex software with the Food Commodity Intake Database (FCID) (D. Drew, 11/18/2014, D424486, *Chlorpyrifos Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review*). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). These analyses were performed for the purpose of obtaining food exposure values for comparison to the chlorpyrifos doses predicted by the PBPK-PD model to cause RBC ChEI. The acute and steady state dietary exposure analyses do not include drinking water which is assessed separately as discussed in Section 7 (Aggregate Exposure/Risk Characterization).

Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed. OPP's Biological and Economic Analysis Division (BEAD) provided estimated percent crop treated information. Food processing factors from submitted studies were used as appropriate.

5.3 Percent Crop Treated Used in Dietary Assessment

The acute and steady state dietary exposure assessment used percent crop treated (%CT) information from BEAD's Screening Level Usage Analysis **(**SLUA; May 2014). BEAD has recently issued an updated SLUA (March 2020) for chlorpyrifos which includes a comparison of the percent crop treated estimates of 2016 and 2020.[17] Those results indicate that there were no appreciable increases in estimated percent crop treated and that most reported crop commodities had a decrease in percent crop treated as well as a decrease in the average yearly amount of chlorpyrifos applied. The use of the 2014 crop treated estimates do not underestimate the dietary exposures.

5.4 Acute Dietary (Food Only) Risk Assessment

Chlorpyrifos acute (food only) dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 3.16, which incorporates consumption data from NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. Acute dietary risk estimates are presented below for the sentinel population subgroups for acute risk assessment: infants (< 1 year old), children (1-2 years old), youths (6-12 years old) and adults (females 13-49 years old). The assessment of these index lifestages will be protective for the other population subgroups.

Acute dietary (food only) risk estimates are all <100 % of the acute PAD for food ($aPAD_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is females (13-49 years old) at 3.2 % $aPAD_{food}$. With the FQPA SF reduced to 1X, the acute dietary risk estimates are <1% of the $aPAD_{food}$ for all populations.

Table 5.4. Acute Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.

Population Subgroup	Food Exposure[1] (µg/kg/day)	$aPOD_{food}$[2] (µg/kg/day)	10X FQPA SF		1X FQPA SF	
			$aPAD_{food}$[3] (µg/kg/day)	% of $aPAD_{food}$	$aPAD_{food}$[4] (µg/kg/day)	% of $aPAD_{food}$
Infants (< 1 yr)	0.273	600	15	1.8	150	<1

[17] L. Hendrick, 03/05/2020, Updated Chlorpyrifos (059101) Screening Level Usage Analysis (SLUA)

Table 5.4. Acute Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.						
Population Subgroup	Food Exposure[1] (µg/kg/day)	aPOD$_{food}$[2] (µg/kg/day)	10X FQPA SF		1X FQPA SF	
			aPAD$_{food}$[3] (µg/kg/day)	% of aPAD$_{food}$	aPAD$_{food}$[4] (µg/kg/day)	% of aPAD$_{food}$
Children (1-2 yrs)	0.423	581	15	2.8	150	<1
Youths (6-12 yrs)	0.189	530	13	1.4	130	<1
Adults (Females 13-49 yrs)	0.150	467	4.7	3.2	47	<1

[1] Acute food only exposure estimates from DEEM (at 99.9th percentile). Refined with monitoring data and %CT.
[2] Acute point of departure; daily dose predicted by PBPK-PD model to cause RBC ChEI of 10% for acute dietary (food) exposures. Table 4.8.4.1.2.
[3]aPAD= acute population adjusted dose = PoD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =100X for females 13-49 yrs (10X intraspecies factor and 10X FQPA uncertainty factor) and 40X for other populations (4X intraspecies factor and 10X FQPA uncertainty factor). Table 5.0.1.
[4]aPAD= acute population adjusted dose = PoD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =10X for females 13-49 yrs (10X intraspecies factor and 1X FQPA uncertainty factor) and 4X for other populations (4X intraspecies factor and 1X FQPA uncertainty factor). Table 5.0.2.

5.5 Steady State Dietary (Food Only) Exposure and Risk Estimates

A chlorpyrifos steady state dietary (food only) exposure analysis was conducted using Calendex-FCID™. HED's steady state assessment considers the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year. For this assessment, the same food residue values used in the acute assessment were used for the 21-day duration. In the Calendex software, one diary for each individual in the WWEIA is selected to be paired with a randomly selected set of residue values for each food consumed. The steady state analysis calculated exposures for the sentinel populations for infant, child, youths, and adult (infants <1 yr, children 1-2 yrs, youths 6-12 yrs, females 13-49 yrs). The assessment of these index lifestages will be protective for the other population subgroups.

Calendex reported dietary exposures for each population subgroup at several percentiles of exposure ranging from 10th percentile to 99.9th percentile. The dietary (food only) exposures for chlorpyrifos were all <100% ssPAD$_{food}$ (all populations, at all percentiles of exposure). Only the 99.9th percentile of exposure is presented in Table 5.5 below. Calendex exposure results for other percentiles of exposure can be found in D424486.

Steady state dietary (food only) risk estimates are all <100 % of the steady state PAD for food (ssPAD$_{food}$) at the 99.9th percentile of exposure and are not of concern. With the 10X FQPA SF retained, the population with the highest risk estimate is children (1-2 years old) at 9.7 % ssPAD$_{food}$. With the FQPA SF reduced to 1X, the steady state dietary risk estimates are <1% of the ssPAD$_{food}$ for all populations.

Table 5.5. Steady State Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos.						
Population Subgroup	Food Exposure[1] (µg/kg/day)	$ssPoD_{food}$[2] (µg/kg/day)	10X FQPA SF		1X FQPA SF	
			$ssPAD_{food}$[3] (µg/kg/day)	% of $ssPAD_{food}$	$ssPAD_{food}$[4] (µg/kg/day)	% of $ssPAD_{food}$
Infants (< 1 yr)	0.186	103	2.6	7.2	26	<1
Children (1-2 yrs)	0.242	99	2.5	9.7	25	<1
Youths (6-12 yrs)	0.128	90	2.3	5.6	23	<1
Adults (Females 13-49 yrs)	0.075	78	0.78	9.6	7.8	<1

[1] Steady state food only exposure estimates from DEEM (at 99.9th percentile). Refined with monitoring data and %CT.
[2] Steady state point of departure; daily dose predicted by PBPK-PD model to cause RBC ChEI of 10% for acute dietary (food) exposures. Table 4.8.4.1.2.
[3]ssPAD= steady state population adjusted dose = POD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =100X for females 13-49 yrs (10X intraspecies factor and 10X FQPA uncertainty factor) and 40X for other populations (4X intraspecies factor and 10X FQPA uncertainty factor). Table 5.0.1.
[4] ssPAD= steady state population adjusted dose = POD (Dose predicted by PBPK-PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor =10X for females 13-49 yrs (10X intraspecies factor and 1X FQPA uncertainty factor) and 4X for other populations (4X intraspecies factor and 1X FQPA uncertainty factor). Table 5.0.2.

5.6 Dietary Drinking Water Risk Assessment

The total dietary exposure to chlorpyrifos is through both food and drinking water. EFED has provided a revised drinking water assessment (DWA) for chlorpyrifos (R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270) which includes the updated EDWCs for dietary risk assessment. A DWLOC approach is used to calculate the amount of exposure available in the total dietary 'risk cup' for chlorpyrifos in drinking water after accounting for chloropyrifos exposure from food and from residential uses. This DWLOC can be compared to the EDWCs to determine if there is a risk of concern for drinking water exposures (See D. Drew, D424485, 12/29/2014 for details on the DWLOC approach and calculations). The acute and steady state dietary exposure analyses discussed above only include food and do not include drinking water; the aggregate assessment, which does incorporate drinking water, is discussed in Section 7 (Aggregate Exposure/Risk Characterization).

6.0 Residential Exposure/Risk Characterization

Residential exposures to chlorpyrifos are currently expected from chlorpyrifos use in residential settings. Formulations/use sites registered for use in residential areas include a granular ant mound use and roach bait in child-resistant packaging. Additionally, chlorpyrifos is labeled for public health aerial and ground-based fogger ULV mosquito adulticide applications and for golf course turf applications. All residential exposures and risks were previously assessed in support of the 2014 HHRA (W. Britton, D424484, 12/29/2014) and 2016 HHRA (W. Britton, D436317, 11/3/2016). The previous assessments included evaluation of residential post-application risks from playing golf on chlorpyrifos-treated courses and from exposures which can occur following aerial and ground-based ULV mosquito adulticide usage. The potential for residential exposures from the roach bait product was determined to be negligible. Further, residential exposures from the ant mound use were also determined to be negligible since these products can only be applied professionally and direct exposure with treated ant mounds is not anticipated.

The previously assessed residential post-application assessments have been updated to incorporate the approach applied for PBPK-derivation of PODs for infants, children, and adults based on 10% RBC AChE inhibition. The results have been summarized assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. If the FQPA SF is retained, the total LOC for residential exposure assessment is 100X for adults (represented by females 13-49) and 40X for all other subpopulations, including children.

6.1 Residential Handler Exposure/Risk Estimates

HED uses the term "handlers" to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. Residential handlers are addressed somewhat differently by HED as homeowners are assumed to complete all elements of an application without use of any protective equipment.

Based upon review of all chlorpyrifos registered uses, only the roach bait products can be applied by a homeowner in a residential setting, but the application of roach bait products has not quantitatively assessed because these exposures are negligible. The roach bait product is designed such that the active ingredient is contained within a bait station which eliminates the potential for contact with the chlorpyrifos containing bait material. Therefore, updated residential handler risks are not required for these uses.

6.2 Residential Post-Application Exposure/Risk Estimates

Residential post-application exposures are likely from being in an environment that has been previously treated with chlorpyrifos. Chlorpyrifos can be used on golf courses and as an aerial and ground based ULV mosquito adulticide application in residential areas. Post-application exposure from residential ant mount treatment was assessed qualitatively because post-application exposures to treated ant mounts are expected to be negligible.

All of the residential post-application exposure scenarios, data and assumptions, and algorithms used to assess exposures and risks from activities on golf course turf following chlorpyrifos application and from aerial and ground based ULV mosquito adulticide applications are the same as those used in the 2016 HHRA. Additionally, this updated assessment makes use of the same chemical-specific turf transferable residue (TTR) data to assess exposures and risks. In the 2016 HHRA (W. Britton, D436317, 11/03/2016), the residential post-application exposures and risks resulting from aerial and ground-based ULV mosquito adulticide applications were updated to reflect 1) the current default deposition fraction recommended for ground applied ULV mosquitocides (i.e., 8.7 percent of the application rate vs the previous 5 percent) and 2) several iterations of aerial applications modeled assuming differing winds speeds and release heights allowed by chlorpyrifos mosquitocide ULV labels. The previously assessed residential post-application assessment has been updated to incorporate the approach applied for PBPK-derivation of PODs for infants, children, and adults based on 10% RBC AChE inhibition and assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. The AgDISP (v8.2.6) model input parameters, outputs, and the algorithms used to estimate residential post-application exposures following aerial and ground based ULV mosquitocide application can be found in Appendix 7.

Combining Exposure and Risk Estimates

Since dermal, incidental oral, and inhalation exposure routes share a common toxicological endpoint, RBC AChE inhibition, risk estimates have been combined for those routes. The incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios with the dermal and inhalation exposure scenarios would be unrealistic because of the conservative nature of each individual assessment. Therefore, the post-application exposure scenarios that were combined for children 1 < 2 years old are the dermal, inhalation, and hand-to-mouth scenarios (the highest incidental oral exposure expected). This combination should be considered a protective estimate of children's exposure to pesticides.

Summary of Residential Post-Application Non-Cancer Exposure and Risk Estimates

Whether the FQPA SF is retained at 10X or reduced to 1X, there are no residential post-application risk estimates of concern for the registered uses of chlorpyrifos. If the FQPA SF is retained at 10X, the assessment of steady state residential golfing post-application exposures (dermal only) to chlorpyrifos treated turf results in no risks of concern for adults or children/youths [i.e., MOEs ≥ 40 for children 6 to < 11 years old and youths 11 to < 16 years old and MOEs ≥ 100 for adults (females 13-49)]. Additionally, the steady state post-application exposures from public health mosquitocide applications results in no combined risk estimates of concern for adults (females 13-49; dermal and inhalation exposures) and children 1 to < 2 years old (dermal, incidental oral, and inhalation exposures) (i.e., MOEs ≥ 40 for children 1 to < 2 years old and MOEs ≥ 100 for adults). If the FQPA SF is reduced to 1X, there are also no residential post-application risk estimates of concern for adults (females 13-49) or children/youths [MOEs > 4 for children 1 to < 2 years old, children 6 to < 11 years old, and children 11 to < 16 years old; and MOEs > 10 for adults (females 13-49 years old)].

The risk estimates are presented in Table 6.2.1 – Table 6.2.8.

Table 6.2.1. Steady State Residential Post-Application Exposure and Risk Estimates for Chlorpyrifos - Golf Course Uses.

Lifestage	Post-application Exposure Scenario		Application Rate[1]	State (TTR Data)	Dose (mg/kg/day)[2]	MOEs[3]
	Use Site	Route of Exposure				
Adult (Females 13-49 years old)	Golf Course Turf	Dermal	1.0 (Emulsifiable Concentrate)	CA	0.010	1,200
				IN	0.0069	1,700
				MS	0.012	1,000
				Mean	0.0095	1,200
Youths 11 to < 16 years old				CA	0.010	1,400
				IN	0.0069	2,000
				MS	0.012	1,200
				Mean	0.0096	1,500
Children 6 to < 11 years old				CA	0.012	1,900

Table 6.2.1. Steady State Residential Post-Application Exposure and Risk Estimates for Chlorpyrifos - Golf Course Uses.

Lifestage	Post-application Exposure Scenario		Application Rate[1]	State (TTR Data)	Dose (mg/kg/day)[2]	MOEs[3]
	Use Site	Route of Exposure				
				IN	0.0082	2,800
				MS	0.014	1,600
				Mean	0.011	2,000
Adult (Females 13-49 years old)			1.0 (Granular)	CA	0.0088	1,400
Youths 11 to < 16 years old					0.0088	1,600
Children 6 to < 11 years old					0.010	2,200

1 Based on the maximum application rates registered for golf course turf.
2 Dose (mg/kg/day) equations for golfing applications are provided in Appendix B of the occupational and residential exposure assessment (W. Britton, D424484, 12/29/2014). For dose estimation from exposures to golfing on treated turf, the TTR data were used. Doses have been presented for all State sites, including the mean of all state sites.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). LOC = if the FQPA SF is retained at 10X, the total LOC for residential exposure assessment is 100X for adults (females 13-49) and 40X for all other subpopulations, including children. If the FQPA SF is reduced to 1X, the total LOC for residential exposure assessment is 10X for adults (females 13-49) and 4X for all other subpopulations, including children. See Table 4.2.2.1.2 for PODs.

Table 6.2.2. Residential Post-Application Inhalation Steady State Exposure Estimates from Chlorpyrifos ULV Aerial Mosquitocide Application - AgDISP Model.

Application Parameters	Population	Air Concentration Estimate (mg/m^3)[1]	MOE[2]
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Adults	0.0047	1,300
	Children 1 to <2 years old		500
10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Adults	0.00070	8,800
	Children 1 to <2 years old		3,400

1 Air concentration estimate modeled using AGDISP v8.2.6 at breathing height of adults and children.
2 MOE = POD (mg/m^3) ÷ Dose (mg/m^3). See Table 4.2.2.1.2 for PODs.

Table 6.2.3. Residential Post-Application Inhalation Steady State Exposure Estimates from Chlorpyrifos ULV Ground Mosquitocide Application – Well Mixed Box (WMB) Model.

Population	Air Concentration Estimate (mg/m^3)[1]	MOE[2]
Adults	0.0051	1,200
Children 1 to <2 years old		460

1 Air concentration estimate modeled using the well mixed box model. The inputs and algorithms used are presented in Appendix C of D424484 (W. Britton, 12/29/2014).
2 MOE = POD (mg/m^3) ÷ Dose (mg/m^3). See Table 4.2.2.1.2 for PODs.

Table 6.2.4. Residential Post-Application Dermal Steady State Exposure Estimates Resulting from Chlorpyrifos Aerial ULV Mosquitocide Application.						
Application Parameters	**Lifestage**	**Application Rate (lb ai/A)**	**AgDISP Deposition Fraction[1]**	**Adjusted TTR[2] ($\mu g/cm^2$)**	**Dermal Dose[3] (mg/kg/day)**	**MOE[4]**
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Adults	0.010	1.0	0.00038	0.0015	16,000
	Children 1 to < 2 Years Old				0.0026	53,000
10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Adults	0.010	0.086	0.000033	0.00013	180,000
	Children 1 to < 2 Years Old				0.00022	610,000

1 The fraction of chlorpyrifos residue deposited following aerial mosquitocide application was determined with use of the AgDISP (v8.2.6) model.
2 TTR_t ($\mu g/cm^2$) = [(Day 0 Residue from MS TTR study ($\mu g/cm^2$) × Application Rate (0.010 lb ai/A)) ÷ Application Rate of MS TTR Study (3.83 lb ai/A))] × AgDISP Deposition Fraction. The MS TTR data was selected for use because it is the worst case and, as a result, most protective of human health.
3 Dermal Dose (mg/kg/day) = [(TTR_t ($\mu g/cm^2$) × CF1 (0.001 mg/µg) × Transfer Coefficient (180,000 cm^2/hr, adults; 49,000 cm^2/hr, children) * ET (1.5 hrs))] ÷ BW (kg).
4 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.5. Residential Post-Application Dermal Steady State Exposure Estimates Resulting from Chlorpyrifos ULV Ground Mosquitocide Application.					
Lifestage	**Application Rate (lb ai/A)**	**Deposition Fraction[1]**	**Adjusted TTR[2] ($\mu g/cm^2$)**	**Dermal Dose[3] (mg/kg/day)**	**MOE[4]**
Adults	0.010	1.0	0.00038	0.00013	180,000
Children 1 to < 2 Years Old				0.00022	610,000

1 Ground fraction of mosquitocide application rate deposited on turf as determined using eight published studies on ground ULV application in which deposition was measured.
2 TTR_t ($\mu g/cm^2$) = [(Day 0 Residue from MS TTR study ($\mu g/cm^2$) × Application Rate (0.010 lb ai/A)) ÷ Application Rate of MS TTR Study (3.83 lb ai/A))] × AgDISP Deposition Fraction
3 Dermal Dose (mg/kg/day) = [(TTR_t ($\mu g/cm^2$) × CF1 (0.001 mg/µg) × Transfer Coefficient (cm^2/hr - 180,000, adults; 49,000, children) × ET (1.5 hrs))] ÷ BW (kg)
4 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.6. Residential Post-Application Steady State Incidental Oral Exposure Estimates Resulting from Chlorpyrifos ULV Aerial Mosquitocide Application.					
Application Parameters	**Lifestage**	**Application Rate (mg ai)**	**Dermal Exposure (mg/day)[1]**	**Incidental Oral Dose (mg/kg/day)[2]**	**MOE[3]**
1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Children 1 to < 2 Years Old	0.010	0.028	5.2×10^{-5}	1,900
10 mph Wind Speed			0.0022	4.5×10^{-6}	22,000

Dv 0.5 = 40 µm 300 Foot Release Height					

1 Dermal exposure (mg/day) as calculated for children's aerial based ULV applications using the algorithms as described in Appendix C of D424484 (W. Britton, 12/29/2014).
2 Incidental Oral Dose estimated using the algorithms as described below in Appendix C of the 2014 HHRA.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.7. Residential Post-Application Steady State Incidental Oral Exposure Estimates Resulting from Chlorpyrifos ULV Ground Mosquitocide Application.

Lifestage	Application Rate (mg ai)	Dermal Exposure (mg/day)[1]	Incidental Oral Dose (mg/kg/day)[2]	MOE[3]
Children 1 to < 2 Years Old	0.010	0.0024	$4.5x10^{-6}$	22,000

1 Dermal exposure (mg/day) as calculated for children's ground based ULV applications using the algorithms described in Table 6.2.5 above, and as described below in Appendix C of D424484 (W. Britton, 12/29/2014).
2 Incidental Oral Dose estimated using the algorithms as described in Appendix C of the 2014 HHRA.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day). See Table 4.2.2.1.2 for PODs.

Table 6.2.8. Combined Residential Post-Application Steady State Exposure Estimates from Chlorpyrifos Mosquitocide Applications.						
Population	**Application Parameter**	**Route of Exposure**	**Dermal or Incidental Oral Dose (mg/kg/day) or Air Concentration estimate (mg/m³)[1]**	**MOE[2]**	**Combined Routes[3]**	**Combined MOEs[4]**
Adults (Females 13-49 years old)	Aerial ULV Mosquitocide Application 1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Inhalation	0.0047	1,300	X	1,200
		Dermal	0.0015	16,000		
	Aerial ULV Mosquitocide Application 10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Inhalation	0.00070	8,800	X	8,400
		Dermal	0.00013	180,000		
	Ground Mosquitocide Application – WMB	Inhalation	0.0051	1,200	X	1,200
		Dermal	0.00013	180,000		
Children 1 to < 2 years old	Aerial ULV Mosquitocide Application 1 mph Wind Speed Dv 0.5 = 60 µm 75 Foot Release Height	Inhalation	0.0047	500	X	400
		Dermal	0.0026	53,000		
		Incidental Oral	$5.2x10^{-5}$	1,900		
	Aerial ULV Mosquitocide Application 10 mph Wind Speed Dv 0.5 = 40 µm 300 Foot Release Height	Inhalation	0.00070	3,400	X	2,900
		Dermal	0.00022	610,000		
		Incidental Oral	$4.5x10^{-6}$	22,000		
	Ground Mosquitocide Application – WMB	Inhalation	0.0051	460	X	450
		Dermal	0.00022	610,000		
		Incidental Oral	$4.54x10^{-6}$	22,000		

1. See Tables 6.2.3 – 6.2.7 for route-specific exposure inputs and risk estimates.
2. MOE = POD (mg/m³) ÷ Dose (mg/m³). See Table 4.2.2.1.2 for PODs.
3. X indicates the exposure scenarios included in the combined MOE.

4. Combined MOE = 1 ÷ [(1/dermal MOE) + (1/inhalation MOE) + (1/incidental oral MOE)], where applicable.

6.3 Residential Risk Estimates for Use in Aggregate Assessment

Table 6.3 reflects the residential risk estimates that are recommended for use in the aggregate assessment for chlorpyrifos.

- Adults (females 13-49 years old): post-application dermal exposures from golfing on treated turf using MS TTR data.
- Children 11 to < 16 years old: post-application dermal exposures from golfing on treated turf using MS TTR data.
- Children 6 to < 11 years old: post-application dermal exposures from golfing on treated turf using MS TTR data.

Exposures to treated turf from mosquitocide applications are completed as stand-alone assessments since mosquitocide applications are typically only made as a result of/in response to a public health need, and require a risk mitigation/risk management determination significantly different from an assessment without a large public health benefit. Therefore, these exposures are not aggregated with exposures from food and drinking water.

Table 6.3. Recommendations for the Residential Exposures for the Chlorpyrifos Aggregate Assessment.

Lifestage	Exposure Scenario	Dose[1]			MOE[2]			
		Dermal (mg/kg/day)	Inhalation (mg/m^3)	Oral (mg/kg/day)	Dermal	Inhalation	Oral	Total
Adults (Females 13-49 Years Old)	Golf Course Turf – MS TTR Data	0.012	N/A	N/A	1,000	N/A	N/A	1,000
Children 11 to < 16 Years Old		0.012	N/A		1,200	N/A		1,200
Children 6 to < 11 Years Old		0.014	N/A		1,600	N/A		1,600

1 Dose = the highest dose for each applicable lifestage of all residential scenarios assessed. Total = dermal + incidental oral (where applicable).

2 MOE = the MOEs associated with the highest residential doses. Total = 1 ÷ [(1/Inhalation MOE) + (1/Dermal MOE) + (1/Incidental Oral MOE)], where applicable.

7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. The durations of exposure identified for chlorpyrifos uses are acute and steady state. The acute aggregate assessment includes food and drinking water only. The steady state aggregate assessment includes food, drinking water, and residential exposures.

A drinking water level of comparison (DWLOC) approach to aggregate risk was used to calculate the amount of exposure available in the total ‘risk cup’ for chlorpyrifos oxon in drinking water after accounting for any chloropyrifos exposures from food and/or residential uses. This DWLOC can then be compared to the EDWCs to determine if there is an aggregate risk of concern. EFED has provided an updated drinking water assessment (DWA) for chlorpyrifos which includes the EDWCs for aggregate risk assessment. For chlorpyrifos, DWLOCs were calculated for both the acute and steady state aggregate assessments for infants, children, youths and adult females.

For complete details on the assumptions, results, and characterization of the drinking water analysis refer to EFED's DWA (R. Bohaty, 09/15/2020, D459269 and 09/15/2020, D459270).

7.1 Acute Aggregate Risk – DWLOC Approach

The acute aggregate assessment includes only food and drinking water. Acute DWLOCs were calculated for infants, children, youths, and adults. The DWLOCs were calculated assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb. With the FQPA SF reduced to 1X, the lowest acute DWLOC calculated was for infants (<1 year old) at 230 ppb.

Table 7.1.1. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA 10X SF.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Drinking Water Exposure (chlorpyrifos oxon)[4]		Acute DWLOC with FQPA 10X[5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	2200	55	51	1.0	23
Children[1] (1-2 yrs)	1400	35	52	1.0	58
Youths[1] (6-12 yrs)	2800	70	51	1.0	150
Adults[2] (Females 13-49 yrs)	3100	31	103	1.0	51

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=50 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 40 with FQPA SF retained) exposures.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE=100 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 100 with 10X FQPA SF retained) exposures.
[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.4). $ARI_{food} = [(MOE_{food})/(MOE_{target})]$.
[4] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) – ((1/ARI_{food}) + (1/ARI_{dermal}))]$; Where $ARI_{agg}=1$ (Note:HED is generally concerned when calculated ARIs are less than 1).
$\mathbf{MOE_{water}} = ARI_{water} \times MOE_{target}$.
WATER (Reciprocal MOE approach): $MOE_{water} = 1 \div [(1/MOE_{agg}) – ((1/MOE_{food}) + (1/MOE_{dermal}))]$; Where MOE_{agg} = Target MOE.
[5] **DWLOC:** DWLOC ppb= POD_{water} (ppb; from Table 4.2.2.1.2) ÷ MOE_{water}

Table 7.1.2. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]

Population	Food Exposure (chlorpyrifos)[3]		Drinking Water Exposure (chlorpyrifos oxon)[4]		Acute DWLOC with FQPA 1X[5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	2200	55	51	1.0	230

Table 7.1.2. Acute Aggregate (Food and Drinking Water) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]					
Population	Food Exposure (chlorpyrifos)[3]		Drinking Water Exposure (chlorpyrifos oxon)[4]		Acute DWLOC with FQPA 1X[5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Children[1] (1-2 yrs)	1400	35	52	1.0	600
Youths[1] (6-12 yrs)	2800	70	51	1.0	1,500
Adults[2] (Females 13-49 yrs)	3100	31	10	1.0	530

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE= 5 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 4 with FQPA SF reduced to 1X) exposures.

[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE= 10 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 10 with FQPA SF reduced to 1X) exposures.

[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.4). $ARI_{food} = [(MOE_{food})/(MOE_{target})]$.

[4] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) - ((1/ARI_{food}) + (1/ARI_{dermal}))]$; Where $ARI_{agg}=1$ (Note:HED is generally concerned when calculated ARIs are less than 1).

$\mathbf{MOE_{water}} = ARI_{water} \times MOE_{target}$.

WATER (Reciprocal MOE approach): $MOE_{water} = 1 \div [(1/MOE_{agg}) - ((1/MOE_{food}) + (1/MOE_{dermal}))]$; Where MOE_{agg} = Target MOE.

[5] **DWLOC:** DWLOC ppb= POD_{water} (ppb; from Table 4.2.1.2) ÷ MOE_{water}

7.2 Steady State Aggregate Risk – DWLOC Approach

The steady state aggregate assessment includes dietary exposures from food and drinking water and dermal exposures from residential uses. Treated golf course turf represent the highest residential dermal exposures. Aggregate DWLOCs are presented below for the population subgroups of infants (< 1 year old), children (1-2 years old), youths (6-12 years old), and adults (females 13-49 years old). The assessment of these index lifestages is protective for the other population subgroups, including youths 11 to < 16 years old. The DWLOCs were calculated assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X. The lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb if the FQPA SF is retained at 10X and the lowest steady state DWLOC calculated was for infants (< 1 year old) at 43 ppb if the FQPA SF is reduced to 1X.

Table 7.2.1. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA 10X SF.[1,2]							
Population	Food Exposure (chlorpyrifos)[3]		Residential Exposure (chlorpyrifos)[4]		Drinking Water Exposure (chlorpyrifos oxon)[5]		Steady State DWLOC with FQPA 10X[6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	550	14	NA	NA	54	1.1	4.0
Children[1] (1-2 yrs)	410	10	NA	NA	55	1.1	9.9
Youths[1] (6-12 yrs)	700	18	1,600	40	44	1.1	21

Table 7.2.1. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA 10X SF.[1,2]							
Population	Food Exposure (chlorpyrifos)[3]		Residential Exposure (chlorpyrifos)[4]		Drinking Water Exposure (chlorpyrifos oxon)[5]		Steady State DWLOC with FQPA 10X[6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Adults[2] (Females 13-49 yrs)	1040	10	1,000	10	124	1.2	7.5

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=50 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 40) exposure.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE=100 with 10X FQPA SF retained) and for food and residential (chlorpyrifos target MOE= 100 with 10X FQPA SF retained) exposure.
[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.5).
$ARI_{food} = [(MOE_{food})/(MOE_{target})]$.
[4] **RESIDENTIAL:** $MOE_{residential} = 1 \div (1/\text{Dermal MOE})$, (see Table 6.3).
[5] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) - ((1/ARI_{food}) + (1/ARI_{residential}))]$; Where $ARI_{agg}=1$ (Note:HED is generally concerned when calculated ARIs are less than 1).
$MOE_{water} = ARI_{water} \times MOE_{target.}$
WATER (Reciprocal MOE approach): $MOE_{water} = 1/[(1/MOE_{agg}) - ((1/MOE_{food}) + (1/MOE_{residential}))]$; Where MOE_{agg} =Target MOE.
[6] **DWLOC:** DWLOC ppb= PoD_{water} (ppb; from Table 4.2.2.1.2) $/MOE_{water}$

Table 7.2.2. Steady State Aggregate (Food, Drinking Water, Residential) Calculation of DWLOCs with FQPA SF Reduced to 1X.[1,2]							
Population	Food Exposure (chlorpyrifos)[3]		Residential Exposure (chlorpyrifos)[4]		Drinking Water Exposure (chlorpyrifos oxon)[5]		Steady State DWLOC with FQPA 1X[6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Infants[1] (<1 yr)	550	140	NA	NA	5.0	1.0	43
Children[1] (1-2 yrs)	410	102	NA	NA	5.0	1.0	110
Youths[1] (6-12 yrs)	700	180	1,600	400	4.0	1.0	230
Adults[2] (Females 13-49 yrs)	1040	104	1,000	100	10	1.0	91

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE=5 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 4 with FQPA SF reduced to 1X) exposure.
[2] DWLOCs for adults (females 13-49 yrs) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE= 10 with FQPA SF reduced to 1X) and for food and residential (chlorpyrifos target MOE= 10 with FQPA SF reduced to 1X) exposure.
[3] **FOOD:** $MOE_{food} = POD_{food}$ (µg/kg/day) (from Table 4.2.2.1.2) ÷ Food Exposure (µg/kg/day) (from Table 5.5).
$ARI_{food} = [(MOE_{food})/(MOE_{target})]$.
[4] **RESIDENTIAL:** $MOE_{residential} = 1 \div (1/\text{Dermal MOE})$, (see Table 6.3).
[5] **WATER (ARI approach):** $ARI_{water} = 1/[(1/ARI_{agg}) - ((1/ARI_{food}) + (1/ARI_{residential}))]$; Where $ARI_{agg}=1$ (Note:HED is generally concerned when calculated ARIs are less than 1).
$MOE_{water} = ARI_{water} \times MOE_{target.}$
WATER (Reciprocal MOE approach): $MOE_{water} = 1/[(1/MOE_{agg}) - ((1/MOE_{food}) + (1/MOE_{residential}))]$; Where MOE_{agg} =Target MOE.
[6] **DWLOC:** DWLOC ppb= PoD_{water} (ppb; from Table 4.2.2.1.2) $/MOE_{water}$

8.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Spray drift is a potential source of exposure to those nearby pesticide applications. This is particularly the case with aerial application, but, to a lesser extent, spray drift can also be a potential source of exposure from the ground application methods (e.g., groundboom and airblast) employed for chlorpyrifos. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling coupled with methods employed for residential risk assessments for turf products.

In the 2011 occupational and residential exposure assessment, the potential risks to bystanders from spray drift and exposure from volatilization were identified as possible concerns. Spray drift is the movement of aerosols and volatile components away from the treated area during the application process. The potential risks from spray drift and the impact of potential risk reduction measures were assessed in July 2012 (J. Dawson *et al.,* D399483, 07/13/2012). This evaluation supplemented the 2011 assessment where limited monitoring data indicated risks to bystanders. To increase protection for children and other bystanders, chlorpyrifos technical registrants voluntarily agreed to lower application rates and to other spray drift mitigation measures (R. Keigwin, 2012). As of December 2012, spray drift mitigation measures and use restrictions appear on all chlorpyrifos agricultural product labels (including a restriction to nozzles and pressures that produce a medium to coarse droplet size). Spray drift risk estimates have been re-presented here for children and adults using endpoints based on 10% RBC AChE inhibition and PODs derived with a PBPK model; and assuming both that the FQPA SF has been retained at 10X and has been reduced to 1X.

If the FQPA SF is retained at 10X, there were no dermal risk estimates of concern from indirect spray drift exposure to chlorpyrifos at the field edge for adults (females 13-49 years old) (MOEs ≥ 100). For children 1 to < 2 years old, there were no combined (dermal + incidental oral) risk estimates of concern from indirect spray drift exposure to chlorpyrifos (MOEs ≥ 40), except for two scenarios. For aerial applications at 2.3 lb ai/A, a distance of 10 feet results in MOEs not of concern. However, the 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of 80 feet for coarse or very coarse droplets and 100 feet for medium droplets for aerial applications are required for application rates ≥ 2.3 lb ai/A. For airblast applications > 3.76 lb ai/A, distances of 10 to 25 feet results in MOEs not of concern (LOC = 40). However, the 2012 agreement between EPA and the technical registrants (R. Keigwin, 2012) indicates that buffer distances of ≥ 25 feet and medium to coarse drops are required for airblast applications at rates >3.76 lb ai/A. Therefore, there are no risk estimates of concern incorporating the agreed-upon buffer distances and droplet sizes/nozzle types by the EPA and the technical registrants in 2012.

If the FQPA SF is reduced to 1X, there were no dermal risk estimates of concern from indirect spray drift exposure to chlorpyrifos at the field edge for adults (females 13-49 years old) (MOEs ≥ 10) and no combined (dermal + incidental oral) risks for children 1 to < 2 years old at the field edge (MOEs ≥ 4).

<table>
<tr><th colspan="8">Table 8.1. Summary of Spray Drift Distances from the Field Edge for Chlorpyrifos MOEs to be > LOCs with 10X FQPA SF Retained.[1]</th></tr>
<tr><th rowspan="3">Application Rate (lb ai/A)</th><th rowspan="3">Nozzle Droplet Type/ Canopy Density</th><th colspan="3">Adult Buffer Summary</th><th colspan="3">Children 1 to < 2 Years Old Buffer Summary (Dermal + Incidental Oral)</th></tr>
<tr><th colspan="3">Distance (Feet) from the Field Edge Needed For MOE > LOC of 100</th><th colspan="3">Distance (Feet) from the Field Edge Needed for MOE > LOC of 40</th></tr>
<tr><th>Aerial[2]</th><th>Groundboom[2]</th><th>Airblast</th><th>Aerial[2]</th><th>Groundboom[2]</th><th>Airblast</th></tr>
<tr><td>6.0</td><td rowspan="9">Medium/ Coarse for Aerial and Ground-boom

Sparse for Airblast</td><td rowspan="5">NA</td><td>NA</td><td rowspan="9">0</td><td rowspan="5">NA</td><td>NA</td><td>25</td></tr>
<tr><td>4.3</td><td rowspan="8">0</td><td rowspan="8">0</td><td>10</td></tr>
<tr><td>4.0</td><td>10</td></tr>
<tr><td>3.76</td><td>10</td></tr>
<tr><td>3.0</td><td rowspan="5">0</td></tr>
<tr><td>2.3</td><td rowspan="4">0</td><td>10</td></tr>
<tr><td>2.0</td><td rowspan="3">0</td></tr>
<tr><td>1.5</td></tr>
<tr><td>1.0</td></tr>
</table>

1 Per December 2012 spray drift mitigation memorandum, aerial application of greater than 2 lb ai/A is only permitted for Asian Citrus Psylla control, up to 2.3 lb ai/A.
2 NA = not allowable.

<table>
<tr><th colspan="8">Table 8.2. Summary of Spray Drift Distances from the Field Edge for Chlorpyrifos MOEs to be > LOCs with FQPA SF Reduced to 1X.[1]</th></tr>
<tr><th rowspan="3">Application Rate (lb ai/A)</th><th rowspan="3">Nozzle Droplet Type/ Canopy Density</th><th colspan="3">Adult Buffer Summary</th><th colspan="3">Children 1 to < 2 Years Old Buffer Summary (Dermal + Incidental Oral)</th></tr>
<tr><th colspan="3">Distance (Feet) from Field Edge Needed for MOE > LOC of 10</th><th colspan="3">Distance (Feet) From Field Edge Needed for MOE > LOC of 4</th></tr>
<tr><th>Aerial[2]</th><th>Groundboom[2]</th><th>Airblast</th><th>Aerial[2]</th><th>Groundboom[2]</th><th>Airblast</th></tr>
<tr><td>6.0</td><td rowspan="9">Medium/ Coarse for Aerial and Ground-boom

Sparse for Airblast</td><td rowspan="5">NA</td><td>NA</td><td rowspan="9">0</td><td rowspan="5">NA</td><td>NA</td><td rowspan="9">0</td></tr>
<tr><td>4.3</td><td rowspan="8">0</td><td rowspan="8">0</td></tr>
<tr><td>4.0</td></tr>
<tr><td>3.76</td></tr>
<tr><td>3.0</td></tr>
<tr><td>2.3</td><td rowspan="4">0</td><td rowspan="4">0</td></tr>
<tr><td>2.0</td></tr>
<tr><td>1.5</td></tr>
<tr><td>1.0</td></tr>
</table>

1 Per December 2012 spray drift mitigation memorandum, aerial application of greater than 2 lb ai/A is only permitted for Asian Citrus Psylla control, up to 2.3 lb ai/A.
2 NA = not allowable.

9.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

In January 2013, a preliminary assessment of the potential risks from volatilization was conducted.[18] The assessment evaluated the potential risks to bystanders, or those who live and/or work in proximity to treated fields, from inhalation exposure to vapor phase chlorpyrifos and chlorpyrifos-oxon emitted from fields following application of chlorpyrifos. The results of the January 2013 assessment indicated that offsite concentrations of chlorpyrifos and

[18] R. Bohaty, C. Peck, A. Lowit, W. Britton, N. Mallampalli, A. Grube. Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization. 1/31/13. U.S. EPA Office of Chemical Safety and Pollution Prevention. D399484, D400781.

chlorpyrifos-oxon may exceed the target concentration based on the toxicological endpoints used at that time.[19]

One significant area of uncertainty described in the preliminary assessment was the use of the aerosolized chlorpyrifos inhalation toxicity study -- as opposed to chlorpyrifos vapor -- for evaluation of lung AChE resulting from field volatilization. Because field volatilization is the production and release of vapor into the atmosphere after sprays have settled on treated soils and plant canopies, the vapor, rather than the aerosol, is the relevant form for evaluation of bystander volatilization exposures. However, EPA lacked chlorpyrifos vapor toxicity data at the time it conducted the preliminary volatilization assessment in 2013. Following the release of the preliminary volatilization assessment, DAS conducted, high quality nose-only vapor phase inhalation toxicity studies for both chlorpyrifos and chlorpyrifos-oxon[20] to address this uncertainty.

In June 2014, a reevaluation of the 2013 preliminary volatilization assessment was conducted to present the results of the vapor studies and their impact. In the vapor studies, female rats were administered a saturated vapor, meaning that the test subjects received the highest possible concentration of chlorpyrifos or chlorpyrifos-oxon which can saturate the air in a closed system. At these saturated concentrations, no statistically significant inhibition of AChE activity was measured in RBC, plasma, lung, or brain at any time after the six-hour exposure period in either study. Under actual field conditions, indications are that exposures to vapor phase chlorpyrifos and its oxon would be much lower as discussed in the January 2013 preliminary volatilization assessment.

Because these new studies demonstrated that no toxicity occurred even at the saturation concentration, which is the highest physically achievable concentration, then there are no anticipated risks of concern from exposure to the volatilization of either chlorpyrifos or chlorpyrifos oxon. In June 2014, the January 2013 volatilization assessment was revised to reflect these findings.[21]

10.0 Cumulative Exposure/Risk Characterization

OPs, such as chlorpyrifos, share the ability to inhibit AChE through phosphorylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic

[19]EPA MRID# 48139303**:**Acute Inhalation Exposure of Adult Crl:CD(SD) Rates to Particulate Chlorpyrifos Aerosols: Kinetics of Concentration-Dependent Cholinesterase (ACHE) Inhibition in Red Blood Cells, Plasma, Brain and Lung; Authors: J. A. Hotchkiss, S. M. Krieger, K. A. Brzak, and D. L. Rick; Sponsor: Dow AgroSciences LLC.

[20]W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D411959. TXR# 0056694. EPA MRID# 49119501.

W. Irwin. Review of Nose-Only Inhalation of Chlorpyrifos-Oxon Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain, and Lung Cholinesterase Activity in Female CD(SD):Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. 6/25/14. D415447. TXR# 0056869. EPA MRID# 49210101.

[21] W. Britton. W. Irwin. J. Dawson. A. Lowit. E. Mendez. Chlorpyrifos:Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies. 6/25/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D417105.

neurotoxicity. This shared MOA/AOP is the basis for the OP common mechanism grouping per OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999). The 2002 and 2006 CRAs used brain AChE inhibition in female rats as the source of dose response data for the relative potency factors and PODs for each OP, including chlorpyrifos. Prior to the completion of Registration Review, OPP will update the OP CRA on AChE inhibition to incorporate new toxicity and exposure information available since 2006.

OPP has conducted the chlorpyrifos human health risk assessment both with retention of the 10X FQPA SF and without retention of the 10X FQPA SF (*i.e*., FQPA SF reduced to 1X) due to uncertainties associated with neurodevelopmental effects in children and exposure to OPs. There is a lack of an established MOA/AOP for the neurodevelopment outcomes which precludes the Agency from formally establishing a common mechanism group per the *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999) based on that outcome. Moreover, the lack of a recognized MOA/AOP and other uncertainties with exposure assessment in the epidemiology studies prevent the Agency from establishing a causal relationship between OP exposure and neurodevelopmental outcomes. As part of an international effort, the ORD has been developing a battery of NAMs for evaluating developmental neurotoxicity. Information from these NAMs may be used in the future as part of the weight of evidence evaluation of neurodevelopmental toxicity potential for OPs. These NAMs will be presented, using the OPs as a case study, to the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Scientific Advisory Panel (SAP) in September 2020. The Agency will also continue to evaluate the epidemiology studies associated with neurodevelopmental outcomes and OP exposure prior to the release of the revised DRA. During this period, the Agency will determine whether or not it is appropriate to apply the guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* for the neurodevelopment outcomes.

11.0 Occupational Exposure/Risk Characterization

11.1 Occupational Handler Exposure and Risk Estimates

The term handlers is used to describe those individuals who are involved in the pesticide application process. There are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of a chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event. Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from chlorpyrifos use. For purpose of occupational handler assessment, the parent chlorpyrifos is the relevant compound.

Current labels generally require that handlers use normal work clothing (i.e., long sleeved shirt and pants, shoes and socks) and coveralls, chemical resistant gloves, and dust/mist respirators. Also, some products are marketed in engineering controls such as water-soluble packets. In order to determine what level of personal protection is required to alleviate risk concerns and to ascertain if label modifications are needed, steady state exposure and risk estimates were updated for occupational handlers of chlorpyrifos for a variety of scenarios at differing levels of personal protection including engineering controls.

The previously assessed occupational handler assessments have been updated to incorporate the approach applied for PBPK-derivation of PODs for adults based on 10% RBC AChE inhibition. The results have been summarized assuming both that the database uncertainty factor has been retained at 10X and has been reduced to 1X. If the database uncertainty factor is retained, the total LOC for occupational exposure assessment is 100X for adults (represented by females 13-49). If the database uncertainty SF is reduced to 1X, the total LOC for occupational exposure assessment is 10X for adults (represented by females 13-49). The occupational handler scenarios, exposure assumptions and inputs have not changed since the previous assessment[22].

Combining Exposures/Risk Estimates:

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological endpoint, RBC AChE inhibition, is the same for these exposure routes.

Summary of Occupational Handler Non-Cancer Exposures and Risk Estimates

Detailed result tables are provided in Appendix 10.

In this assessment for the non-seed treatment scenarios, a total of 288 occupational handler exposure scenarios were assessed. Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the database uncertainty 10X SF has been retained (LOC = 100), 119 scenarios are of concern with label-specified personal protective equipment (PPE; baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100). Risks of concern for 45 additional exposure scenarios could potentially be mitigated if engineering controls are used. If the database uncertainty 10X SF is reduced to 1X (LOC = 10), 19 scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 10). Risks of concern for 15 additional scenarios could potentially be mitigated if engineering controls are used.

For the seed treatment scenarios, a total of 93 scenarios were assessed (40 short-term primary handler scenarios + 40 intermediate-term primary handler scenarios + 13 short- and intermediate-term planting scenarios). Assuming the 10X database uncertainty factor has been retained (LOC = 100), 12 short-term exposure and 10 intermediate-term scenarios are of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs < 100) for primary handlers; there are no short- or intermediate scenarios of concern for seed planters. Assuming the 10X database uncertainty factor has been reduced to 1X (LOC = 10), there are no short- or intermediate-term risk estimates of concern with label-specified PPE (baseline attire, chemical resistant gloves, coveralls, and a PF10 respirator) (MOEs > 10) for primary handlers or seed planters.

[22] Some occupational handler exposure inputs have changed since the previous ORE assessments were completed in 2011 (W. Britton, D388165, 06/27/2011), 2014 (W. Britton, D424484, 12/29/2014), and 2016 (W. Britton, D436317, 11/03/2016) (e.g., amount of seed treated per day, seed planted per day). The changes to the inputs are not expected to result in significant changes to the risk estimates and have not been updated at this time.

11.2 Occupational Post-Application Exposure and Risk Estimates

11.2.1 Dermal Post-Application Exposure and Risk Estimates

Detailed result tables are provided in Appendix 11.

A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessments; these assumptions and exposure factors remain unchanged from the previous assessment (W. Britton, D424484, 12/29/2014).

The 2011 and 2014 occupational and residential exposure assessments incorporated 7 Chemical-specific DFR studies. These studies used 5 different formulations and were conducted on 12 different crops. Specifically, the DFR studies examined the use of 1) emulsifiable concentrate formulations on sugarbeets, pecans, citrus, sweet corn, cotton, and turf; 2) wettable powder formulations on almonds, apples, pecans, cauliflower, tomato and turf; 3) granular formulations on sweet corn and turf; 4) a total release aerosol formulation on ornamentals; and 5) a microencapsulated liquid formulation on ornamentals. The submitted studies were reviewed by HED. Despite limitations, HED recommended the use of all or some of the data in the studies to assess post-application risks to chlorpyrifos except for the tomato DFR data. Summaries for all DFR studies can be referenced in Appendix I of D424484 (W. Britton, 12/29/2014).

The current assessment uses the same DFR data and crop pairings as the previous occupational and residential exposure assessments. For example, DFR data for an individual crop was applied to that specific crop, as well as to crops in the same crop grouping (e.g., cauliflower data was used for cauliflower and all other cole crops). For other crops in which no crop-specific or crop group-specific data are available, the DFR data for the crop deemed the closest match were used as surrogates to calculate potential exposure (e.g., cauliflower data were also used for strawberries, cranberries, and leafy vegetables). Additionally, whenever possible, a label use was assessed using DFR data for the same formulation type. A full description of the criteria for selection of DFR data for assessment of post-application exposures to individual crops/crop groupings can be referenced in Section 2.4.3 of D388165 (W. Britton, 06/27/2011).

Summary of Occupational Post-Application Dermal Exposure and Risk Estimates

Current labels require a Restricted Entry Interval (REI) of 24 hours from most crops and activities, but in some cases such as tree fruit, REIs are up to 5 days after application. Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} of 10X has been retained, the majority of the post-applications scenarios are not of concern 1 day after application (REI = 24 hours). However, for some activities such as irrigation, hand harvesting, scouting, and thinning result in risks of concern up to as many as 10 days following application for the non-microencapsulated formulations and > 35 days for the microencapsulated formulation.

Using the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the UF_{DB} has been reduced to 1X, the majority of the post-application risk estimates are not of concern 1 day after application (REI = 24 hours).

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Berry: Low	Strawberry	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 - 4
	Cranberry	1.5			0	0 - 5
Field and Row Crops: Low to Medium	Clover (Grown for Seed)	1.9	MRID 44748102 (sugar beet EC)	MN	1	1
				OR	0	1
	Perennial Grass Seed Crops	1.0	MRID 44748102 (sugar beet EC)	MN	0	1
				OR	0	1
	Alfalfa	1.0	MRID 44748102 (cotton EC)	TX	0 – 1	1
	Cotton[1]	1.0	MRID 44748102 (cotton EC)	CA	0	0
				MS	0	0 – 1
				TX	0	0 – 1
	Peppermint/ Spearmint	2.0	MRID 44748102 (sugar beet EC)	MN	0 - 1	1
				OR	0	0 – 1
	Wheat	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 - 1
				MN	0	0 - 1
	Soybean	1.0	MRID 44748102 (cotton EC)	MS	0	0 – 1
	Sugar Beet	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 – 1
				MN	0	0 – 1
				OR	0	0 – 1
Field and Row Crops: Tall	Corn: Sweet; Corn: Field, Including Grown for Seed	1.5	MRID 44748102 (sweet corn EC)	IL	0 – 1	0 – 3
				MN	0 – 1	0 – 3
				OR	0 – 1	0 – 2
	Corn: Sweet; Corn: Field, Including Grown for Seed	1.0	MRID 44748102 (sweet corn EC)	IL	0 – 1	0 – 2
				MN	0 – 1	0 – 2
				OR	0 – 1	0 – 2
	Sorghum	1.0	MRID 44748102 (sweet corn EC)	IL	0	0 – 1
				MN	0	0 – 1
	Sunflowers	1.5	MRID 44748102 (sweet corn EC)	IL	0	1
				MN	0	1
Tree Fruit: Deciduous	Apples, Cherries, Peaches, Pears, Plums, Prunes, Nectarines	2.0	MRID 44748101 (apple WP)	CA	0	1
				WA	0	1 – 2
				NY	0	1 – 2

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
	(Dormant and Delayed Dormant)					
	Nectarine & Peaches (Dormant and Delayed Dormant)	3.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	2 - 3
	Cherries (Sour)	4.0	MRID 44748101 (apple WP)	CA	0 – 1	1 – 5
				WA	0 – 2	2 – 6
				NY	0 – 3	2 – 6
Tree Fruit: Evergreen	Conifer Trees and Christmas Tree Plantations	1.0	MRID 43062701 (citrus EC)	CA (scouting, harvesting seed cone, irrigation)	0	0 – 1
			MRID 44839601 (turf EC)	MS (harvesting/ seedling production)	0	0
	Citrus	6.0 (CA and AZ)	MRID 43062701 (citrus EC)	CA	0	0 – 2
		4.0	MRID 43062701 (citrus EC)	CA	0	0
Forestry	Hybrid Cottonwood/ Poplar Plantations (Dormant and Delayed Dormant)	2.0	MRID 44748101 (apple WP)	WA	0 – 1	2 – 4
				NY	0 – 1	2 – 4
	Deciduous Trees (Plantations and Seed Orchards)	1.0	MRID 44748101 (apple WP)	CA	0	0 – 1
				WA	0	0 – 1
				NY	0	0 – 1
Tree Nuts[2]	Almonds	2.0	MRID 44748101 (almond WP)	CA (arid)	0	1
	Almonds (Dormant and Delayed Dormant)	4.0	MRID 44748101 (almond WP)	CA (arid)	0	1 – 3
	Filberts, Pecans, Walnuts	2.0	MRID 44748101 (pecan EC)	GA	0	0
				LA	0	0
				TX	0	0

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
	Filberts & Walnuts (Dormant and Delayed Dormant)[3]	2.0	MRID 44748101 (pecan EC)	GA	0	0
Ornamentals/ Nurseries (Outdoor Only)	Deciduous Trees in Nurseries and Orchards Except Apples (Dormant and Delayed Dormant) Non-bearing Apple Trees	1.0	MRID 44748101 (apple WP)	CA	0	0
				WA	0	1
				NY	0	0
Ornamentals/ Nurseries (Outdoor Only)	Non-bearing Fruit and Nut Trees (Almonds, Citrus, Filbert, Cherry, Pear, Plum/Prune)	4.0	MRID 43062701 (citrus EC)	CA	0	0
	Non-bearing Fruit Trees (Peach, Nectarine)	3.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	2
	Non-bearing Fruit Trees (Apple)	2.0	MRID 44748101 (apple WP)	CA	0	1
				NY	0	1
	Conifers in Nurseries	1.0	MRID 43062701 (citrus EC)	CA	0	0
Field and Row Crops: Low to Medium (Outdoor Only)	Ornamentals	2.0	MRID 44748102 (sugar beet EC)	CA	0 – 1	1 – 5
				MN	0 – 1	1 – 3
				OR	0 – 1	1 – 2
Vegetable: Root and Tuber	Carrot	0.94	MRID 44748102 (sugar beet EC)	CA	0	0 – 1
				MN	0 – 1	0 – 1
	Radish	1.0	MRID 44748102 (sugar beet EC)	MN	0 – 1	0 – 1
Vegetable: Fruiting	Pepper	1.0	MRID 44748102 (cotton EC)	CA	0	0 – 2
				MS	0 – 1	1
				TX	0 – 1	1
Vegetable: Head and Stem Brassica	Broccoli, Brussel Sprouts, Cabbage, and Cauliflower	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 – 10
Vegetable: Leafy	Bok Choy, Collards, Kale, Kohlrabi	1.0	MRID 42974501 (cauliflower WP)	AZ	0	0 – 6
	Asparagus	1.0	MRID 44748102 (sugar beet EC)	CA	0	0 – 1

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Stalk and Stem: Vegetable				MN	0 – 1	1
				OR	0	0 – 1
	Non-bearing Pineapple	2.0	MRID 44748102 (cotton EC)	MS	0	1
Vine/ Trellis	Grapes (Dormant and Delayed Dormant) Grapes (Post-harvest and Prior to Budbreak)	2.0	MRID 43062701 (citrus EC)	CA	0	1
Turf	Turf for Sod and Seed	3.76	MRID 44829601 (turf EC and WP)	CA	0	1
				IN	0	1
				MS	0	1
	Turf for Golf Course	1.0	MRID 44829601 (turf EC and WP)	CA	0	0
				IN	0	0
				MS	0	0
Granular Applications						
Field and Row Crops: Low to Medium	Soybeans	1.0	MRID 44748102 (sweet corn G)	IL	0	0
	Sugar Beet	2.0	MRID 44748102 (sweet corn G)	IL	0	0
				OR	0	0 – 1
	Peanuts	4.0	MRID 44748102 (sweet corn G)	IL	0	0 – 1
Field and Row Crops: Tall	Corn, Sweet; Corn, Field; Corn, Grown for Seed	2.0	MRID 44748102 (sweet corn G)	IL	0	0 – 1
				OR	0 – 1	0 – 1
Nursery	Woody Ornamentals (In Container and Field Grown) – Preharvest	6.0 (Note: all other ornamental application rates are either 1.1 or 1.0 lb ai/A)	MRID 44748102 (sweet corn G)	IL	0	0
				OR	0	0
Turf	Turf for Sod or Seed	1.0	MRID 44829601 (turf G and fertilizer)	CA	0	0
	Golf Course				0	0
Microencapsulated Formulation Application						

Table 11.2.1. Chlorpyrifos Occupational Post-application Exposure and Risk Summary.						
Crop Group	**Crop**	**App. Rate (lbs ai/A)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Nursery (Microencap. Formulations)	Ornamentals – Nurseries and Greenhouses	1.4	MRID 46722702 (smooth ornamentals ME)	Greenhouse	0 - 3	1 to > 35
Greenhouse						
Greenhouse (Total Release Fogger and. Liquid Concentrate Formulations)	Ornamentals – *Liquid Concentrates*	2	MRID 46722701 (hairy ornamentals ME)	Greenhouse	0 – 1	1 – 5
	Commercial Ornamentals, Greenhouse Production: Bedding Plants, Cut Flowers, Flowering Hanging Baskets, Potted Flowers, Ornamentals, Trees and Shrubs – *Total Release Foggers*	0.29	MRID 46722701 (hairy ornamentals ME)	Greenhouse	0	0 – 2

1. Mechanical harvesting (tramper) activities are not anticipated to result in significant chlorpyrifos exposures due to the 14-day pre-harvest interval (PHI).
2. Exposure during nut sweeping and windrowing results from contact with soil, for which transfer coefficients are currently unavailable. Assessment options include requesting exposure data or a qualitative comparison with a post- application exposure scenario assumed to result in higher exposure. Note that dislodgeable soil residue would be needed for an exposure assessment, as this would be the media contacted by worker's performing this activity. A study monitoring such exposure is available (Exposure of Workers During Reentry into Pecan Groves Treated with Super-Tim 80WP, Griffin Corporation, 1994; EPA MRID 43557401), however has yet to be evaluated for derivation of transfer coefficients.
2. Transfer coefficients for dormant pruning are unavailable. Assessment options include requesting exposure data or a qualitative comparison with a post-application exposure scenario assumed to result in higher exposure. Note that dislodgeable branch or bark residue would be needed for an exposure assessment, as this would be the surface contacted by workers performing this activity.

11.2.2 Dermal Post-Application Exposure and Risk Estimates: Chlorpyrifos Oxon

Chlorpyrifos is activated by desulfuration, reacting in bioactivation to the more toxic and potent AChE inhibitor, chlorpyrifos oxon. The oxon is highly unstable due to rapid deactivation through hydrolytic cleavage by a process called dearylation which releases TCP. Workers reentering an indoor environment (i.e., greenhouses) previously treated with chlorpyrifos could potentially be exposed to the oxon as chlorpyrifos degrades. Available exposure data indicate chlorpyrifos oxon may form in indoor environments.[23] Toxicity adjustment factors (TAFs) were used to estimate the potency of chlorpyrifos oxon relative to chlorpyrifos. HED determined the oxon to be between 11.9 (acute) and 18 (chronic) times more toxic than the parent.

Dermal exposure to the oxon on foliar surfaces from reentry into an outdoor environment (e.g., field crops and orchards) previously treated with chlorpyrifos is not anticipated and, therefore, has not been assessed. No occupational exposure studies (handler, post-application, or DFR) were identified that quantified the levels of oxon present in the environment. However, a search of open literature for the 2011 assessment resulted in 4 plant metabolism studies which measured surface residues. Three plant metabolism studies[24] measured leaf surface residues of the oxon in outdoor environments that were either well below the parent, not detectable, or detected at a level just above the level of detection (LOD). The potential for exposure to the oxon is further minimized due to rapid deactivation of the oxon to TCP. Further, the dietary exposure risk assessment[25] conducted in support of registration review concludes the following, "all residues in food are assumed to be parent chlorpyrifos since the chlorpyrifos oxon is not typically found in foods in monitoring data or crop field trials."

The 4th plant metabolism study, a tomato and green bean metabolism study conducted in a greenhouse, was less definitive than the other three plant metabolism studies regarding oxon presence; therefore, there is concern that the formation of the oxon may be greater and its deactivation to TCP slower in greenhouses when compared to the outdoor environment. The study results indicate that oxon residue is from 9 to 14X less than the parent from fruit analyzed on the day of application in flat and asymmetric roof greenhouses. The proportion of oxon to parent is less for all days which measurable levels were observed (all but 8 and 15 days after application). The oxon was detected until day 5 with levels between 5 and 6X below that of the parent. It should be noted that residues of chlorpyrifos and oxon were measured from analysis of whole fruit samples. HED typically assesses occupational post-application exposure and risk based upon the potential for transfer from surface residues. The whole fruit samples, which include surface residues, as well as residues which may have been contained within the fruit

[23] J.L. Martinez Vidal, et al. 1998. Diminution of Chlorpyrifos and Chlorpyrifos Oxon in Tomatoes and Green Beans Grown in Greenhouses. J. of Agric. and Food Chem. 46 (4), 1440–1444.
[24] Iwata, Y. et al. 1983. Chlorpyrifos Applied to California Citrus: Residue Levels on Foliage and On and In Fruit. J. Agric. Food Chem. 31(3), 603-610.
H. Jin and G.R. Webster. 1997. Persistence, Penetration, and Surface Availability of Chlorpyrifos, Its Oxon, and 3,5,6-Trichloro-2-pyridinol in Elm Bark. 45(12), 4871-4876.
R. Putnam, et al. 2003. The Persistence and Degradation of Chlorthalonil and Chlorpyrifos in a Cranberry Bog. J. Agric. Food Chem. 51(1), 170-176.
[25] D. Drew. Chlorpyrifos: Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review. 11/18/2014. U.S. EPA Office of Chemical Safety and Pollution Prevention. D424486.

sample, may overestimate the amount of oxon on the fruit surface. Regardless, the 2011 occupational and residential exposure assessment recommended additional data to measure the chlorpyrifos and oxon residues on leaf surfaces following treatment with a liquid formulation in greenhouses in order to address these uncertainties and more accurately address the risk potential for exposure from occupational reentry into greenhouses treated with chlorpyrifos. To date, no data have been submitted to address these uncertainties. As a result, HED has assessed occupational dermal post-application exposures in greenhouses using conservative assumptions of oxon formation.

In order to account for the formation of and potential increased toxicity from exposure to chlorpyrifos oxon, a total toxic residue approach was applied which combines chlorpyrifos and chlorpyrifos oxon (expressed as toxicity equivalents). The total toxic residue approach[26] estimates the chlorpyrifos oxon equivalent residues by 1) assuming a specific fraction of the measured chlorpyrifos dislodgeable foliar residues are available as the oxon and 2) factoring in the relative potency of chlorpyrifos oxon with use of a TAF. It was conservatively assumed that 5% (0.05) of the total chlorpyrifos present as DFR in greenhouses is available for worker contact during post-application activities. This assumption is based on a review of available TTR and DFR data for other OPs where both the parent and metabolite were measured in residue samples. Five percent was found to be the high-end value for the percent of parent that metabolized during the course of the residue studies. The chronic TAF (which is appropriate for steady state assessment) of 18 was derived from BMD analysis of inhibition of RBC AChE in adult female rats (adult male rats not examined) observed in the repeated phase of the CCA study. Once predicted, these total toxic (dislodgeable foliar) residues are used to estimate exposures from post-application activities in greenhouse and risks are estimated with used of the steady state POD for occupational exposures, 3.63 mg/kg/day.

Summary of Occupational Post-Application Dermal Exposure and Risk Estimates with Use of Total Toxic Residue Approach

Due to uncertainty regarding the formation of chlorpyrifos oxon in greenhouses, HED also estimated risks for reentry into treated greenhouses (all 4 formulations) for the parent chlorpyrifos plus chlorpyrifos oxon using a total toxic residue approach. When the total toxic residue approach is used and with the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming a 10X UF_{DB} has been retained, MOEs are not of concern 0 to 6 days after treatment for non-microencapsulated formulations. For the microencapsulated formulation, MOEs are not of concern 3 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

When the total toxic residue approach is used and with the updated PBPK-derived steady state PODs based on 10% RBC AChE inhibition and assuming the 10X UF_{DB} has been reduced to 1X, there are no risk estimates of concern with the current labeled REI (24 hours), except for the microencapsulated formulation. For the microencapsulated formulation, MOEs are of concern 0 to > 35 days after treatment (the completion of the monitoring period), depending on the exposure activity considered.

[26] Total DFR ($\mu g/cm^2$) = [Chlorpyrifos DFR ($\mu g/cm^2$) * TAF] + [Chlorpyrifos DFR ($\mu g/cm^2$)]

Table 11.2.2.1. All Formulations - Summary of Post-Application Risk Assessment for Total Toxic Residue (Chlorpyrifos + Chlorpyrifos Oxon) Using Chlorpyrifos -Specific DFR Data.						
Crop Group	**Crop**	**App Rates (lbs. ai/ acre)**	**DFR Data Source**	**DFR Study Location**	**Estimated REI Range (days) (Dermal LOC = 10)**	**Estimated REI Range (days) (Dermal LOC = 100)**
Nursery	Ornamentals – Nurseries and Greenhouses	0.0070 lb ai/gal 1.4 lb ai/A	MRID 46722702 (smooth ornamentals ME)	Greenhouse	0 to >35	3 to > 35
Field and Row Crops – Low to Medium	Ornamentals – Nurseries and Greenhouses	2.0	MRID 44748102 (sugar beet EC)	CA	0 – 1	1 – 6
				OR	0 – 1	1 – 2
				MN	0 – 1	1 – 5
Nursery	Ornamentals - Greenhouse	0.29	DFR: MRID 46722701 (hairy ornamentals -aerosol)	Greenhouse	0 – 1	0 – 5

Restricted Entry Interval

Chlorpyrifos is classified as Toxicity Category II via the dermal route and Toxicity Category IV for skin irritation potential. It is not a skin sensitizer. There were some risk estimates of concern related to contacting chlorpyrifos treated foliage both outdoors and in greenhouses; therefore, HED is recommending that the REI be revised on the label to address those concerns.

Table 11.2.2.2. Acute Toxicity Profile: Chlorpyrifos.				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute Oral (rat)	44209101	LD_{50} = 223 mg/kg (M & F)	II
870.1200	Acute Dermal (rabbit)	44209102	$LD_{50} \geq$ 5000 mg/kg (M & F)	IV
870.1300	Acute Inhalation (rat)	00146507	LC_{50} > 0.2 mg/L (M & F)	II[1,2]
870.2400	Primary Eye Irritation (rabbit)	44209103	Minimum to mild irritant	IV
870.2500	Primary Skin Irritation (rabbit)	44209104	Mild irritant	IV
870.2600	Dermal Sensitization (guinea pig)	44209105	Non-Sensitizing (Buehler Method)	N/A

[1] Study classified as Supplementary (TXR 0004633, S. Saunders, 08/26/1985)
[2] Study requirement waived and Toxicity Category II assigned (TXR 5001957, M. Hashim, 12/20/1997)

11.2.3 Inhalation Post-Application Exposure and Risk Estimates

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037). The Agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219). During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for chlorpyrifos.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments.

The Worker Protection Standard for Agricultural Pesticides contains requirements for protecting workers from inhalation exposures during and after greenhouse applications through the use of ventilation requirements. [40 CFR 170.110, (3) (Restrictions associated with pesticide applications)].

A post-application inhalation exposure assessment is not required as exposure is expected to be negligible. Seed treatment assessments provide quantitative inhalation exposure assessments for seed treaters and secondary handlers (i.e., planters). It is expected that these exposure estimates would be protective of any potential low-level post-application inhalation exposure that could result from these types of applications. As described in Section 4, a quantitative occupational post-application inhalation risk assessment is not required for chlorpyrifos or chlorpyrifos oxon due to the lack of toxicity from the vapor phase of these chemicals, even at the saturation concentration.

12.0 References

Akhtar, N., Srivastava, M., Raizada, R. 2006. Transplacental disposition and teratogenic effects of chlorpyrifos in rats. *J. of Toxicol. Sciences,* 31(5):521-527.

Albers, J., Garabrant, D., Berent, S., Richardson, R. 2010. Paraoxonase status and plasma butyrylcholinesterase activity in chlorpyrifos manufacturing workers. *J Expo Sci Env Epid,* 20:79-100.

Aldridge, J., Levin, E., Seidler, F., Slotkin, T. 2005. Developmental exposure of rats to chlorpyrifos leads to behavioral alterations in adulthood, involving serotonergic mechanisms and resembling animal models of depression. *Environ Health Perspect,* 113(5), 527-531.

Ankley, G., Bennett, R., Erickson, R., *et al.* 2010. Adverse outcome pathways: a conceptual framework to support ecotoxicology research and risk assessment. *Environ Toxicol Chem,* 29(3):730−741.

Atterberry, T., Burnett, W., Chambers, J. 1997. Age-related differences in parathion and chlorpyrifos toxicity in male rats: target and nontarget esterase sensitivity and cytochrome P450-mediated metabolism. *Toxicol Appl Pharmacol, 147*(2), 411-418.

Augustinsson, K., Barr, M. 1963. Age Variation in Plasma Arylesterase Activity in Children. *Clin Chim Acta,* 8, 568-573.

Avila, J., Dominguez, J., Diaz-Nido, J. 1994. Regulation of microtubule dynamics by microtubule-associated protein expression and phosphorylation during neuronal development. *Int J Dev Biol,* 38(1), 13-25.

Barter, Z., Chowdry, J., Harlow, J., Snawder, J., Lipscomb, J., Rostami-Hodjegan. 2008. A (2008) Covariation of human microsomal protein per gram of liver with age: absence of influence of operator and sample storage may justify interlaboratory data pooling. *Drug Metab Dispos,* 36, 2405-2409.

Benke, G., Murphy S. 1975. The influence of age on the toxicity and metabolism of methyl parathion and parathion in male and female rats. *Toxicol Appl Pharmacol,* 31(2), 254-269.

Berkowitz, G., Obel, J., Deych, E., Lapinski, R., Godbold, J., Liu, Z., Wolff, M. 2003. Exposure to indoor pesticides during pregnancy in a multiethnic, urban cohort. *Environ Health Perspect,* 111(1), 79-84.

Berkowitz, G., Wetmur, J., Birman-Deych, E., Obel, J., Lapinski, R., Godbold, J., Wolff, M. 2004. In utero pesticide exposure, maternal paraoxonase activity, and head circumference. *Environ Health Perspect,* 112(3), 388-391.

Billauer-Haimovitch, H., Slotkin, T., Dotan, S., Langford, R., Pinkas, A., Yanai, J. 2009. Reversal of chlorpyrifos neurobehavioral teratogenicity in mice by nicotine administration and neural stem cell transplantation. *Behav Brain Res,* 205(2), 499-504.

Bohaty, R. 09/15/2020, D459269, Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review.

Bohaty, R. 09/15/2020, D459270, D432921. Evaluating the Impact of Removal of the 10x FQPA Safety Factor on Chlorpyrifos.

Bohaty, R. 4/14/2016, D432921. Chlorpyrifos Revised Drinking Water Assessment for Registration Review.

Boobis, A., Cohen, S., Dellarco, V., McGregor, D., Meek, M., Vickers, C., *et al.* 2006. IPCS framework for analyzing the relevance of a cancer mode of action for humans. *Crit Rev Toxicol,* 36(10), 781-792.

Boobis, A., Doe, J., Heinrich-Hirsch, B., *et al.* 2008. IPCS framework for analyzing the relevance of a noncancer mode of action for humans. *Crit Rev Toxicol,* 38:87−96.

Bouchard M., Bellinger, D., Wright, R., Weisskopf, M. 2010. Attention-deficit/hyperactivity disorder and urinary metabolites of organophosphate pesticides. *Pediatrics,* 125(6):e1270-7. doi: 10.1542/peds.2009-3058

Bouchard, M., Chevrier, J., Harley, K., Kogut, K., Vedar, M., Calderon, N., *et al.* 2011. Prenatal exposure to organophosphate pesticides and IQ in 7-year-old children. *Environ Health Perspect,* 119(8), 1189-1195.

Bradman, A., Whitaker, D., Quiros, L., Castorina, R., Claus Henn, B., Nishioka, M., *et al.* 2007. Pesticides and their metabolites in the homes and urine of farmworker children living in the Salinas Valley, CA. *J Expo Sci Environ Epidemiol, 17*(4), 331-349.

Britton, W. 2011. D388165. Chlorpyrifos: Occupational and Residential Exposure Assessment.

Britton, W. 2014. D424484. Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review.

Britton, W. *et al.* 2016. D436317. Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review.

Brown, D., Lindsted S., Rhomber L., Belites R., 1997. Physiological Parameter Values for Physiologically Based Pharmacokinetic Models. *Toxicology and Industrial Health,* 13, 77.

Busby-Hjerpe, A., *et al.* 2010. Comparative pharmacokinetics of chlorpyrifos versus its major metabolites following oral administration in the rat. *Toxicology,* 268, 55-63.

Byrne, S., Shurdut, B., Saunders, D. 1998. Potential Chlorpyrifos Exposure to Residents following Standard Crack and Crevice Treatment. *Environ Health Perspect,* 106 (11): 725 -731.

Campanha, H., Carvalho, F., Schlosser, P. 2014. Active and peripheral anionic sites of acetylcholinesterase have differential modulation effects on cell proliferation, adhesion and neuritogenesis in the NG108-15 cell line. *Toxicol Lett,* epub ahead of print.

Carr, R., Adams, A., Kepler, D., Ward, A., Ross, M. 2013. Induction of endocannabinoid levels in juvenile rat brain following developmental chlorpyrifos exposure. *Toxicol Sci,* 135(1), 193-201.

Carr, R.L. *et al.* (2017). Decreased anxiety in Juvenile Rats Following Exposure to Low Levels of Chlorpyrifos During Development. Neurotoxicology. 59: 183-190. MRID No. 51123802

Carr, R., Borazjani, A., Ross, M. 2011. Effect of developmental chlorpyrifos exposure, on endocannabinoid metabolizing enzymes, in the brain of juvenile rats. *Toxicol Sci,* 122(1), 112-120.

Carr, R. L., Chambers, J. 1996. Kinetic Analysis of the *in Vitro* Inhibition, Aging, and Reactivation of Brain Acetylcholinesterase from Rat and Channel Catfish by Paraoxon and Chlorpyrifos-oxon. *Toxicology and Applied Pharmacology,* 139(2), 365–373.

Carr, R., Graves, C., Mangum, L., Nail, C., Ross, M. 2014 Low level chlorpyrifos exposure increases anandamide accumulation in juvenile rat brain in the absence of brain cholinesterase inhibition. *Neurotoxicol,* 43, 82-89.

Chambers, J., Carr, R. 1993. Inhibition patterns of brain acetylcholinesterase and hepatic and plasma aliesterases following exposures to three phosphorothionate insecticides and their oxons in rats. *Fundam Appl Toxicol,* 21(1), 111-119.

Chambers, J. 2013. In vitro Sensitivity of Cholinesterase to Inhibition by Chlorpyrifos-oxon in Several Tissues of the Rat. College of Veterinary Medicine, Mississippi State University.

Chanda, S., Harp, P., Liu, J., Pope, C. 1995. Comparative developmental and maternal neurotoxicity following acute gestational exposure to chlorpyrifos in rats. *J Toxicol Environ Health,* 44(2), 189-202.

Chapman, R., McDonald, L. 1968. Red cell life span after splenectomy in hereditary spherocytosis. *J Clin Invest.* 47(10), 2263-2267.

Chen, J., Kumar, M., Chan, W., Berkowitz, G., Wetmur, J. 2003. Increased Influence of Genetic Variation on PON1 Activity in Neonates. *Environ Health Perspect*, 111(11), 1403-1409.

Chen, X., Chen, W., Wang, F., Liu, J. 2012. Selective cognitive impairments are related to selective hippocampus and prefrontal cortex deficits after prenatal chlorpyrifos exposure. *Brain Research,* 20(1474), 19-28.

Clement, J. 1984. Role of aliesterase in organophosphate poisoning. *Fundam Appl Toxicol, 4*(2 Pt 2), S96-105.

Cole, T., Jampsa, R., Walter, B., Arndt, T., Richter, R., Shih, D., Tward, A., Lusis, A., Jack, R., Costa, L., Furlong, C. 2003. Expression of human paraoxonase (PON1) during development. *Pharmacogenetics.* 13, 357-364.

Cole, T., *et al.,* 2005. Toxicity of chlorpyrifos and chlorpyrifos oxon in a transgenic mouse model of the human paraoxonase (PON1) Q192R polymorphism. *Pharmacogenet Genomics.* 15, 589-598.

Cowles, A., Borgstedt, H., Gillies, A. 1971. Tissue weights and rates of blood flow in man for the prediction of anesthetic uptake and distribution, *Anesthesiology*, 35(5), 523–526.

Crumpton T., Seidler, F., Slotkin, T. 2000. Is oxidative stress involved in the developmental neurotoxicity or chlorpyrifos? *Bran Rev Dev Brain Res.* 12, 189-195.

Dam, K., Seidler, F., Slotkin, T. 1998. Developmental neurotoxicity of chlorpyrifos: delayed targeting of DNA synthesis after repeated administration. *Brain Res Dev Brain Res,* 108(1-2), 39-45.

Dawson J, *et al.*, 2012. D399483 and D399485. Chlorpyrifos: Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures. 7/13/12.

Dimitriadis, E., Syrmos, N. 2011. Sources of Interindividual Variation in Red Blood Cell Cholinesterase Activity. *Arch Inst Neurol* 14(2).

Dow AgroSciences, Dow Chemical Company Battelle Pacific Northwest National Laboratory. 2011. Source-to-Outcome Modeling Physiologically Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Model linked to a Dietary Exposure Model: Chlorpyrifos as a Case Study. Prepared for the FIFRA Scientific Advisory Panel meeting on February 15-18, 2011 meeting: http://www.epa.gov/scipoly/sap/meetings/2010/index.html.

Dow AgroSciences. 2014a. Memo from Paul Price dated October 1, 2014. Additional PBPK modeling to estimate 1% RBC AChE inhibition levels from simulated exposures to chlorpyrifos.

Dow AgroSciences. 2014b. Memo from Paul Price dated October 29, 2014. Development of Chemical Specific Adjustment Factors for Chlorpyrifos and Chlorpyrifos Oxon Using Target Red Blood Cell Acetyl Cholinesterase Inhibition Levels of 10%, 5%, and 1%.

Dow AgroSciences. 2014c. Memo from Paul Price dated November 19, 2014. Additional information on PBPK modeling for Chlorpyrifos and Chlorpyrifos - Oxon.

Drew, D. 2014. D424486, *Chlorpyrifos Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review.*

Drew D, *et al.* 2014. D424485. *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review*

Ecobichon, D., Stephens, D. 1973. Perinatal development of human blood esterases. *Clin Pharmacol Ther,* 14(1), 41-47.

Engel, S., Berkowitz, G., Barr, D., Teitelbaum, S., Siskind, J., Meisel, S., . . . Wolff, M. 2007. Prenatal organophosphate metabolite and organochlorine levels and performance on the

Brazelton Neonatal Behavioral Assessment Scale in a multiethnic pregnancy cohort. *Am J Epidemiol.* 165(12), 1397-1404.

Engel, S., Wetmur, J., Chen, J., Zhu, C., Barr, D., Canfield, R., Wolff, M. 2011. Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood. *Environ Health Perspect,* 119(8), 1182-1188.

Engel S., Bradman A., Wolff M., Rauh V., Harley K., Yang J., Hoepner L., Barr D., Yolton K., Vedar M., Xu, Y., Hornung, R., Wetmur, J., Chen, J., Holland, N., Perera, F., Whyatt, R., Lanphear, B., Eskenazi, B. 2015. Prenatal Organophosphorus Pesticide Exposure and Child Neurodevelopment at 24 Months: An Analysis of Four Birth Cohorts. *Environ Health Perspect,* 124:822-830.

Eskenazi, B., Harley, K., Bradman, A., Weltzien, E., Jewell, N. P., Barr, D. B., . . . Holland, N. T. 2004. Association of in utero organophosphate pesticide exposure and fetal growth and length of gestation in an agricultural population. *Environ Health Perspect,* 115: 192-198.

Eskenazi, B., Huen, K., Marks, A., Harley, K. G., Bradman, A., Barr, D. B., & Holland, N. 2010. PON1 and neurodevelopment in children from the CHAMACOS study exposed to organophosphate pesticides in utero. *Environ Health Perspect,* 118(12), 1775-1781.

Eskenazi, B., Marks, A., Bradman, A., Harley, K., Barr, D. B., Johnson, C., . . . Jewell, N. 2007. Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children. *Environ Health Perspect,* 115(5), 792-798.

Fenske, R., et al 1990. Potential Exposure and Health Risks of Infants following Indoor Residential Pesticide Applications. *American Journal of Public Health,* 80(6), 689-693.

FIFRA Scientific Advisory Panel. 2008. “The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos.” Report from the FIFRA Scientific Advisory Panel Meeting of September 16-19, 2008. FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. Available: http://www.epa.gov/scipoly/sap/meetings/2008/091608_mtg.htm.

FIFRA Scientific Advisory Panel. 2010. February 2-4, 2010: Incorporation of Epidemiology and Human Incident Data into Human Risk Assessment.

FIFRA Scientific Advisory Panel. 2011. “Chlorpyrifos Physiologically Based Pharmacokinetic and Pharmacodynamic (PBPK-PD) Modeling linked to Cumulative and Aggregate Risk Evaluation System (CARES).” Report from the FIFRA Scientific Advisory Panel Meeting of February 15-18, 2011. FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. Available: http://www.epa.gov/scipoly/sap/meetings/2011/index.html.

FIFRA Scientific Advisory Panel. 2012. "Scientific Issues Associated with Chlorpyrifos". FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. Available at: http://www.epa.gov/scipoly/sap/meetings/2012/041012meeting.html.

Fonnum, F., Sterri, S., Aas, P., & Johnsen, H. 1985. Carboxylesterases, importance for detoxification of organophosphorus anticholinesterases and trichothecenes. *Fundam Appl Toxicol,* 5(6 Pt 2), S29-38.

Fortenberry G., Meeker J., Sanchez B., *et al*., 2014. Urinary 3,5,6-tichloro-2-pyridinol (TCPY) in pregnant women from Mexico City: Distribution, temporal variability, and relationship with child attention and hyperactivity. *International Journal of Hygiene and Environmental Health.* 217, 405–412.

Friedman, D., 10/2016, Record of Correspondence. EPA–HQ– OPP–2015–0653.

Frederick, A., Stanwood, G. 2009. Drugs, biogenic amine targets and the developing brain. *Dev. Neurosci,* 31(1-2), 7-22.

Fukushima, N., Furuta, D., Hidaka, Y., Moriyama, R., Tsujiuchi, T. 2009. Post-translational modifications of tubulin in the nervous system. *J Neurochem,* 109(3), 683-693.

Furlong, M., Engel, S., Boyd Barr, D., Wolff, M., 2014. Prenatal exposure to organophosphate pesticides and reciprocal social behavior in childhood. *Environment International,* 70, 125–131.

Gagne, J., Brodeur, J. 1972. Metabolic studies on the mechanisms of increased susceptibility of weaning rats to parathion. *Can J Physiol Pharmacol,* 50(9), 902-915.

Garabrant, D., Aylward, L., Berent, S., Chen, Q., Timchalk, C., Burns, C., *et al.* 2009. Cholinesterase inhibition in chlorpyrifos workers: Characterization of biomarkers of exposure and response in relation to urinary TCPy. *J Expo Sci Environ Epidemiol,* 19(7), 634-642.

Glantz, L., Gilmore, J., Hamer, R., Lieberman, J., Jarskog, L. 2007. Synaptophysin and postsynaptic density protein 95 in the human prefrontal cortex from mid-gestation into early adulthood. *Neuroscience,* 149(3), 582-591.

Gómez-Giménez, B. *et al.* (2017). Sex-dependent Effects of Developmental Exposure to Different Pesticides on Spatial Learning. The Role of Induced Neuroinflammation in the Hippocampus. Food Chem. Toxicol. 99: 135-148. MRID No. 51123803.

Gómez-Giménez, B. *et al.* (2018). Developmental Exposure to Pesticides Alters Motor Activity and Coordination in Rats: Sex Differences and Underlying Mechanisms. Neurotox Res 33:247–258. MRID No. 51123804

Gonzalez, V., Huen, K., Venkat, S., Pratt, K., Xiang, P., Harley, K., Kogut, K., Trujillo, C., Bradman, A., Eskenazi, B., Holland, N. 2012 Cholinesterase and paraoxonase (PON1) enzyme activities in Mexican-American mothers and children from an agricultural community. *J Expo Sco Environ Epidemiol,* 22, 641-648.

Guodong D., Pei W., Ying T., Jun Z., *et al*., 2012. Organophosphate Pesticide Exposure and Neurodevelopment in Young Shanghai Children. *Environ Sci. Technol.* 46, 2911–2917.

Hill AB (1965). The Environment and Disease: Association or Causation? *Proc R Soc Med.* 58(5), 295–300.

Hinderliter, P., Price, P., Bartels, M., Timchalk, C., Poet, T. 2011. Development of a source-to-outcome model for dietary exposures to insecticide residues: an example using chlorpyrifos. *Regul Toxicol Pharmacol.* 2011 Oct;61(1):82-92.

Hines, R. 2007. Ontogeny of human hepatic cytochromes P450. *J Biochem Mol Toxicol,* 21(4), 169-175.

Hirokawa, N., Takemura, R. 2004. Molecular motors in neuronal development, intracellular transport and diseases. *Curr Opin Neurobiol,* 14(5), 564-573.

Hirokawa, N., Noda, Y. 2008. Intracellular transport and kinesin superfamily proteins, KIFs: structure, function, and dynamics. *Physiol Rev,* 88(3), 1089-1118.

Hohmann, C., Berger-Sweeney, J. 1998. Cholinergic regulation of cortical development and plasticity. New twists to an old story. *Perspect Dev Neurobiol,* 5(4), 401-425.

Hojring N, Svensmark O. (1976). Carboxylesterases with different substrate specificity in human brain extracts. *J Neurochem,* 27(2):525-8.

Holland, N., Furlong, C., Bastaki, M., Richter, R., Bradman, A., Huen, K., Beckman, K., and Eskenazi, B. 2006. Paraoxonase Polymorphisms, Haplotypes, and Enzyme Activity in Latino Mothers and Newborns. *Environ Health Perspect,* 114(7), 985-991.

Holman E. 2016. D432184. *Summary Reviews for Additional Epidemiological Literature Studies from Prospective Birth Cohort Studies*

Hore, P. *et al.* 2005. Children's Residential Exposures to Chlorpyrifos: Application of CPPAES Field Measurements of Chlorpyrifos and TCPy within MENTOR/SHEDS – Pesticides Model. *Science of the Total Environment,* 336(2-3), 525-537.

Hotchkiss, J., Krieger, S., Mahoney, K., *et al.* 2013. Nose-only inhalation of chlorpyrifos vapor: limited toxicokinetics and determination of time-dependent effects on plasma, red blood cell, brain and lung cholinesterase activity in female CD(SD): Crl rats. Report of The Dow Chemical Company.

Hotchkiss, J., Krieger, S., Brzak, K., Rick, D., EPA MRID 48139303. Acute Inhalation Exposure of Adult Crl:CD(SD) Rates to Particulate Chlorpyrifos Aerosols: Kinetics of Concentration-Dependent Cholinesterase (ACHE) Inhibition in Red Blood Cells, Plasma, Brain and Lung.

Huen, K., Harley, K., Books, J., Hubbard, A., Bradman, A., Eskenazi, B., Holland, N. 2009. Developmental changes in PON1 enzyme activity in young children and effects of PON1 polymorphisms. *Environ. Health Perspect,* 117, 1632-1638.

Huff, R., Abou-Donia, M. 1994a. cis-Methyldioxolane specifically recognizes the m2 muscarinic receptor. *J Neurochem,* 62(1), 388-391.

Huff, R., Corcoran, J., Anderson, J., Abou-Donia, M. 1994b. Chlorpyrifos oxon binds directly to muscarinic receptors and inhibits cAMP accumulation in rat striatum. *J Pharmacol Exp Ther,* 269(1), 329-335.

Hunter, D., Lassiter, T., Padilla, S. 1999. Gestational exposure to chlorpyrifos: comparative distribution of trichloropyridinol in the fetus and dam. *Toxicol Appl Pharmacol,* 158, 16-23.

Irwin, W. 2014. Review of Nose-Only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. U.S. EPA Office of Chemical Safety and Pollution Prevention. D411959. TXR# 0056694. EPA MRID# 49119501.

Icenogle, L., Christopher, N., Blackwelder, W., Caldwell, D., Qiao, D., Seidler, F., *et al.* 2004. Behavioral alterations in adolescent and adult rats caused by a brief subtoxic exposure to chlorpyrifos during neurulation. *Neurotoxicol Teratol,* 26(1), 95-101.

Jameson, R., Seidler, F., Qiao, D., Slotkin, T. 2006. Chlorpyrifos affects phenotypic outcomes in a model of mammalian neurodevelopment: critical stages targeting differentiation in PC12 cells. *Environ Health Perspect,* 114(5), 667-672.

Janssen, I., *et al.,* 2000. Skeletal muscle mass and distribution in 468 men and women aged 18-88 yr. *J Appl Physiol.* 89, 81-8.

Jett, D., Navoa, R., Beckles, R., McLemore, G. 2001. Cognitive function and cholinergic neurochemistry in weanling rats exposed to chlorpyrifos. *Toxicol Appl Pharmacol,* 174(2), 89-98.

Karanth, S., Pope, C. 2000. Carboxylesterase and A-esterase activities during maturation and aging: relationship to the toxicity of chlorpyrifos and parathion in rats. *Toxicol Sci,* 58(2), 282-289.

Keigwin R, 07/20/2012, EPA-HQ-OPP-2008-0850-0103. U.S. EPA Office of Chemical Safety and Pollution Prevention.

Kisicki J., Seip, C., Combs M. 1999. A Rising Dose Toxicology Study to Determine the No-Observable-Effect-Levels (NOEL) for Erythrocyte Acetylcholinesterase (AChE) Inhibition and Cholinergic Signs and Symptoms of Chlorpyrifos at Three Dose Levels. MDC Harris Laboratory, Lincoln Nebraska, Study No. 21438 (for the Harris Project) and DR K-0044793-284 (for Dow AgroSciences), April 19, 1999, MRID No. 44811002.

Kousba, A., *et al.,* 2007. Age-related brain cholinesterase inhibition kinetics following in vitro incubation with chlorpyrifos-oxon and diazinon-oxon. *Toxicological Sciences.* 95, 147-155.

Lafortuna, C., *et al.,* 2005. Gender variations of body composition, muscle strength and power output in morbid obesity. *Int J Obes (Lond).* 29, 833-841.

Lassiter, T., Padilla, S., Mortensen, S., Chanda, S., Moser, V., Barone, S., Jr. 1998. Gestational exposure to chlorpyrifos: apparent protection of the fetus? *Toxicol Appl Pharmacol,* 152(1), 56-65.

Le Belle, J., Orozco, N., Paucar, A., Saxe, J., Mottahedeh, J., Pyle, A., *et al.* 2011. Proliferative neural stem cells have high endogenous ROS levels that regulate self-renewal and neurogenesis in a PI3K/Akt-dependant manner. *Cell Stem Cell,* 8(1), 59-71.

Lee, I. *et al.* (2015). Developmental Neurotoxicity Effects of Two Pesticides: Behavior and Biomolecular Studies on Chlorpyrifos and Carbaryl. Toxicol. Appl. Pharmacol. 288: 429-438. MRID No. 51123805.

Lee, L. 2009. Neonatal fluoxetine exposure affects the neuronal structure in the somatosensory cortex and somatosensory-related behaviors in adolescent rats. *Neurotox Res,* 15(3), 212-223.

Li, W., Matthews, C., Disteche, C., Costa, L., Furlong, C. 1997. Paraoxonase (PON1) gene in mice: sequencing, chromosomal localization and developmental expression. *Pharmacogenetics, 7*(2), 137-144.

Li, B., Sedlacek, M., Manoharan, I., Boopathy, R., Duysen, E., Masson, P., Lockridge, O. 2005. Butyrylcholinesterase, paraoxonase, and albumin esterase, but not carboxylesterase, are present in human plasma. *Biochem Pharmacol.* 70 (11), 1673-84.

Li, Z., Dong, T., Proschel, C., Noble, M. 2007. Chemically diverse toxicants converge on Fyn and c-Cbl to disrupt precursor cell function. *PLoS Biol, 5*(2), e35.

Luecke, R., *et al.,* 2007. Postnatal growth considerations for PBPK modeling. *Journal of Toxicology and Environmental Health* 70, 1027-1037.

Levin, E., Addy, N., Baruah, A., Elias, A., Christopher, N., Seidler, F., *et al.* 2002. Prenatal chlorpyrifos exposure in rats causes persistent behavioral alterations. *Neurotoxicol Teratol,* 24(6), 733-741.

Levin, E., Addy, N., Nakajima, A., Christopher, N., Seidler, F., Slotkin, T. 2001. Persistent behavioral consequences of neonatal chlorpyrifos exposure in rats. *Brain Res Dev Brain Res,* 130(1), 83-89.

Li, W., Matthews, C., Disteche, C., Costa, L., Furlong, C. 1997. Paraoxonase (PON1) gene in mice: sequencing, chromosomal localization and developmental expression. *Pharmacogenetics,* 7(2), 137-144.

Li, Z., Dong, T., Proschel, C., Noble, M. 2007. Chemically diverse toxicants converge on Fyn and c-Cbl to disrupt precursor cell function. *PLoS Biol,* 5(2), e35.

Lovasi, G., Quinn, J., Rauh, V., Perera, F., Andrews, H., Garfinkel, R., . . . Rundle, A. 2011. Chlorpyrifos exposure and urban residential environment characteristics as determinants of early childhood neurodevelopment. *Am J Public Health,* 101(1), 63-70.

Lowe, E., *et al.,* 2009. The Effect of Plasma Lipids on the Pharmacokinetics of Chlorpyrifos and the Impact on Interpretation of Blood Biomonitoring Data. *Toxicological Sciences.* 108, 258-272.

Lu, C., Fenske, R. 1998. Air and Surface Chlorpyrifos Residues following Residential Broadcast and Aerosol Pesticide Applications. *Environmental Science and Technology.* 32(10), 1386 -1390.

Lu, C., Holbrook, C., Andres, L. 2010. The implications of using a physiologically based pharmacokinetic (PBPK) model for pesticide risk assessment. *Environ Health Perspect,* 118(1), 125-130.

Marty, M., *et al.,* 2007. The effect of route, vehicle, and divided doses on the pharmacokinetics of chlorpyrifos and its metabolite trichloropyridinol in neonatal Sprague-Dawley rats. *Toxicological Sciences,* 100, 360-373.

Mason, H., Sams, C., Stevenson, A., Rawbone, R. 2000. Rates of spontaneous reactivation and aging of acetylcholinesterase in human erythrocytes after inhibition by organophosphorus pesticides. *Hum Exp Toxicol.* 19(9), 511-516.

Materne, R., Van Beers, B., Smith, A., Leconte, I., Jamart, J., Dehoux, J., Keyeux, A., Horsmans Y. 2000. Non-invasive quantification of liver perfusion with dynamic computed tomography and a dual-input one-compartmental model. *Clin Sci (Lond).* 99(6), 517-525.

Mattson, M., Guthrie, P., Kater, S. 1988. Intracellular messengers in the generation and degeneration of hippocampal neuroarchitecture. *J Neurosci Res,* 21(2-4), 447-464.

Mattsson J., Maurissen J., Spencer, P., Brzak K., Zablotny C. 1998. Effects of Chlorpyrifos administered via gavage to CD rats during gestation and lactation on plasma, erythrocyte, heart and brain cholinesterase and analytical determination of chlorpyrifos and metabolites. Health and Environmental Research Laboratories, The Dow Chemical Co. for Dow AgroSciences, August 31, 1998. Unpublished Study. MRID 44648101.

Mattsson, J., Maurissen, J., Nolan, R., Brzak, K. 2000. Lack of differential sensitivity to cholinesterase inhibition in fetuses and neonates compared to dams treated perinatally with chlorpyrifos. *Toxicol Sci,* 53(2), 438-446.

Matus, A. 1988. Microtubule-associated proteins: their potential role in determining neuronal morphology. *Annu Rev Neurosci,* 11, 29-44.

Matus, A. 1990. Microtubule-associated proteins and the determination of neuronal form. *J Physiol (Paris),* 84(1), 134-137.

Maxwell, D., Lenz, D., Groff, W., Kaminskis, A., Froehlich, H., 1987. The effects of blood flow and detoxification on in vivo cholinesterase inhibition by soman in rats. *Toxicol. Appl. Pharmacol.* 88, 66–76.

Maxwell, D. 1992a. Detoxication of organophosphorus compounds by carboxylesterases. In J. E. Chambers & P. E. Levi (Eds.), *Organophosphate Chemistry,* 183-199.

Maxwell, D. 1992b. The specificity of carboxylesterase protection against the toxicity of organophosphorus compounds. *Toxicol Appl Pharmacol,* 114(2), 306-312.

Meek, M., Boobis, A., Cote, I., Dellarco, V., Fotakis, G., Munn, S., Seed, J., Vickers, C. 2014. New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. *J Appl Toxicol.* 34(1), 1-18.

Mendez, E. 2020. D457378, Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Lifestage Exposure.

Morgan, E., Yan, B., Greenway, D., Parkinson, A. 1994. Regulation of two rat liver microsomal carboxylesterase isozymes: species differences, tissue distribution, and the effects of age, sex, and xenobiotic treatment of rats. *Arch Biochem Biophys,* 315(2), 513-526.

Mortensen, S., Chanda, S., Hooper, M., Padilla, S. 1996. Maturational differences in chlorpyrifos-oxonase activity may contribute to age-related sensitivity to chlorpyrifos. *J Biochem Toxicol,* 11(6), 279-287.

Moore, J., Dukes, J., Clark, J., Malone, J., Hallmon, C., Hester, P. 1993. Downwind Drift and Deposition of Malathion on Human Targets From Ground Ultra-Low Volume Mosquito Sprays. *Journal of the American Mosquito Control Association.* Vol. 9, No. 2.

Moser, V., Chanda, S., Mortensen, S., Padilla, S. 1998. Age- and gender-related differences in sensitivity to chlorpyrifos in the rat reflect developmental profiles of esterase activities. *Toxicol Sci,* 46(2), 211-222.

Mueller, R., Hornung, S., Furlong, C., Anderson, J., Giblett, E., Motulsky, A. 1983. Plasma paraoxonase polymorphism: a new enzyme assay, population, family, biochemical, and linkage studies. *Am J Hum Genet,* 35(3), 393-408.

Needham, L. 2005. Assessing exposure to organophosphorus pesticides by biomonitoring in epidemiologic studies of birth outcomes. *Environ Health Perspect,* 113(4), 494-498.

Negrón-Encarnación, I., 2011. D388164, Chlorpyrifos. Registration Review Action for Chlorpyrifos. Summary of Analytical Chemistry and Residue Data.

Nolan, R., Rick, D., Feshour, M., Saunders, J. 1982. Chlorpyrifos: Pharmacokinetics in human volunteers following single oral and dermal doses (MRID 00124144). The Dow Chemical Co. Biomedical Medical Research Laboratory. Toxicology Research Laboratory. Midland, MI.

Nolan, R. *et al.,* 1984. Chlorpyrifos: pharmacokinetics in human volunteers. *Toxicology and Applied Pharmacology.* 73, 8-15.

NRC. 2007. Toxicity Testing in the 21st Century: A Vision and a Strategy. http://www.nap.edu/catalog.php?record_id=11970

Obach, R., Zhang, Q., Dunbar, D., Kaminsky, L. 2001. Metabolic characterization of the major human small intestinal cytochrome p450s. *Drug Metab Dispos.* 29(3), 347-52.

Ohishi, T., Wang, L., Akane, H., Itahashi, M., Nakamura, D., Yafune, A., Mitsumori, K., Shibutani, M. 2013. Reversible effect of maternal exposure to chlorpyrifos on the intermediate granule cell progenitors in the hippocampal dentate gyrus of rat offspring. *Reprod. Toxicol.* 35, 125-136.

Oulhote, Y., Bouchard, M., 2013. Urinary Metabolites of Organophosphate and Pyrethroid Pesticides and Behavioral Problems in Canadian Children. *Environmental Health Perspectives.* 121, 1378–1384.

Padilla, S., Buzzard, J., Moser, V. 2000. Comparison of the Role of Esterases in the Differential Age-Related Sensitivity to Chlorpyrifos and Methamidophos. *Neurotoxicology*, 21, 49-56.

Padilla, S., Sung, H., Jackson, L., Moser, V. 2002. Development of an *in vitro* assay which may identify which organophosphorus pesticides are more toxic to the young. Presented at the Society of Toxicology meeting, March 2002

Pellegrini, F., Budman, D. R. 2005. Review: tubulin function, action of antitubulin drugs, and new drug development. *Cancer Invest,* 23(3), 264-273

Poet, T., *et al.* 2003. In vitro rat hepatic and intestinal metabolism of the organophosphate pesticides chlorpyrifos and diazinon. *Toxicological Sciences: An Official Journal of the Society of Toxicology.* 72, 193-200.

Poet, T., Timchalk, C., Hotchkiss, J., Bartels, M. 2014 Chlorpyrifos PBPK/PD model for multiple routes of exposure. *Xenobioticam*, 44(10), 868-881

Pope, C., Chakraborti, T., Chapman, M., Farrar, J., Arthun, D. 1991. Comparison of in vivo cholinesterase inhibition in neonatal and adult rats by three organophosphorothioate insecticides. *Toxicology,* 68(1), 51-61.

Pope, C., Karanth, S., Liu, J., Yan, B. 2005. Comparative carboxylesterase activities in infant and adult liver and their in vitro sensitivity to chlorpyrifos oxon. *Regul Toxicol Pharmacol,* 42(1), 64-69.

Price, P., Conolly, R., Chaisson, C., Gross, E., Young, J., Mathis, E., Tedder, D. 2003. Modeling interindividual variation in physiological factors used in PBPK models of humans. *Crit Rev Toxicol.* 33(5), 469-503.

Price, P., Schnelle, K., Cleveland, C., Bartels, M., Hinderliter, P., Timchalk, C., Poet, T. 2011. Application of a source-to-outcome model for the assessment of health impacts from dietary exposures to insecticide residues. *Regul Toxicol Pharmacol.* 61(1), 23-31.

Qiao, D., Seidler, F., Slotkin, T. 2001. Developmental neurotoxicity of chlorpyrifos modeled in vitro: comparative effects of metabolites and other cholinesterase inhibitors on DNA synthesis in PC12 and C6 cells. *Environ Health Perspect,* 109(9), 909-913.

Qiao, D., Seidler, F., Padilla, S., Slotkin, T. 2002. Developmental neurotoxicity of chlorpyrifos: what is the vulnerable period? *Environ Health Perspect,* 110(11), 1097-1103.

Qiao, D., Seidler, F., Tate, C., Cousins, M., Slotkin, T. 2003. Fetal chlorpyrifos exposure: adverse effects on brain cell development and cholinergic biomarkers emerge postnatally and continue into adolescence and adulthood. *Environ Health Perspect,* 111(4), 536-544.

Rauh, V., Arunajadai, S., Horton, M., Perera, F., Hoepner, L., Barr, D., Whyatt, R. 2011. Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide. *Environ Health Perspect,* 119(8), 1196-1201.

Rauh, V., Garfinkel, R., Perera, F., Andrews, H., Hoepner, L., Barr, D., . . . Whyatt, R. 2006. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics,* 118(6), e1845-1859.

Rauh, V., Perera, F., Horton, M., Whyatt, R., Bansal, R., Hao, X., . . . Peterson, B. 2012. Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proc Natl Acad Sci USA,* 109(20), 7871-7876.

Rauh, V., Garcia, W., Whyatt, R., Horton, M., Barr, D., Louis, E. 2015. Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor. *Neurotoxicology.* 51:80–86.

Resende, R., Adhikari, A. 2009. Cholinergic receptor pathways involved in apoptosis, cell proliferation and neuronal differentiation. *Cell Commun Signal,* 7, 20.

Ricceri, L., Markina, N., Valanzano, A., Fortuna, S., Cometa, M. F., Meneguz, A., *et al.* 2003. Developmental exposure to chlorpyrifos alters reactivity to environmental and social cues in adolescent mice. *Toxicol Appl Pharmacol,* 191(3), 189-201.

Rice, D., Barone, S., Jr. 2000. Critical periods of vulnerability for the developing nervous system: evidence from humans and animal models. *Environ Health Perspect,* 108 Suppl 3, 511-533.

Rodier, P. 2004. Environmental causes of central nervous system maldevelopment. *Pediatrics,* 113(4 Suppl), 1076-1083.

Sanchez, C., Perez, M., Avila, J. 2000. GSK3beta-mediated phosphorylation of the microtubule-associated protein 2C (MAP2C) prevents microtubule bundling. *Eur J Cell Biol,* 79(4), 252-260.

Sanchez, C., Diaz-Nido, J., Avila, J. 2000a. Phosphorylation of microtubule-associated protein 2 (MAP2) and its relevance for the regulation of the neuronal cytoskeleton function. *Prog Neurobiol,* 61(2), 133-168.

Sanchez, C., Diaz-Nido, J., Avila, J. 2000b. Phosphorylation of microtubule-associated protein 2 (MAP2) and its relevance for the regulation of the neuronal cytoskeleton function. *Prog Neurobiol,* 61(2), 133-168.

Sanchez, C., Diaz-Nido, J., Avila, J. 2000c. Phosphorylation of microtubule-associated protein 2 (MAP2) and its relevance for the regulation of the neuronal cytoskeleton function. *Prog Neurobiol,* 61(2), 133-168.

Sanchez, C., Diaz-Nido, J., Avila, J. 2000d. Phosphorylation of microtubule-associated protein 2 (MAP2) and its relevance for the regulation of the neuronal cytoskeleton function. *Prog Neurobiol,* 61(2), 133-168.

Shelton, J., Geraghty, E., Tancredi, D., Delwiche, L., Schmidt, R., Ritz, B., Hansen, R., Hertz-Picciotto, I., 2014. Neurodevelopmental disorders and prenatal residential proximity to agricultural pesticides: The CHARGE Study. *Environ Health Perspect,* 122, 1103–1109.

Seed, J., Carney, E., Corley, R., *et al.* 2005. Overview: using mode of action and life stage information to evaluate the human relevance of animal toxicity data. *Crit Rev Toxicol,* 35(8−9), 664−672

Sidell, F., Kaminskis, A. 1975. Temporal intrapersonal physiological variability of cholinesterase activity in human plasma and erythrocytes. *Clin Chem.* 21(13), 1961-1963.

Silva, J.G. *et al.* (2017). Chlorpyrifos Induces Anxiety-like Behavior in Offspring Rats Exposed During Pregnancy. Neurosci. Lett. 641: 94-100. MRID No. 51123801.

Simon, T., Simons, S., Preston, R., Boobis, A., Cohen, S., Doerrer, N., Fenner-Crisp, P., McMullin, T., McQueen, C., Rowlands, J.; RISK21 Dose-Response Subteam. 2014. The use of mode of action information in risk assessment: Quantitative key events/dose-response framework for modeling the dose-response for key events. *Crit Rev Toxicol.* 44 Suppl 3, 17-43.

Singh, S. J., Gibbons, N. J., Blackshaw, P. E., Blackshaw, P. E., Vincent, M., Wakefield, J., … Perkins, A. C. (2006b). Gastric emptying of solids in normal children--a preliminary report. *Journal of Pediatric Surgery*, *41*(2), 413–417.

Singh, V., Panwar, R. 2014. In vivo antioxidative and neuroprotective effect of 4-allyl-2-methoxyphenol against chlorpyrifos-induced neurotoxicity in rat brain. *Mol Cell Biochem.* 388, 61-74.

Slotkin, T., MacKillop, E., Ryde, I., Seidler, F. 2007. Ameliorating the developmental neurotoxicity of chlorpyrifos: a mechanisms-based approach in PC12 cells. *Environ Health Perspect,* 115(9), 1306-1313.

Slotkin, T., Seidler, F. 2007. Comparative developmental neurotoxicity of organophosphates in vivo: transcriptional responses of pathways for brain cell development, cell signaling, cytotoxicity and neurotransmitter systems. *Brain Res Bull,* 72(4-6), 232-274.

Slotkin, T., Card, J., Infante, A., Seidler, F. 2013 Prenatal dexamethasone augments the sex-selective developmental neurotoxicity of chlorpyrifos: Implications for vulnerability after pharmacotherapy for preterm labor. *Neurotoxicol Teratol.* 37:1-12.

Smith, J., Timchalk, C., Bartels, M., Poet, T. 2011. In vitro age-dependent enzymatic metabolism of chlorpyrifos and chlorpyrifos-oxon in human hepatic microsomes and chlorpyrifos-oxon in plasma. *Drug Metab Dispos.* 39(8), 1353-62.

Smith, J., Hinderliter, P.,Timchalk C., et al. 2014. A human life-stage physiologically based pharmacokinetic and pharmacodynamic model for chlorpyrifos: Development and validation. *Regulatory Toxicology and Pharmacology* 69: 580-597.

Soderberg, D. 6/30/11, D388166, *Chlorpyrifos: Revised Acute (Probabilistic) and Chronic Dietary Exposure and Risk Assessments for Food Only (with and without Food Handling Use included) and for Water Only for the Registration Review Action – Typical Use Rates/Water Included.*

Song, X., Violin, J., Seidler, F., Slotkin, T. 1998. Modeling the developmental neurotoxicity of chlorpyrifos in vitro: macromolecule synthesis in PC12 cells. *Toxicol Appl Pharmacol,* 151(1), 182-191.

Sonich-Mullin, C; Fielder, R; Wiltse, J; *et al.* 2001. IPCS conceptual framework for evaluating a mode of action for chemical carcinogenesis. *Regul Toxicol Pharmacol,* 34, 146−152.

Stout, D., Mason, M. 2003. The Distribution of Chlorpyrifos following a Crack and Crevice Type Application in the US EPA Indoor Air Quality Research House. Atmospheric Environment. 37 (39-40), 5539-5549.

Thompson, B., Stanwood, G. 2009. Pleiotropic effects of neurotransmission during development: modulators of modularity. *J Autism Dev Disord,* 39(2), 260-268.

Tietze, N., Hester, P., Shaffer, K. 1994. Mass Recovery of Malathion in Simulated Open Field Mosquito Adulticide Tests. *Archives of Environmental Contamination and Toxicology,* 26, 473-477.

Timchalk, C., *et al.,* 2002a. Monte Carlo analysis of the human chlorpyrifos-oxonase (PON1) polymorphism using a physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model. *Toxicology Letters.* 135, 51.

Timchalk, C., *et al.,* 2002b. A Physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model for the organophosphate insecticide chlorpyrifos in rats and humans. *Toxicological Sciences.* 66, 34-53.

Timchalk, C., Poet, T., Hinman, M., Busby, A., Kousba, A. 2005. Pharmacokinetic and pharmacodynamic interaction for a binary mixture of chlorpyrifos and diazinon in the rat. *Toxicol Appl Pharmacol,* 205(1), 31-42.

Timchalk, C., Poet, T., Kousba, A. 2006. Age-dependent pharmacokinetic and pharmacodynamic response in preweanling rats following oral exposure to the organophosphorus insecticide chlorpyrifos. *Toxicology,* 220(1), 13-25

Timchalk, C., Poet, T., 2008. Development of a physiologically based pharmacokinetic and pharmacodynamic model to determine dosimetry and cholinesterase inhibition for a binary mixture of chlorpyrifos and diazinon in the rat. *Neurotoxicology.* 29, 428-443.

Turgeman, G., Pinkas, A., Slotkin, T., Tfilin, M., Langford, R., Yanai, J. 2011. Reversal of chlorpyrifos neurobehavioral teratogenicity in mice by allographic transplantation of adult subventricular zone-derived neural stem cells. *J Neurosci Res,* 89(8), 1185-1193.

U.S. Environmental Protection Agency, MRID: 42887201. Contardi, J. (1993). An Evaluation of the Appropriate Drying Time via Air Monitoring, Dislodgable Residue Determination, Unpublished study prepared by Dow Chemical Co., Health and Environmental Sciences. 29 pp.

U.S. Environmental Protection Agency. 1994. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. October. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Washington, DC; EPA/600/8-90/066F.

.

U.S. Environmental Protection Agency. 1998. MRID 44458201: Byrne, S., Saunders, D., Cook, W., *et al.* Residential Exposure to Chlorpyrifos from Reentry to Structures Treated with Crack and Crevice and Spot Applications of Dursban Pro. Unpublished study prepared by Dow AgroSciences. 133 pp.

U.S. Environmental Protection Agency. 2000. Human Health Risk Assessment: Chlorpyrifos. Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington, D.C. Available at http://www.epa.gov/scipoly/sap/meetings/2008/september/hed_ra.pdf.

U.S. Environmental Protection Agency. 2002. Revised Organophosphorous Pesticide Cumulative Risk Assessment: June 10, 2002. Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington, D.C. Available at http://www.epa.gov/pesticides/cumulative/rra-op.

U.S. Environmental Protection Agency. 2005. Guidelines for Carcinogen Risk Assessment. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC. EPA/630/P-03/001F. Federal Register 70(66):17765-17817. Available at http://epa.gov/cancerguidelines/

U.S. Environmental Protection Agency. 2006a. Revised Organophosphorous Pesticide Cumulative Risk Assessment, July 31, 2006. Office of Pesticide Programs, U.S. Environmental Protection Agency. Washington, D.C. Available http://www.epa.gov/pesticides/cumulative/rra-op/

U.S. Environmental Protection Agency. 2006b. Approaches for the application of physiologically based pharmacokinetic (PBPK) models and supporting data in risk assessment (final report). U.S. Environmental Protection Agency, Washington, DC; EPA/600/R-05/043F.

U.S. Environmental Protection Agency. 2008. The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos.

U.S. Environmental Protection Agency. 2009. Scientific Issues Associated with Field Volatilization of Conventional Pesticides

U.S. Environmental Protection Agency. 2010. Draft Framework for Incorporating Human Epidemiologic and Incident Data in Health Risk Assessment, January 7, 2010.

U.S. Environmental Protection Agency. 2011. Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0025.

U.S. Environmental Protection Agency. 2012. Draft Issue Paper: Scientific Issues Concerning Health Effects of Chlorpyrifos. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0040-0002

U.S. Environmental Protection Agency. 2014. Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors (DDEF) for Interspecies and Intraspecies Extrapolation http://www.epa.gov/raf/DDEF/pdf/ddef-final.pdf. EPA/100/R-14/002F

U.S. Environmental Protection Agency. 2015. D331251. *Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides*

Valentin, J., 2002. In, *Basic Anatomical and Physiological Data for Use in Radiological Protection: Reference Value*s. Pergamon, Oxford.

Vallee, R. B., Williams, J. C., Varma, D., Barnhart, L., 2004. Dynein: An ancient motor protein involved in multiple modes of transport. *J Neurobiol,* 58(2), 189-200.

Vieira, H., Alves, P., Vercelli, A. 2011. Modulation of neuronal stem cell differentiation by hypoxia and reactive oxygen species. *Prog Neurobiol,* 93(3), 444-455.

Venerosi, A., Calamandrei, G., Ricceri, L. 2006. A social recognition test for female mice reveals behavioral effects of developmental chlorpyrifos exposure. *Neurotoxicol Teratol,* 28(4), 466-471.

Venerosi, A., Ricceri, L., Rungi, A., Sanghez, V., Calamandrei, G. 2010. Gestational exposure to the organophosphate chlorpyrifos alters social-emotional behaviour and impairs responsiveness to the serotonin transporter inhibitor fluvoxamine in mice. *Psychopharmacology (Berl), 208*(1), 99-107.

Vogel, D., 10/2016, Record of Correspondence. EPA–HQ– OPP–2015–0653.

Ward, T., Ferris, D., Tilson, H., Mundy, R. 1993. Correlation of the anticholinesterase activity of a series of organophosphates with their ability to compete with agonist binding to muscarinic receptors. *Toxicol Appl Pharmacol,* 122(2), 300-307.

Ward, T., Mundy, W. 1996. Organophosphorus compounds preferentially affect second messenger systems coupled to M2/M4 receptors in rat frontal cortex. *Brain Res Bull,* 39(1), 49-55.

Whyatt, R., Camann, D., Kinney, P., Reyes, A., Ramirez, J., Dietrich, J., Diaz, D., Holmes, D., Perera, F. 2002. Residential pesticide use during pregnancy among a cohort of urban minority women. *Environ Health Perspect.* 110(5):507–14.

Whyatt, R., Barr, D., Camann, D., Kinney, P., Barr, J., Andrews, H., . . . Perera, F. 2003. Contemporary-use pesticides in personal air samples during pregnancy and blood samples at delivery among urban minority mothers and newborns. *Environ Health Perspect,* 111(5), 749-756.

Whyatt, R., Rauh, V., Barr, D., Camann, D., Andrews, H., Garfinkel, R., . . . Perera, F. 2004. Prenatal insecticide exposures and birth weight and length among an urban minority cohort. *Environ Health Perspect,* 112(10), 1125-1132.

Whyatt, R., Garfinkel, R., Hoepner, L., Holmes, D., Borjas, M., Williams, M., . . . Camann, D. 2007. Within- and between-home variability in indoor-air insecticide levels during pregnancy among an inner-city cohort from New York City. En*viron Health Perspect,* 115(3), 383-389.

Whyatt, R., Garfinkel, R., Hoepner, L., Andrews, H., Holmes, D., Williams, M. K., . . . Barr, D. 2009. A biomarker validation study of prenatal chlorpyrifos exposure within an inner-city cohort during pregnancy. *Environ Health Perspect,* 117(4), 559-567.

Whyatt, R., Rauh, V. 2011. [Chlorpyrifos Correspondence with Columbia Researchers: (1) Responses to Scientific Advisory Panel (SAP) comments (Whyatt and Rauh 2010), and (2) Responses to Dow AgroSciences inquiries (Whyatt 2010).].

Yang, D., Pearce, R., Wang, X., Gaedigk, R., Wan, Y., Yan, B. 2009. Human carboxylesterase HCE1 and HCE2: Ontogenic expression, inter-individual variability and differential hydrolysis of oseltamivir, aspirin, deltamethrin and permethrin. *Biochem. Pharmacol,* 77, 238-247.

Yang, D., Lauridsen, H., Buels, K., Chi, L., LaDu, J., Bruun, D., Olson, J., Tanguay, R., Lein, P. 2011. Chlorpyrifos-oxon disrupts zebrafish axonal growth and motor behavior. *Toxicol. Sci.* 121:146-159.

Young, J., Eskenazi, B., Gladstone, E., Bradman, A., Pedersen, L., Johnson, C., . . . Holland, N. T. 2005. Association between in utero organophosphate pesticide exposure and abnormal reflexes in neonates. *Neurotoxicology,* 26(2), 199-209.

Young, J., *et al.,* 2009. Human Organ/Tissue Growth Algorithms that Include Obese Individuals and Black/White Population Organ Weight Similarities from Autopsy Data. *Journal of Toxicology and Environmental Health-Part a-Current Issues,* 72, 527-540.

Zhu, H., Appel, D., Yiang, Y., Markowitz, J. 2009 Age- and sex-related expression and activity of carboxylesterase 1 and 2 in mouse and human liver. *Drug Metab. Dispos,* 37, 1819-1825.

13.0 List of Appendices

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Appendix 1: Summary of OPP's ChE Policy and Use of BMD Modeling

OPP's ChE policy (USEPA, 2000[27]) describes the way ChE data are used in human health risk assessment. The following text provides a brief summary of that document to provide context to points of departure selected.

AChE inhibition can be inhibited in the central or peripheral nervous tissue. Measurements of AChE or cholinesterase (ChE) inhibition in peripheral tissues (e.g., liver, diaphragm, heart, lung etc) are rare. As such, experimental laboratory studies generally measure brain (central) and blood (plasma and red blood cell, RBC) ChE. Blood measures do not represent the target tissue, per se, but are instead used as surrogate measures for peripheral toxicity in studies with laboratory animals or for peripheral and/or central toxicity in humans. In addition, RBC measures represent AChE, whereas plasma measures are predominately BuChE. Thus, RBC AChE data may provide a better representation of the inhibition in target tissues. As part of the dose response assessment, evaluations of neurobehavior and clinical signs are performed to consider the dose response linkage between AChE inhibition and apical outcomes.

Refinements to OPP's use of ChE data have come in the implementation of BMD approaches in dose response assessment. Beginning with the OP CRA, OPP has increased its use of BMD modeling to derive PODs for AChE inhibiting compounds. Most often the decreasing exponential empirical model has been used.

OPP does not have a defined benchmark response (BMR) for OPs. However, the 10% level has been used in the majority of dose response analyses conducted to date. This 10% level represents a 10% reduction in AChE activity (i.e., inhibition) compared to background (i.e., controls). Specifically, the BMD_{10} is the estimated dose where ChE is inhibited by 10% compared to background. The $BMDL_{10}$ is the lower confidence bound on the BMD_{10}.

The use of the 10% BMR is derived from a combination of statistical and biological considerations. A power analysis was conducted by the Office of Research and Development (ORD) on over 100 brain AChE datasets across more than 25 OPs as part of the OP CRA (USEPA, 2002). This analysis demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies. In addition, the 10% level is generally at or near the limit of sensitivity for discerning a statistically significant decrease in ChE activity in the brain compartment and is a response level close to the background brain ChE level. With respect to biological considerations, a change in 10% brain AChE inhibition is protective for downstream cholinergic clinical signs and apical neurotoxic outcomes. With respect to RBC AChE inhibition, these data tend to be more variable than brain AChE data. OPP begins its BMD analyses using the 10% BMR for RBC AChE inhibition but BMRs up to 20% could be considered on a case by case basis as long as such PODs are protective for brain AChE inhibition, potential peripheral inhibition, and clinical signs of cholinergic toxicity.

[27] USEPA (2000) Office of Pesticide Programs, US Environmental Protection Agency, Washington DC 20460. August 18, 2000 Office of Pesticide Programs Science Policy of The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides.

Appendix 2: Summary of Regulatory and Scientific Activities to Address Uncertainty Around Neurodevelopmental Effects

1. Regulatory Context & History:

Historically, data on the AChE inhibition has been the critical effect used to derive points of departure (PODs) for OPs, including chlorpyrifos. The Registration Eligibility Decision (RED) for chlorpyrifos was completed in 2006 and relied on AChE inhibition results from laboratory animals to derive PODs but retained the FQPA 10X Safety Factor due to concerns over age-related sensitivity and uncertainty associated with potential neurodevelopmental effects observed in laboratory animals. Since that time, numerous epidemiology, laboratory animal, and mechanistic studies have evaluated the hypothesis that chlorpyrifos exposure results in adverse effects on the developing brain. This body of studies has raised concerns that EPA's historical practice of using AChE inhibition as the critical effect for deriving PODs may not be protective of neurodevelopmental outcomes.

EPA-OPP initiated a science evaluation of the potential effects on neurodevelopment in 2007 following the receipt of a petition from Pesticide Action Network of North America (PANNA) and Natural Resources Defense Council (NRDC) seeking revocation of all tolerances and cancellation of all FIFRA registrations of products containing chlorpyrifos. EPA has three times presented approaches and proposals to the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP).[28] for evaluating epidemiologic, laboratory animal, and mechanistic data exploring the possible connection between *in utero* and early childhood exposure to chlorpyrifos and adverse neurodevelopmental effects. The SAP's reports have rendered numerous recommendations for additional study and sometimes conflicting advice for how EPA should consider (or not consider) the epidemiology data in conducting EPA's registration review human health risk assessment for chlorpyrifos. For over a decade, EPA has evaluated the scientific evidence surrounding the different health effects associated with chlorpyrifos. Despite these efforts, unresolved scientific questions remain. EPA has continued to pursue some aspects of these uncertainties but has not found resolution.

2. Previous Risk Assessments, Peer Review & Public Process:

The public process surrounding science issues on chlorpyrifos and in the PANNA/NRDC petition has been extensive and began with the September 2008 FIFRA SAP. The 2008 SAP evaluated the Agency's preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action (USEPA, 2008). The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the PODs but noted that despite some uncertainties, the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies were "indeed quite strong and provided extremely valuable information (p. 35, FIFRA SAP, 2008)" and "concluded that the Columbia

[28] FIFRA SAP is a federal advisory committee created by Congress through FIFRA and is the primary venue for external, independent scientific advice to the EPA on major health and safety issues related to pesticides:

study is epidemiologically sound and that there is minimal selection and information bias (p. 32, FIFRA SAP, 2008)."

In 2010, EPA developed the Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which describes the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. The draft epidemiology framework was reviewed favorably by the FIFRA SAP in 2010. As suggested by the FIFRA SAP, EPA did not immediately finalize the draft epidemiology framework but instead used the document in several pesticide evaluations prior to making revisions and finalizing. OPP's epidemiology framework was finalized in December 2016.[29] (USEPA, 2016).

In 2011, EPA released the preliminary human health risk assessment for chlorpyrifos.[30]. The preliminary assessment used red blood cell (RBC) AChE inhibition from laboratory rats as the critical effect for extrapolating risk. The preliminary assessment also used the standard 10X factors for inter- and intra-species extrapolation. The 10X FQPA SF was removed with a note to the public that a weight of evidence (WOE) as described in the Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" evaluation would be forthcoming.

In 2011, EPA convened a meeting of the FIFRA SAP to review the PBPK-PD model for chlorpyrifos. The panel made numerous recommendations for the improvement of the model for use in regulatory risk assessment, including the inclusion of dermal and inhalation routes. From 2011-2014, Dow AgroSciences, in consultation with EPA, refined the PBPK-PD model for use in the revised human health risk assessment.

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the U.S., including those from the CCCEH, Mt. Sinai and CHAMACOS. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies. The 2012 Panel described the Agency's epidemiology review as "very clearly written, accurate" and "very thorough review". The 2012 Panel went further to note that "The Panel believes that the [Agency's] epidemiology review *appropriately concludes* that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age….." [*italics added*]. Although the 2012 Panel noted that the RBC AChE inhibition remained the most robust dose-response data, the 2012 Panel expressed significant concerns about the degree to which 10% AChE inhibition is protective for neurodevelopmental effects pointing to evidence from epidemiology, *in vivo* animal studies, and

[29] https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf
[30] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025

in vitro mechanistic studies, and urged the EPA to find ways to use the CCCEH cord blood data (pp. 50-52, FIFRA SAP, 2012).

In 2014, EPA released the revised human health risk assessment. The revised assessment used the chlorpyrifos PBPK-PD model for deriving human PODs for RBC AChE inhibition, thus obviating the need for the inter-species extrapolation factor and providing highly refined PODs which accounted for gender, age, duration and route specific exposure considerations. The PBPK-PD model was also used to develop data derived intra-species factors for some lifestages. The 10X FQPA SF was retained based on the outcome of the 2012 FIFRA SAP and development of a WOE analysis on potential for neurodevelopmental outcomes according to OPP's *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*.

Based on the aggregate human health risks identified in 2014, a proposed rule (PR) for revoking all tolerances of chlorpyrifos was published in the Federal Register on November 6, 2015 (80 FR 69079). The 2014 human health risk assessment (HHRA), which used the 10% RBC AChE inhibition endpoint, was the basis for the proposed tolerance revocation for chlorpyrifos since a determination of 'reasonable certainty of no harm' could not be met due to risks identified from drinking water using a national-scale assessment.

In 2015, EPA conducted additional hazard analyses using data on chlorpyrifos levels in fetal cord blood reported by the CCCEH study investigators. The Agency convened another meeting of the FIFRA SAP in April 2016 to evaluate a proposal of using cord blood data from the CCCEH epidemiology studies as the source of data for PODs. The 2016 SAP did not support the "direct use" of the cord blood and working memory data for deriving the regulatory endpoint due in part to lack of raw data from the epidemiology study, insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, and lack of a second laboratory to reproduce the analytical blood concentrations.

Despite their critiques regarding uncertainties in the CCCEH studies, the 2016 SAP expresses concern throughout the report that 10% RBC AChE inhibition is not sufficiently protective of human health. Specifically, the Panel stated that it "agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell (RBC) acetylcholinesterase (AChE) inhibition (i.e., toxicity at lower doses) (p. 18, FIFRA SAP, 2016)." This statement is repeated multiple times throughout the 2016 SAP report (e.g., pp. 22, 25, 39-40, and 53, FIFRA SAP, 2016).

The 2016 SAP was supportive of the EPA's use of the PBPK model as a tool for assessing internal dosimetry from typical OPP exposure scenarios using peer reviewed exposure assessment approaches (e.g., food, water, residential, occupational). The 2016 SAP recommended the use of a time weighted average (TWA) blood concentration of chlorpyrifos for the CCCEH study cohort as the PoD for risk assessment (p. 36, 42, 45, FIFRA SAP, 2016) and EPA's 2016 chlorpyrifos HHRA followed this approach.

3. Regulatory and Scientific Activities Since 2016

In March 2017, EPA denied the NRDC/PANNA petition to revoke all tolerances and cancel all FIFRA registrations of products containing chlorpyrifos. In the 2017 denial, EPA noted that "further evaluation of the science is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos." The denial went on to state that EPA "will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution on those issues." Since that time, EPA has continued to pursue acquisition of the raw data from new laboratory animal studies and the epidemiology studies conducted by Columbia University; evaluated the new laboratory animal studies with results suggesting effects on the developing brain occur at doses lower than does that cause AChE inhibition; and evaluated whether or not additional statistical analysis, including bias analysis, would be useful in characterizing the epidemiology results.

3.1 Transparency in Regulatory Decision Making: Availability of Raw Data

For conventional pesticides, like chlorpyrifos, EPA receives numerous toxicology studies in laboratory animals conducted according to OCSPP[1] and OECD[2] guidelines to comply with pesticide registration data requirements listed in the 40CFR Part 158. Most of these studies are conducted in accordance with Good Laboratory Practice (GLP), as set forth in 40 CFR Part 160. In accordance with GLP regulations, registrants certifying compliance with Good Laboratory Practice are required to retain the raw data from these toxicology studies. Raw data must also be retained by pesticide producers pursuant to EPA's Books and Records regulations (40 CFR section 169.2(k)) and EPA must, upon request, be furnished with (or given access to) such records (see sections 160.15 and 169.3). These toxicology studies (including the raw data, if it is in EPA's possession) used by EPA in human health risk assessment can, in turn, be obtained through a Freedom of Information Act request as long as the person affirms under FIFRA section 10(g) that he or she will not provide the data to a multinational pesticide producer. As such, EPA and stakeholders interested in pesticide risk assessment have high expectations with regard to the transparency of data used to develop hazard assessment and characterization. Although for most conventional pesticides, EPA uses the guideline studies submitted by pesticide registrants, there are some cases where studies from the open scientific literature are used. In those situations, in line with EPA's commitment to transparency, EPA often makes an effort to obtain the raw data from the investigators. EPA will often, but not always, receive such requested information.

- With regard to the new laboratory animal studies (reviewed by Mendez, 2020, D457378), EPA contacted the primary investigators in July-August 2018. Dr. Russell Carr from Mississippi State University kindly provided the requested information. However, none of the others provided EPA with the raw data.

- With regard to the raw data from CCCEH, EPA has a history of requesting this information as detailed on EPA's website (https://www.epa.gov/ingredients-used-

[1] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances
[2] http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm

pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data). Throughout 2018, EPA continued to pursue the raw data from CCCEH but to no avail. See Attachment 1.

3.2 Review of New Laboratory Animal Studies

Chlorpyrifos has numerous studies in laboratory animals evaluating effects on behavior and learning in young animals exposed during gestation and/or post-natal period. Beginning with the 2008 preliminary evaluation, EPA evaluated the open literature studies in 2008 in a preliminary evaluation, in 2012 in a comprehensive systematic review of the literature, and again in 2016 with additional studies. EPA has consistently concluded, with support from the FIFRA SAP, that these studies provide evidence of the potential effects on the developing brain from exposure to chlorpyrifos but that they lack robustness for using as PODs for extrapolating human health risk. Moreover, until recently, the dose levels used in these animal behavior studies typically were only high enough to elicit AChE inhibition. The newest studies have used lower doses, including some below doses required to elicit 10% AChE inhibition.

In 2018, the California Department of Pesticide Regulation (CDPR) proposed to adopt a regulation designating chlorpyrifos as a toxic air contaminant (TAC) in California[31]. As part of this determination, CDPR developed its "Final Toxic Air Contaminant Evaluation of Chlorpyrifos Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders[32]." The CDPR risk characterization document cites five new laboratory animal studies not previously reviewed by EPA (Gomez-Gimenez *et al.,* 2017, 2018; Silva *et al*., 2017; Lee *et al.,* 2015; Carr *et al.,* 2017). CDPR is using these studies as the main source of information for their new POD for acute oral exposure (Table 23 in CDPR, 2018). EPA-OPP in consultation with the Office of Research and Development, has reviewed these five studies (Mendez, 2020, D457378) in accordance with OPP's Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment.[33]
In short, EPA concludes that the Gomez-Gimenez et al (2017, 2018) and Silva et al (2017) papers are of unacceptable quality due to a number of deficiencies described in Mendez, 2020, D457378. Lee et al (2015) is considered acceptable but only for use qualitatively as some key deficiencies surrounding the assignment of pups from litters were noted. EPA finds the Carr et al (2017) study to be of high quality and provides strong support for the conclusion that effects on the developing brain may occur below a dose eliciting 10% AChE inhibition. Using the raw data provided by Dr. Carr, EPA conducted an independent statistical analysis of these results[34]. EPA's statistical analysis confirms the conclusions of Carr et al (2017) that young rats exposed to chlorpyrifos, at doses lower than those eliciting brain AChE inhibition, spent significantly less time in the dark container prior to emerging as compared to the control group.

[31] https://www.cdpr.ca.gov/docs/emon/pubs/tac/tacpdfs/chlorpyrifos/proposed_determination_chlorpyrifos.pdf
[32] https://www.cdpr.ca.gov/docs/emon/pubs/tac/tacpdfs/chlorpyrifos/final_eval_chlorpyrifos_tac.pdf
[33] https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf
[34] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939

EPA-OPP continues to view the laboratory animal studies as part of the weight of the evidence surrounding the effects on the developing brain. Despite the strength of the new Carr paper, EPA continues to conclude these studies are not robust enough for deriving a POD.

3.3 Potential for Additional Statistical Analysis of CCCEH Studies

One of the areas of additional evaluation by EPA was a consideration of whether additional statistical analyses would be useful in characterizing the epidemiology results.

As described by Lash et al (2014[35]), quantitative bias analysis (QBA) evaluates nonrandom errors that may affect the results and interpretation of epidemiological studies. The purpose is to estimate the potential magnitude and direction of biases and to quantify the uncertainty about these biases. EPA held a series of conference calls with Dr. Timothy Lash at Emory University about the CCCEH studies. Dr. Lash is a recognized expert in this area. These conference calls and associated activities are described in the docket[36]. Some stakeholders have identified the limited blood lead testing in the CCCEH cohort to be an area of uncertainty and potential unresolved confounder in the epidemiology results. Dr. Lash noted that given that lead abatement was conducted by New York City prior to the start of the CCCEH study that this was not a major concern for him. Dr. Lash initially identified potential selection bias in the interpretation of working memory IQ from Rauh et al (2011) as a possible area for QBA. Upon further evaluation of this issue, it was determined that a QBA would not be useful or possible since working memory was only evaluated in children at age 7 but not at other ages.

EPA has recently pursued some additional questions about the statistical analysis conducted in CCCEH papers[37]. In Rauh et al (2011), CCCEH investigators log-transformed the working memory composite score but not log-transforming the chlorpyrifos exposure in the data analysis. EPA asked the investigators why this was done. The researchers explained that the natural log-transformation was applied to the outcome variables to stabilize the variance and improve the linear model fit. EPA inquired about further sensitivity analysis and if any model-fit diagnostics were available. CCCEH investigators responded that they did perform various transformations of the data in an exploratory mode but did not publish or further detail these results or share the results of these exploratory analyses with EPA.

EPA also recently asked CCCEH investigators about the impact of including/excluding extremely high exposure data points. The CCCEH investigators noted that there are three subjects with non-missing data had chlorpyrifos levels above 25 pg/g. These three subjects were not included in the final model because one subject with 63 pg/mg was a highly influential observation (outlier) and drastically impacted inference and the data from the two other subjects were too sparse and the splines too unstable in this region. The CCCEH investigators did not share the results of these exploratory analyses with EPA.
Although EPA does not have a specific reason to believe that CCCEH have inappropriately handled the data or statistical analysis, without the availability of the raw data, EPA remains

[35] Lash TL, Fox MP, MacLehose RF, Maldonado G, McCandless LC, Greenland S. 2014. Good practices for quantitative bias analysis. Int J Epidemiol. 2014 Dec;43(6):1969-85. doi: 10.1093/ije/dyu149. Epub 2014 Jul 30.
[36] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939
[37] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939

unable to verify the reported findings of the CCCEH papers. Moreover, EPA and interested stakeholders are unable to conduct alternative statistical analyses to evaluate the robustness and appropriateness of the approaches used by the investigators.

4. FQPA 10X Safety Factor for the 2020 Human Health Risk Assessment

The Food Quality Protection Act (FQPA, 1996) requires EPA in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, *an additional tenfold margin of safety* for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account *potential pre- and postnatal toxicity and completeness of data with respect to exposure and toxicity to infants and children*." The statute goes on to state that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Over the last decade, EPA has used several different approaches for assessing the human health risk to chlorpyrifos. EPA began registration review with a 2011 preliminary assessment using a traditional risk assessment based on laboratory animal data with standard 10X inter- and inter-species extrapolation factors but without the FQPA 10X SF. The 2014 revised human health risk assessment applied the PBPK-PD model to derive PODs for 10% RBC AChE inhibition which obviated the need for the inter-species factor and applied the FQPA 10X SF based on uncertainty identified regarding the potential for chlorpyrifos to effect neurodevelopment. In 2016, EPA used the PBPK model to derive an internal human POD based on the TWA for blood concentrations to women potentially exposed to chlorpyrifos from residential uses voluntarily cancelled in 2000. Despite the distinct differences in approach, EPA's acute and chronic population adjusted doses (PADs) in the 2011 and 2014 risk assessments are quite similar. Specifically, in the 2011 preliminary assessment, the acute and chronic PADs were 0.0036 mg/kg/day and 0.0003 mg/kg/day respectively, whereas in the 2014 revised assessment, the acute and chronic PADs are 0.005 mg/kg/day and 0.0008 mg/kg/day for females ages 13-49, respectively. In the 2016 assessment and using a PBPK model to derive a TWA for blood concentrations to women potentially exposed to chlorpyrifos from residential uses voluntarily cancelled, a PAD of 0.00005 mg/kg/day was calculated which is approximately an order of magnitude lower than the 2011 and 2014 assessments.

In conclusion, despite several years of study, peer review, and public process, the science addressing neurodevelopmental effects remains unresolved. Therefore, the dietary, residential, aggregate, and non-occupational risk assessments have been conducted with retention of the 10X Food Quality Protection Act (FQPA) safety factor (SF) and without retention of the 10X FQPA SF (*i.e.*, FQPA SF reduced to 1X). Similarly, the occupational risk assessments have been conducted both with and without retention of a 10X UF_{DB}.

Appendix 2 Attachment 1: Summary of Regulatory and Scientific Activities to Address Uncertainty Around Neurodevelopmental Effects

Despite a stated public commitment to "share all data gathered," CCCEH has not provided EPA with the data used in the CCCEH epidemiology studies. In the summer of 2015, Dr. Dana Barr of Emory University (formerly of CDC) provided the EPA with limited raw urine and blood data in her possession from the three cohorts. However, the files provided from Dr. Barr are not useful for the EPA's current purpose of assessing risk to chlorpyrifos. The EPA does not have any of the other measurements of the children in the cohort (e.g., chlorpyrifos blood data, interviews, test or IQ scores). CCCEH researchers have asserted that the pesticide component of the cohort study was privately funded, not federally funded, and therefore disclosure of underlying data is not required. EPA has described its efforts to acquire the CCCEH data on its website (https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data).

Some recent requests include[38].

- April 19, 2016: EPA letter to Linda P. Fried, Dean, Mailman School of Public Health
- May 18, 2016: Linda P. Fried, Dean, Mailman School of Public Health letter to EPA
- June 27, 2016: EPA letter to Linda P. Fried, Mailman School of Public Health
- January 17, 2017: USDA letter to EPA citing Scientific Integrity Policy
- January 2, 2018: EPA letter to Linda Fried, once again requesting dataset
- January 8, 2018: Email from Linda Fried saying EPA needs to "clarify the information requests"

Throughout 2018, EPA continued to request the raw data from Columbia University:

- February 1, 2018: Teleconference and email to Howard Andrews regarding continued interest in reviewing the raw data and questions regarding statistical analysis of the Columbia dataset[39]
- February 6, 2018: Email from Howard Andrews requesting additional details on EPA's questions regarding the statistical analysis of the Columbia dataset
- March 26, 2018: Email to Howard Andrews with additional questions regarding statistical analysis of the Columbia dataset
- May 31, 2018: Teleconference with Howard Andrews regarding statistical analysis of Columbia dataset and reiterated request for the raw dataset
- June 27, 2018: Teleconference with Howard Andrews regarding raw dataset and CCCEH concern about the identification of study participants[40]

Following the June 2018 conference call with CCCEH, EPA contacted the CDC in July 2018 to discuss HIPAA and data de-identification issues as it relates to the CCCEH. The CDC

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[38] Links to each letter can be found on https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos-epas-seven-year-quest-columbias-raw-data.

[39] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0939

[40] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0937

representative noted that even after taking out personally identifiable information (PII) from the dataset, the data that remain can still pose identification issues because of the possibility of linking it with information currently in the public domain. The CDC representative further noted there are some datasets that cannot be deidentified given the nature of the data and specified that geographic location is one of the variables that makes something highly identifiable. In the case of CCCEH, the study participants live within a small geographical range with New York City. The CDC representative noted that for those cases, there is the possibility of allowing the data to be viewed in a secure data center[41].

Since June 2018, EPA has not made further attempts at obtaining or viewing the raw data from CCCEH.

[41] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0936

Appendix 3: Physical/Chemical Properties

Physical/Chemical Properties of Chlorpyrifos.		
Parameter	Value	Reference
Melting point/range	41.5-42.5 ºC	Chlorpyrifos IRED
pH	NR	
Density (21ºC)	1.51 g/mL	
Water solubility (25°C)	1.05 mg/L	
Solvent solubility (20°C)	Acetone >400 g/L Dichloromethane >400 g/L Methanol 250 g/L Ethyl acetate >400 g/L Toluene >400 g/L n-hexane >400 g/L	
Vapor pressure, (25°C)	1.87×10^{-5} torr[1]	
Dissociation constant, pK_a	NR	
Octanol/water partition coefficient, $Log(K_{OW})$	4.7	
UV/visible absorption spectrum	NR	

NR – not reported.

[1] R. Bohaty, June 2011, D368388 and D389480, *Chlorpyrifos Drinking Water Assessment for Registration Review* (CRF assessment, Oct. 16, 2009 product chemistry BC 2062713)

Appendix 4: Current U.S. Tolerances and International Residue Limits for Chlorpyrifos

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico**[2]	**Codex**[3]
40CFR180.342 chlorpyrifos *per se* (*O,O* -diethyl *O* -(3,5,6-trichloro-2-pyridyl) phosphorothioate	*O,O*-diethyl-*O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate (apples, grapes, tomatoes) *O,O*-diethyl-*O*-(3,5,6- trichloro-2-pyridyl) phosphorothioate, including the metabolite 3,5,6-trichloro-2-pyridinol (citrus fruits; fat, kidney, and liver of cattle; kiwifruit; peppers; rutabagas; green onion subgroup (crop subgroup 3-07B); meat and meat byproducts of cattle (calculated on the fat content))			Chlorpyrifos. The residue is fat soluble.
Commodity[1,]	Tolerance (ppm) /Maximum Residue Limit (mg/kg)			
	US	Canada	Mexico[2]	Codex[3]
Alfalfa, forage	3.0			
Alfalfa, hay	13			5 alfalfa fodder
Almond	0.2			0.05
Almond, hulls	12			
Apple	0.01	0.01		1 pome fruits
Apple, wet pomace	0.02			
Banana	0.1			2
Beet, sugar, dried pulp	5.0			
Beet, sugar, molasses	15			
Beet, sugar, roots	1.0			0.05
Beet, sugar, tops	8.0			
Cattle, fat	0.3	1		
Cattle, meat	0.05	1		1 (fat)
Cattle, meat byproducts	0.05	1		0.01 cattle, kidney and liver
Cherry, sweet	1.0			
Cherry, tart	1.0			
Citrus, dried pulp	5.0			
Citrus, oil	20			
Corn, field, forage	8.0			
Corn, field, grain	0.05	0.05		0.05 maize
Corn, field, refined oil	0.25			0.2 maize oil, edible
Corn, field, stover	8.0			10 maize fodder (dry)
Corn, sweet, forage	8.0			

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico[2]**	**Codex[3]**
Corn, sweet, kernel plus cob with husk removed	0.05	0.05		0.01 sweet corn (corn-on-the-cob)
Corn, sweet, stover	8.0			
Cotton, undelinted seed	0.2			0.3 cotton seed
Cranberry	1.0			1
Cucumber	0.05	0.05		
Egg	0.01			0.01 (*)
Fig	0.01			
Fruit, citrus, group 10	1.0	1		1
Goat, fat	0.2			
Goat, meat	0.05			
Goat, meat byproducts	0.05			
Hazelnut	0.2			
Hog, fat	0.2			
Hog, meat	0.05			0.02 (fat)
Hog, meat byproducts	0.05			0.01 (*) pig, edible offal
Horse, fat	0.25			
Horse, meat	0.25			
Horse, meat byproducts	0.25			
Kiwifruit	2.0	2		
Milk, fat (Reflecting 0.01 ppm in whole milk)	0.25			0.02 milk
Nectarine	0.05	0.05		
Onion, bulb	0.5	0.2		0.2
Peach	0.05	0.05		0.5
Peanut	0.2			
Peanut, refined oil	0.2			
Pear	0.05			1 pome fruits
Pecan	0.2			0.05 (*)
Pepper	1.0	1		2 peppers sweet including pimento or pimiento); 20 peppers chili, dried
Peppermint, tops	0.8			
Peppermint, oil	8.0			
Plum, prune, fresh	0.05			0.5 plums (including prunes)
Poultry, fat	0.1			
Poultry, meat	0.1			0.01 (fat)
Poultry, meat byproducts	0.1			0.01 (*) poultry, edible offal
Pumpkin	0.05			
Radish	2.0			
Rutabaga	0.5	0.5		
Sheep, fat	0.2			

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	**Canada**		**Mexico**[2]	**Codex**[3]
Sheep, meat	0.05			1 (fat)
Sheep, meat byproducts	0.05			0.01 sheep, edible offal
Spearmint, tops	0.8			
Spearmint, oil	8.0			
Sorghum, grain, forage	0.5			
Sorghum, grain, grain	0.5			0.5
Sorghum, grain, stover	2.0			2 sorghum straw and fodder, dry
Soybean, seed	0.3			0.1 soya bean (dry)
Strawberry	0.2			0.3
Sunflower, seed	0.1	0.1		
Sweet potato, roots	0.05			
Turnip, roots	1.0			
Turnip, tops	0.3			
Vegetable, brassica, leafy, group 5	1.0			2 Broccoli 1 Cabbages, head 0.05 Cauliflower 1 Chinese cabbage (type pe-tsai)
Vegetable, legume, group 6 except soybean	0.05	0.05 lentils		0.01 common bean (pods and/or immature seeds); peas (pods and succulent=immature seeds)
Walnut	0.2			0.05 (*)
Wheat, forage	3.0			
Wheat, grain	0.5			0.5
Wheat, straw	6.0			5 wheat straw and fodder, dry
Prepared 05/19/2020 D. Drew				

[1] Includes commodities listed in the CFR as of 5/19/2020. The 40CFR 180.342 (a) (3) also stipulates that "a tolerance of 0.1 part per million is established for residues of chlorpyrifos, per se, in or on food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food service establishments where food and food products are prepared and served, as a result of the application of chlorpyrifos in microencapsulated form."
[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.
[3] * = absent at the limit of quantitation. (fat) = to be measured on the fat portion of the sample.

Tolerances with regional registrations

Commodity	**Parts per million**	**Canada**	**Codex**
Asparagus	5.0		
Grape	0.01	0.01	0.5

Appendix 5: Master Use Summary Document

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
AGRICULT-URAL FARM PREMISES Livestock housing and holding areas (such as hog barns, empty chicken houses, dairy areas, milkrooms, calf hutches, calving pens and parlors).		✓		Indoor general surface spray	backpack sprayer; high and low sprayer (pressure or volume)	0.075 lb a.i./ 1000 ft sq 1.2 EC, ME	[14.4] NS	NA	12	NA	NA	NS	NS		Only permitted for use in poultry houses
ALFALFA		✓		At plant	groundboom	1.0 G	1.0	1.0	[1] NS	1	21	24	[10] NS	Missouri only	Lower PHI permitted for EC rates 0.33 lb a.i./A (7 d) and 0.67 lb a.i./A (14 d) e.g. Reg. No. 62719-591 Stand is in production 3-5 years. Planted ¼” to ½” deep.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓		Foliar	aerial or ground/ broadcast, chemigation	1.0 EC	[4.0] NS	4.0	[4] NS	4	21	24	10		Lower PHI permitted for EC rates 0.33 lb a.i./A (7 d) and 0.67 lb a.i./A (14 d) *e.g.*, Reg. No. 62719-591 Multiple harvests (or cuttings) per year when used for feed/fodder and 1 harvest per year when grown for seed. Cuttings occur about every 30 days. Only 1 crop cycle per year but up to 9 cuttings, varies by geography.
				Total		**1.0**	**5.0**	**5.0**	**[5] NS**	**5**	**21**	**24**	**[10] NS**		Represents Missouri scenario otherwise 4.0 lb a.i./A per is max.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
ALMOND		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WDG, WP	2.0	NA	1	NA	NA		10	Restricted use in California.	
		✓		**foliar**; broadcast	aircraft, airblast	2.0 WDG,WP	6.0	NA	3	NA	14		10		
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) WDG	2.5	NA	1	NA	14	24	NS		
		✓		Dormant/ delayed dormant; foliar; **orchard floors** broadcast	ground boom, handgun, chemigation	4.0 EC*	4.0	NA	2	NA	14		10	Restricted use in California. Only one dormant application can be made.	
				Total	**--**	**4.0**	**14.5**	**NA**	**7**	**NA**	**14**		**NS**		Excludes nursery applications (See general "Fruits" listing)
APPLE		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 EC 2.0 WDG 1.5 WP	2	2.0	1	1	NA	24/ 4 d	10d		Reflects spray drift mitigation measures.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**; ground	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	1.5 (1.5 lb ai/100 gal) WDG	1.5	NA	1	1	28	4d	NS	Use permitted in states east of the Rockies except Mississippi.	
				Total		**2.0**	**3.5**		**2**						
ASPARAGUS		✓		Foliar, pre-harvest; broadcast	aircraft, ground boom	1.0 EC, WDG	1.0	1.0	1	1	1	24	10		
		✓		Postharvest, broadcast	aircraft, ground boom	1.0 EC, WDG	2.0	2.0	2	1	1	24	10		
					granular soil band treatment ground boom	1.5 G	3.0	3.0	2	2	180	24	[10] NS	Permitted in California, the Midwest, and the Pacific Northwest 19713-505, 19713-521, 5481-525, 62719-34, 83222-34	Do not apply more than 3.0 lb a.i./A between harvests.
				Total		**1.5 G**	**3.0 G 2.0**	**3.0 G 2.0**	3	3	1	24	10		

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
BEANS		✓		Preplant; Seed treatment	Seed Treatment	*0.016-0.348* 0.000798 lb ai/lb seed ME *0.013-0.272* 0.000625 lb ai/lb seed WP *0.012-0.253* 0.00058 lb ai/lb seed EC	NS	[0.348] NS	NS	[1] NS	NS	NS	NS	ME is SLN only for ID	Italics highlight the range of application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding rate information provide by BEAD.[4]
BEEF/RANGE/ FEEDER CATTLE (MEAT)/ DAIRY CATTLE (NON-LACTATING)				Summer, late fall, spring; impregnated collar/tag	Animal treatment (ear tag)	0.0066 lb/animal	[0.0099] NS	NA	3	NA	NS	NS	NS		Reg. No. 39039-6 Cattle ear tags are assumed to last 4-6 months Two tags per animal at 0.0033 lb a.i./tag in the summer and one tag per animal at 0.0033 lb a.i./A.
BEETS (UNSPECIFIED; TABLE OR SUGAR)		✓		At plant, soil band treatment	Ground boom	1.0 EC	NS	1	NS	1		24		Allowed in Oregon Court ordered	Minimum Incorporation: 2 inches

Table A.5. Summary of Current Chlorpyrifos Usage																
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
"grown for seed"														buffer of 60 ft for ground chlorpyrifos application is required for "affected waterways".	
		✓		Preplant, soil incorporated treatment	Broadcast/ ground boom	1.9 EC	NS (2.8 ID)	NS	1	NS				Allowed in Oregon and Idaho	OR-09007; 62719-591 ID-090002; 62719-591
				Total		**1.9**	**NS**	**NS**	**NS**	**NS**		**24**			One or the other type of application.
SUGAR BEETS		✓		Preplant, soil incorporated treatment	Broadcast/ ground boom	1.0 EC 2.0 G	3.0	2.0	1	1	NA	24	10		Minimum Incorporation: 1 inch
		✓		At plant, soil band treatment	Broadcast/ ground boom	1.0 EC, WDG 2.0 G	3.0	2.0	1	1	30	24	10		
		✓		Post plant, soil band	Broadcast/ ground boom	2.0 G	3.0	2.0	1	1	30	24	10		
		✓		Post-emergence band treatment; broadcast	Broadcast/ ground boom	1.0 EC, WDG	3.0	1.0	3	1	30	24	10		

Table A.5. Summary of Current Chlorpyrifos Usage																
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓		broadcast	Aircraft, ground boom, chemigation	1.0 EC, WDG	3.0	1.0	3	1	30	24	10		EC is not for use in MS
				Total		**1.0 EC 2.0 G**	**4.0**	**[4.0] NS**	**3**	**[3] NS**	**30**	**24**	**10**		One granular application at 2.0 a.i./A and two liquid applications at 1.0 a.i./A per year. Also assumed per crop cycle.
CARROT Grown for Seed (INCLUDING TOPS)		✓		Foliar pre-bloom broadcast	aircraft, ground boom	0.94 EC	0.94	1	1	1	7	24	NA	Oregon and Washington Court ordered buffer of 60 ft for ground and 300 ft for aerial application is required for "affected waterways".	OR090011 SLN Expires: 12/31/2018 WA090011 SNL Expires: 12/31/2016 Carrots take two years to produce seed. All commercial production of the carrot (vegetable) takes place in the first year when the plant

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							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															is nowhere near blooming.
CHERRIES		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WDG, EC 1.5 WP	2.0	NA	1	NA	NS	24	10		
		✓		**foliar**; broadcast	airblast	4.0 EC	10.0	NA	5	NA	14	24	10		Tart cherry only
					aircraft	2.0									Reflects spray drift mitigation
		✓		Foliar, post-harvest; **trunk spray/drenc h**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) WDG, EC	2.5	NA	1	NA	2	24	[10] NS		Only some labels specify a 10 d MRI.
				Total	**--**	**4.0**	**4.5 (sweet)** **14.5 (tart only)**		**6**						Excludes nursery applications (See general "Fruits" listing) The foliar applications only apply to tart cherries, thus, sweet cherry scenarios (*e.g.*, Pacific NW) annual

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															application rate would be 4.5 lb total a.i./year.
CHRISTMAS TREE PLANTATIONS		✓		**foliar**; broadcast	helicopter, orchard blast	1.0 EC, WDG, WP	3.0	NA	3	NA	[0] NS	24	7	Aerial applications via helicopter are only permitted in Washington and Oregon.	
		✓		post-harvest; **Stump Treatment**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 (3.0/100 gal) EC, WDG	2.5	NA	1	NA	NA		7		
				Total		**2.5**	**5.5**		**4**						
CITRUS		✓		**foliar**; broadcast	airblast, ground boom	6.0 WP, WSP, EC	7.5	NA	2	NA	35 (21 for low rate s)	5d	30 (10 for low rates)	6.0 lb a.i. /A is only permitted in California and Arizona. The max single rate in other states is restricted to 4 lb a.i./A.	
		✓			aircraft	2.3 WP, WSP, EC					21	5	10	Florida, California,	Aerial application used

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
														and potentially Texas	to control psyllid, the vector for citrus greening. Reflects spray drift mitigation
		✓		foliar; **orchard floors broadcast**	ground boom, chemigation, handheld, backpack, drench/dip, handgun, and low-pressure hand wand	1.0 G*, WSP, EC	3.0	NA	3	NA	28	24/ 5 d	10		
				Total	**--**	**6.0**	**10.5**		**5**						Registered labels permit both foliar and soil applications in the same orchard. Total excludes nursery applications (See general “Fruits” listing)
CLOVER (GROWN FOR SEED)		✓		Preplant	Ground boom	1.9 EC	1.9	1.9	1	1	NS	24	NA	Use only permitted in Oregon.	OR-0900100; master label: 62719-591

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							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓		Post-Plant Foliar	aircraft and ground boom										Either a preplant or post plant application is allowed.
COLE CROPS (EXCLUDES CAULIFLOWER AND BRUSSELS SPROUTS)		✓		Preplant, soil incorporated treatment	Ground boom	2.0 EC, WDG, G	4.0	2.0	2	1	30	24	10		Min. incorporation: 2 inches
		✓		At plant, soil band treatment	Ground boom					1					One granular application permitted per year.
		✓		Post plant	Ground boom					1					
		✓		Foliar Established Plantings, soil sidedress treatment	Ground boom					1					
		✓		Foliar, broadcast	Aircraft, ground boom, chemigation	1.0 EC, WDG, WP	4.0	3.0	4	3	21		10		Multiple crops per year are possible in some locations.
				Total			**8.0**	**5**	**6**	**4**					Some labels restrict the yearly application rate to 3 lb a.i./A.

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															The maximum number of crops per year is 2.
BRUSSELS SPROUTS		✓		At plant, soil band treatment	Ground boom	2.0 EC; G	2.0	[2.0] NS	2	1	21	24	10		
		✓		Preplant, soil incorporated treatment	Ground boom										Minimum incorporation is 2 inches
		✓		Post plant, soil application	Ground boom	2.25 EC, G	2.25	[2.25] NS							
		✓		Foliar broadcast	Aircraft, Ground boom	1.0 EC	[5.3] NS	3.0	NS	3			10		83222-20, 84930-7, 86363-3 specify a 7-day MRI. All other labels specify a 10-day MRI. The PHI stated 84930-7 is conflicting [p. 4 (21 days and p. 19 (30 days)]
				Total		**2.3**	**5.3**		**NS**		**21**	**24**	**7**		Assume one application of either at plant, preplant, or post plant followed with additional

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															foliar applications.
CAULI-FLOWER		✓		At plant, soil band treatment	Ground boom	2.0 EC 2.3 G	2.0 EC 2.25 G	NS	[1] NS	1	21	3d	10		Only one granular application.
		✓		Preplant, soil incorporated treatment	Ground boom	2.3 G 2.0 EC	2.3	NS	[1] NS	1	30, EC, 21 G				Minimum incorporation is 2 inches
		✓		Post plant, soil application	Ground boom										
		✓		Foliar broadcast	aircraft, ground boom	1.0 EC	[5.3] NS	3.0	NS	3	21		10		
				Total		**2.3**	**5.3**	**[5.3] NS**	**NS**	**[4] NS**	**21**	**24**	**10**		Assume one application at either plant, preplant, or post plant followed with additional foliar applications.
COMMERCIAL /INSTITUTION-AL/ INDUSTRIAL PREMISES/ EQUIP. (INDOOR)				Broadcast	Product Container	0.4373 lb a.i./100 sq ft 190.5 G	NS	NA	NS	NA	NA	NS	NS		For treatment of fire ants
				Crack and Crevice/Void	Sprayer/ Injection	0.0625 lb a.i./1000 sq ft	NS	NA	NS	NA	NA	NS	NS		499-419

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
Non-food areas of manufacturing, industrial, and food processing plants; warehouses; ship holds; railroad boxcars.						2.7 ME									
				Crack and Crevice/Spot	Sprayer/ Injection	0.0424 lb/gal ME	NS	NA	NS	NA	NA	NS	7		
COMMERCIAL /INSTITUTIONAL /INDUSTRIAL PREMISES/EQUIP. (OUTDOOR) Outdoor commercial use around non-food areas of manufact-uring, industrial, and food processing plants; warehouses; ship holds; railroad boxcars				Soil broadcast	Low and High Pressure, Backpack, Handgun Sprayers	0.0247 lb a.i./1000 sq ft 1.1 ME	NS	NA	NS	NA	NA	NS	NS		
				Directed spray		0.1132 lb a.i./1000 sq ft 4.9 ME	NS	NA	NS	NA	NA	NS	NS		Specific to: Inside and outside dumpsters and other trash holding containers, trash corrals and other trash storage areas.
				Crack and Crevice/void/ general outdoor		0.0424 lb/gal ME	NS	NA	NS	NA	NA	NS	7		
CONIFERS AND DECIDUOUS TREES;		✓	?	**foliar**; broadcast	Ground boom	1.0 EC	3	NA	6	NA	7	24	7		

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
PLANTATION, NURSERY		✓	?	foliar; **stump treatment**	backpack, drencher, low pressure hand wand	0.3 EC	0.3	NA	1	NA	7	24	7		
				Total		**1.0**	**3**	**NA**	**6**	**NA**	**7**	**24**	**7**		The total number of applications assumed is either 3 foliar applications or 2 foliar applications with one stump treatment.
CORN (ALL)		✓		Preplant	ground/ **soil incorporated** conservation tillage, in furrow, broadcast, chemigation, soil band	3.0 EC 2.0 G	3.0	3.0	NS	3	NA	24/ 5 EC	10		19713-520, 19713-599, 33658-26, 34704-857, 72693-11, 83222-20 The minimum incorporation depth is 2 inches.
					soil incorporated aerial conservation tillage	2.0 EC, G									

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓			ground/ conservation tillage, in furrow, broadcast, chemigation, soil band	1.0 EC 2.0 G	3.0	3.0	NS	3	21		10		19713-520
		✓		Storage or preplant seed treatment	Seed treatment	*0.001-0.021* 0.000625 lb a.i./ lb seed WP *0.1-1.9* 0.058 lb a.i./ lb seed FC	[?] NS	[1.9] NS	[?] NS	1	NS	NS	NS		Italics highlight the range of application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding rate information provide by BEAD.[4]
		✓		At plant	soil incorporated, conservation tillage	2.0 G	[?] NS	3.0	[?] NS	3	21	24	10		
		✓		Post emergence	Aerial or ground, broadcast, chemigation	1.5 EC 1.0 WDG	NS	3.0	NS	3	21	24/ 5d (EC	10		A brush on max single rate is permitted at 1.0 lb ai/a (72693-11)

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Foliar	Aerial or ground/ broadcast, granule, seed and chemigation	1.5 EC	3.0	3.0	NS	3	21		10		
				Total		**3.0**	**8.1**	**8.1**	**NS**	**4**	**21**		**10**		Two granular applications are allowed with a maximum single rate of 1.0 lb a.i./A or one granular application at 2 lb a.i./A. Total with seed treatment PHI: 21 d except Delaware and Florida (7 d)
COTTON		✓		Storage or preplant seed treatment	Seed treatment	*0.8-2.2* 0.00116 lb/lb seed EC	[2.2] NS	[2.2] NS	[1] NS	1	NS	NS	NS		264-932 Rates in italics highlight the potential range of application rates depending on the number of seeds per lb and the number

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															of seeds planted per acre. Seeding rate information provide by BEAD.[2]
		✓		Foliar	aerial, chemigation, ground boom	1.0 EC, WDGP	3	3.0	3	3	14	24	10		Except MS
				Total		**1.0**	**3.2**	**3.2**	**3**	**3**	**14**	**24**	**10**		1.6 lb a.i./A is max single rate (seed treatment) **Total with seed treatment** 1 crop cycle per year assumed
CRANBERRY		✓		Foliar	aircraft, ground boom/ broadcast and chemigation	1.5 EC, WDG	3.0	NA	2	NA	60	24	10	Not for use in Mississippi.	Do not apply to bogs when flooded.
CUCUMBER		✓		Storage or preplant seed treatment	Commercial seed treatment	*0.4* 0.00058 lb/lb seed EC	NS	0.1	2	1	NS	NS	NS		Seeding rate information provide by BEAD.[2] 264-932, 62719-221, CA040004 Per registrant 2 CCs per year

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							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
FIGS		✓		**dormant/ delayed dormant**; soil application	ground boom	2.0 WDG, EC	2.0	NA	1	NA	217	4 d	NS	Use is restricted to California only.	Incorporation to 3 inches is suggested but not required following application.
FILBERTS/ HAZELNUT		✓		**dormant/ delayed dormant**; broadcast	aircraft, airblast	2.0 WP	2.0	NA	1	NA	14	24	10		
		✓		**foliar**; broadcast	aircraft, airblast	2.0 WDG, WP, EC	6.0	NA	3	NA	14		10		Some labels specify a retreatment interval of 10 days.
				Total		**2.0**	**6.0**	**NS**	**3.0**	**NA**	**14**	**24**	**10**		Excludes nursery applications (See general "Fruits" listing)
FOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT)				When needed, crack and crevice treatment, spot treatment		0.0424 lb/ gal ME	NS	NA	NS	NA	NA	NS	7		53883-264, 84575-3 Spot Treatment: Do not exceed two square feet per individual spot.
FOREST PLANTINGS (REFORESTAT			✓	Foliar, broadcast	ground boom	1.0 EC	6.0	NA	6	NA		24	7		

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
ION PROGRAMS) (TREE FARMS, TREE PLANTATION, ETC.)															
			✓	Foliar, stump treatment	direct spray, drencher	0.34 EC	6.0	NA	[18] NS	NA			7		
FOREST TREES (SOFTWOODS, CONIFERS)			✓	Foliar, broadcast	ground boom, drencher	0.61 EC	3.6	NA	NS	NA	24		7		
			✓	Foliar, stump treatment	direct spray	[3.6] 2.4 lb a.i./100 gal EC	3.6	NA	NS	NA			7		Application rate is provided as a dilution factor.
FRUITS & NUTS Non-bearing (not to bear fruit within 1 year) fruit trees in nurseries (includes: almonds, citrus, filbert, apple, cherry, nectarine, peach, pear, plum, prune).		✓		Foliar-Non-bearing nursery broadcast	High/low volume spay/ handheld sprayer/power sprayer	4.0 EC	4.0	NA	NS	NA	14	NS	7		For nectarines and peaches, the use is restricted to one application of no more than 3 lb a.i./A per cc. For apples, the max rate is 2 lb a.i./A per crop cycle and the use is restricted to 1 application (either canopy or trunk drench) per year.

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															Example label, 62719-254
		✓		Foliar-Non-bearing nursery trunk drench	drencher, high- and low-pressure sprayer	2.0 WDG	2.0	NA	NS	1	14		7		
				Total		**4.0**	**6.0**								Maximum Single Rates: 3.0 (nectarines and peaches) 2.0 (apples) Maximum Yearly Rates: 3.0 (nectarines and peaches) 2.0 (apples)
GINSENG (MEDCINAL)		✓		Preplant, post-emergence	Ground, soil broadcast	2.0 G	2.0	NA	1	NA	365	24	NA	Permitted in Michigan and Wisconsin	MI110006,WI110003) Minimum incorporation: 4 inches Application should be followed by rainfall or overhead watering. Valid until June 29, 2016.

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							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
GOLF COURSE TURF				When needed, soil broadcast/ spot treatment	Ground, low pressure	1.0 EC	2.0	NA	2	NA		24	NS		
				Foliar, broadcast,	Ground boom, handgun, low pressure and backpack	1.0 EC, G, B	2.0	NA	2	NA		24	NS		Chemigation not allowed for the EC formulation.
					Tractor drawn spreader, push type spreader, belly grinder	1.0 G						[24] NS	7		
				Mound treatment	Granule applicator	1.0 G	2.0	NS	2	NS		NS	7		
				Total		**2.0**	**2.0**	**NA**	**2**	**NA**	**NS**		**NS**		
GRAPES		✓		Dormant/ Delayed Dormant (pre-bloom)	Ground boom, broadcast, drench high/low spray volume	1.0 WDG, EC	1.0	1	1	NA	35	24	NS	East of the continental divide only.	Do not use in conjunction with soil surface applications for grape borer control.
		✓				2.0 EC	2.0	1	1	NA	35			Permitted in Colorado, Idaho, and Washington	CO080008, ID090004, WA090002 Master label: 62719-591

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓		Foliar	Ground/ broadcast, basal spray and drench (soil treatment)	2.25 EC	2.25	1	1	NA	35		NS	Permitted east of the continental divide.	
		✓				1.0 EC	3.0	3	3	NA	35		NS	California	CA080010
		✓		Postharvest, dormant/ delayed dormant	Ground boom, broadcast	2.0 EC	2.0	1	1	NA	NS		NS	California	CA080009
				Total		**2.25**	**2.25**	**1**			**35**	**24**	**NS**	Permitted east of the continental divide.	
						2.0	**5.0**	**4**			**NS**		**NS**	California	
GRASS FORAGE/ FODDER/HAY		✓		Foliar, broadcast	Aircraft, ground boom, chemigation	1.0 EC	3.0	NA	3	NA	NS	24		Permitted in Nevada, Oregon, Washington, and Idaho	NV080004, NV940002, OR090009, WA090010, ID090003
GREENHOUSE		✓		early evening, aerosol, fog or fumigation	Total release fogger	0.029 0.0066 lb a.i./1000 sq. ft PL	NS	NA	NS	NA	NS	NS	2		
HOUSEHOLD/ DOMESTIC DWELLINGS INDOOR PREMISES	✓			When needed	Bait station	0.0003 lb/bait station	NS	NA	NS	NA	NA	NS	NS		9688-67

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
HYBRID COTTONWOOD/ POPLAR PLANTATIONS		✓		Foliar, dormant, delayed dormant; broadcast	High volume (dilute) Low volume (concentrate)	1.9 EC	[2.0] NS	6.0	[1] NS	3		24	7	Washington	WA090004 Energy wood plantations may be harvested as often as every 2-3 years; pulpwood 5-10 years; and saw timber 15-20 years. (Arkansas production guide). In Washington the crop takes 2-8 years
LEGUME VEGETABLES		✓		Preplant, soil treatment	Ground boom	1.0 EC, WDG	1.0	NA	1	NA	NS	24	NA		No MRI because application only once a year
		✓		At planting, soil treatment	Ground boom	1.0 EC, WDG	1.0	NA	1	NA	NS		NA		
				Total		**1.0**	**1.0**	**NA**	**1**	**NA**	**NS**	**24**	**NS**		Assumed either a preplant or an at plant treatment.
MINT/ PEPPERMINT/ SPEARMINT		✓		Preplant soil incorporated	Aerial or ground/ broadcast	2.0 EC, WDG	[2.0] NS	2.0	[1] NS	1	90	24	NA	No use in Mississippi.	19713-599, 33658-26, 34704-857, 67760-28, 84229-25,

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
															84930-7, OR940027 MRI NA due to once per crop cycle application
		✓		Post-emergence, Postharvest, Foliar	Chemigation, ground/ airblast	2.0 EC	2.0	2.0	[1] NS	2	90		NS	No use in Mississippi.	Postharvest application retreatment not specified on some labels.
				Total		**2.0**	**4.0**	**4.0**	**2.0**	**3**	**90**	**24**	**NS**		Labels allow one growing season application including pre-plant and one post-harvest application per season.
MOSQUITO CONTROL; HOUSEHOLD/ DOMESTIC DWELLINGS OUTDOOR PREMISES; RECREATIONAL AREAS	✓			When needed; broadcast	Ultra-low volume air and ground	0.01 EC	0.26	NA	26	NS	NA	NS	24 h	In Florida: Do not apply by aircraft unless approved by the Florida Dept of Ag.	Aerial applications may be made at altitudes ranging from 75-300 ft (see labels for specifics).

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															For use by federal, state, tribal or local government officials or by persons certified in the appropriate category or authorized by the state or tribal lead regulatory agency.
NECTARINE		✓		**dormant/ delayed dormant** broadcast	airblast, handgun	3.0 WDG, EC	3.0	NA	1	NA	NS	24/ 4d	10		83222-20 others at 2 lb a.i./a
					Aircraft	2.0 WDG, EC									Updated to reflect spray drift mitigation.
		✓		pre-plant, foliar; **trunk spray/drench or pre-plant dip**	Handgun, low pressure backpack, dip	2.5 (3.0/100 gal) WDG, EC	2.5	NA	1	NA	14		5		There is no application retreatment interval specified on some of the label. The application rate is provided as a dilution factor.

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
				Total		**3.0**	**5.5**	**NA**	**2**	**NA**					Some labels limit the amount a.i./A per year. Multiple types of applications can occur such as preplant, trunk drench and dormant, delayed dormant applications. Excludes nursery applications (See general "Fruits" listing)
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES to and around outside surfaces of nonresidential buildings and structures. Permitted areas of use include				Outdoor general surface/ Band (may be better if called perimeter)	Ground sprayer/ band sprayer	1.0 EC	NS	NA	NS	NA	NA	NS	NS		

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
fences, pre-construction foundations, refuse dumps, outside of walls, and other areas where pests congregate or have been seen															
NURSERY-STOCK: : Ornamental nursery stock annuals, perennials and woody plants being grown in the field, in ball and burlap or in containers outdoor and in greenhouses				Dormant/ Delayed Dormant	high spray	3.0 EC	3.0	NA	1	NA		24	NS		
				Preplant	Ground boom, soil incorporated	4.0 EC, WP	NS	NA	NS	NA					
				foliar, soil directed	Tractor drawn spreader, push type spreader, belly grinder, gravity fed	1.1 G									

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
					backpack, spoon										
				Total		**4.0**	**CBD**		**3**						
ONIONS		✓		Post plant (seeding) Broadcast	Ground boom	1.0 EC	1.0	NS	2	NS	60	24	NS		
		✓		At plant, soil drench or basal spray	Ground boom	1.0 EC, WDG, G	1.0		1						2-inch incorporation
				Total		2.0	2.0		2		60	24	NS		
ORNAMENTAL AND/OR SHADE TREES, HERBACEOUS PLANTS		✓		Foliar broadcast	Ground boom, air blast, handgun, low- and high-pressure hand wands	2.0 EC, WP 1.0 G, B	2.0	NA	[2] NS	NA	NS	24	NS		Some labels include an MRI of 7 days.
		✓		Dormant /Delayed Dormant	Handgun, low pressure and backpack	3.0 EC	3.0	NA	1	NA	NS		7		Low volume spray permitted for concentrated solutions and lower rates.
ORNAMENTAL LAWNS AND TURF, SOD FARMS (TURF)		✓		When needed, broadcast, soil or spot treatment	ground boom (WP only), high pressure hand wand	3.76 EC, WP	7.52	NA	2	NA	NS	24	NS		
		✓		NS	Tractor drawn spreader, push type spreader, belly grinder	1.0 B	2.0	NA	2	NA	NS	24	NS		Bait is used for fire ant control.

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
ORNAMENTAL NON-FLOWERING PLANTS		✓		Foliar, broadcast, soil drench	Chemigation, ground boom, low and high pressure handwand, handgun, backpack sprayer, sprinkling can	0.007/gal ME	NS	NA	12	NA	NA	24	NS		Application rate provided as a dilution factor. Restricted use—occupational only
ORNAMENTAL WOODY SHRUBS AND VINES				Foliar broadcast	Ground boom, air blast, handgun, low- and high-pressure sprayer, backpack	2.0 EC, WDG 0.01 lb/gal EC	2.0 0.01 lb/gal	NA	[1] NS	NA	NS	24	NS		Several labels do not restrict the application rate in lb a.i./A. Examples include 16.5 lb/100 gal (228-625) and 1.0 lb/100 gal (829-280).
				Dormant/ delayed dormant		1.0 EC 0.005 lb/gal EC	1.0	NA	[1] NS	NA					
				Preharvest	Tractor drawn spreader, push type spreader, belly grinder	6.0 G	6.0	NA	[1] NS	NA					
				Preplant, potted, bailed-and	groundboom, handgun, low- and high-	1.0 EC	NS	1	NS	1					

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
				burlapped, containerized	pressure sprayer, backpack, drench										
				Pretransplant	groundboom	4.0 WP	[48.0] NS	4	12	4					
				Total		**6.0 G 4.0 WP**	**CBD**		**CBD**						
PEACH		✓		**dormant/ delayed dormant** broadcast	airblast	3.0 EC 2.0 WDG	3.0	NA	1	NA	10	24/ 4d	NS		83222-20 (all other labels restrict to 2 lb ai/a)
					aircraft,	2.0 EC 2.0 WDG							NS		Updated to reflect spray drift mitigation.
		✓		**Post-harvest** broadcast	airblast	2.5 (3.0/100 gal) EC	2.5	NA	1	NA	NA		NS	Permitted in Georgia and South Carolina	GA0400001, SC040001 SLN Expires:
					aircraft	2.0 (3.0/100 gal) EC	2.0								GA0400001, SC040001 SLN Expires: Updated to reflect spray drift mitigation
		✓		pre-plant, foliar;	handheld, backpack, drench/dip,	2.5 (3.0/100 gal) WDG	2.5	NA	1	NA	14	5	NS		Some labels do not specify minimum

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
				trunk spray/drench or pre-plant dip; ground	handgun, and low-pressure hand wand										retreatment interval.
				Total		**3.0**	**5.5**	**NA**	**3**	**NA**	**NA**	**24**	**NS**		It is possible that multiple types of applications can occur such as soil, foliar and/or post-harvest and dormant/ delayed dormant applications. Excludes nursery applications (See general "Fruits" listing)
						3.0	**8.0**	**NA**	**3**	**NA**	**NA**	**24**	**NS**	Permitted in Georgia and South Carolina	
PEANUT		✓		Preplant	Aerial or ground/ broadcast	2.0 EC, WDG	[4.0] NS	4.0	[2] NS	2	NA	24	10	Do not apply aerial in Mississippi	Assumes one crop cycle per year.
		✓		At plant, post plant		4.0 G	[4.0] NS	4.0	2	2	21	24	10		
		✓		At pegging		2.0 G EC, WDG	[4.0] NS	4.0	2	[2] NS	21	24	10		

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
				Total		**4.0 G 2.0 EC, WDG**	**4.0**	**4.0**	**2**	**2**	**10**	**24**	**10**		
PEAR		✓		**dormant/ delayed dormant** broadcast	aircraft, airblast	2.0 WDG, EC	2.0	NA	1	NA	NA	24	NA	Restricted use in California.	83222-20 allows 3.0 lb a.i./ A; however, this does not match the 2001 RED.
		✓		**Post-harvest** broadcast	aircraft, airblast	2.0 WDG, EC	2.0	NA	1	NA	NA	24	NS	Permitted in California, Oregon and Washington.	
				Total		**2.0 WDG, EC**	**4.0**	**NA**	**2**	**NA**	**NA**	**24**	**NS**		Multiple types of applications may occur in within a year in California, Oregon and Washington such as a post-harvest application and a dormant, delayed dormant. Excludes nursery applications

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
															(See general "Fruits" listing)
PEAS		✓		Preplant Seed treatment	Seed Treatment	0.30 0.000625 lb/lb seed WP 0.28 0.00058 lb/lb seed EC	NS	NS	NS	NS	NS	NS	NS		There is a range of potential application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding information provide by BEAD.[2]
PECANS		✓		**dormant/ delayed dormant** broadcast	aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	14	24	10		66222-19 and 66222-233
		✓		**foliar**; broadcast	airblast	4.3 EC, WDG	6.3	NA	3	NA	14		10		Some labels require a 28 d PHI
					aircraft	2.0 EC, WDG									Updated to reflect spray drift mitigation.
		✓		foliar; **orchard floors broadcast**	Ground boom, chemigation	4.3 EC, WDG	4.3	NA	2	NA	14		10		

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
				Total		**4.3**	**12.6**	**NA**	**6**	**NA**	**14**	**24**	**10**		Considers multiple type of applications (*e.g.*, dormant, foliar broadcast, and orchard floor) but excluding nursery For nursery applications (See general "Fruits" listing)
PEPPER		✓		Foliar	Ground broadcast	1.0 WDG	[8] NS	8.0	[8] NS	8	7	24	10	Permitted in Florida	FL040005; 1 crop cycle per year.
PINEAPPLE		✓		Post plant	Ground boom, broadcast	2.0 EC	6.0	6.0	3	NA	365	24	30	Permitted in Hawaii	HI090001 SNL Expires: March 29, 2014. Do not make applications beyond three months after planting.
PLUM/ PRUNE		✓		**dormant/ delayed dormant**; broadcast	Aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	NA	24/ 4d	10		

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		foliar; **trunk spray/drench**	handheld, backpack, drench/dip, handgun, and low-pressure hand wand	2.5 3.0/100 gal WDG	2.5	NA	1	NA	NA		10		
				Total		**2.5**	**4.5**	NA	2	NA					Excludes nursery applications (See general “Fruits” listing)
POULTRY LITTER		✓		When needed, animal bedding/litter treatment.	Sprayer	0.07126 a.i./1000 sq ft 3.1 ME	NS	NA	NS	NA	NA		NS		53883-264, 84575-3
PUMPKIN		✓		Preplant Seed treatment	Seed treatment	0.3 0.00058 lb /lb seed WP	[0.3] NS	[1] NS	[1] NS	1	NS	NS	NS	California maximum single rate 0.000625 lb a.i./lb.	There is a range of potential application rates depending on the number of seeds per lb and the number of seeds planted per acre. Seeding information provide by BEAD.[4]

Table A.5. Summary of Current Chlorpyrifos Usage

Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
RADISH		✓		Foliar	Broadcast ground	1.0 EC	NS	1	NS	1	NS	24	NS	permitted in Oregon	OR090012 on radish grown for seed. Label valid until December 31, 2012. (per registrant SLN still valid)
		✓		Preplant	Soil incorporation ground	3.0 EC	12.0	3	4	1	NS	NS	10		
		✓		At plant/post-plant	In furrow drench/ treatment	3.0 EC 2.8 G	[15.0] NS	3	[5] NS	1	30, EC, 7, G	24	10		Only one granular application permitted.
				Total		**3.0**	**[22.0] NS**	**2**	**[9] NS**						Only one preplant or at plant application is assumed.
RIGHTS OF WAY, ROAD MEDIANS				When needed, soil broadcast	Granular or low-pressure wand	1.0 EC, G, Bait	[2.0] NS	NA	2	NA	NA	NS	7		Apply when needed
RUTABAGA		✓		Preplant	Chemigation, Groundboom	2.4 EC, WDG	[4.8] NS	2.4	[2] NS	1	30	24	10		
					Aerial	2.0 EC, WDG		2.0							Updated to reflect spray drift mitigation.

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Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
		✓		At plant/post-plant	In furrow drench/ treatment	2.4 EC, G WDG	4.8	2.4	[2] NS	1	7	24	10	Disallowed in California and Arizona.	Two crop cycles per year
				Total		**2.4**	**[9.6] NS**	**4.8**	**[4] NS**	**2**		**24**	**10**		
SEWER MANHOLE COVERS AND WALLS				When needed	Low pressure	0.31 lb/manhole RTU	NS	NA	NS	NA	NA	NA	NS		3 pints product/ manhole
SEED ORCHARD TREES		✓		**foliar**; broadcast	Ground boom	1.0 EC	3.0	3.0	NS	NA	30	24	7		62719-575, 62719-615
		✓			High volume sprayer	2.5 0.01 a.i./tree 0.02 EC	2.5	NS	[1] NS	NA	30	24	7		Cone worm treatment (62719-575 and 62719-615) Treatment of 1000 trees per acre would results in a single application rate of 10 lb a.i./a. DAS: 1000 is a bit high, typically for orchards 312 trees per acre
		✓		foliar; **stump treatment**	backpack, drencher, low	0.3 EC	0.3	1.0	NS	NA	30	24	7		62719-575, 62719-615

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							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
					pressure hand wand,										
				Total		**1.0**	**5.8**	**3**	**NS**	**NA**	**30**	**24**	**7**		The total number of applications assumed is either three foliar applications or two foliar applications with one stump treatment.
SORGHUM GRAIN		✓		Seed Treatment	Seed treatment	[0.0009] 0.01-0.0024 lb ai/ 100 lbs seed EC	0.01	0.01	[1] NS	1	NA	NS	NS		264-932
		✓		Preplant Soil Directed	Ground Spreader/T Band	1.5 G	1.5	1.5	[1] NS	1	60	24	10		
		✓		Foliar/Post emergent	Ground, Aerial, Chemigation	1.0 EC, WDG	1.5	[1.5] NS	[1] NS	3	30	24	10		PHI varies across labels
				Total		**3.3 G 1.0 EC, WDG**	**3.01**	**3.01**	**[3] CBD**	**3**	30	24	10		One crop cycle per year.
SOYBEAN		✓		foliar , post-emergence soil broadcast	broadcast ground, aerial, chemigation	1.0 EC, WDG	3.0	3.0	3	3	28	24	14		One crop cycle per year.

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Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		At plant/post plant treatment; soil band	ground boom	2.2 G 1.0 EC	3.0	3.0	1 (G), 3 (EC)	1 (G), 3 (EC)	28	24	10		
				Total		**1.0 EC, WDG 2.2 G**	**3.0**	**3.0**	**3**	**3**					One crop cycle per year.
STRAW-BERRIES		✓		Pre-plant	Aerial or ground/ broadcast	2.0 EC	2.0	**NS**	1	NS	NA	24	10	No use in Mississippi	33658-26
		✓		Foliar	Aerial or ground/ broadcast, foliar spray	1.0 EC, WDG	2.0	**NS**	2	**NS**	21	24	10		Two applications (2 lb ai) for all products per cc.
		✓		Post-harvest	Ground directed spray	1.0 EC, WDG	2.0	**NS**	2	**NS**	21		14		
				Total		**2.0**	**4.0**		**3**						One preplant application and two foliar and/or postharvest application permitted per year.
SUNFLOWER		✓		At plant	Aerial/ground	2.0 G	3.0	3.0	[1] NS	1	42	24	10		Per registrant 1 cc per year

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							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
		✓		Preplant		2.0 EC, WDG	3.0	3.0	[1] NS	1	42		10		2 inches min incorporation
		✓		Post emergent or foliar		1.5 EC, WDG	3.0	3.0	[2] NS	2	42		10		
				Total		**2.0**	**5.0**	**5.0**	**3**	**3**					Assumed either an at plant or preplant application followed with two foliar applications. One crop cycle per year
SWEET POTATO		✓		Preplant, soil broadcast	Aircraft, ground boom	2.1 G, EC, WDG	2.1	NS	1	1	125	24		LA090002, MS080007, NC090001 permits 60 PHI	
					Aircraft	2.0 G, EC, WDG									Updated to reflect spray drift mitigation.
TOBACCO		✓		Preplant	Aircraft, ground boom	2.0 EC, G, WDG	2.0	NS	1	1	7	24	NA		
TRITICALE		✓		Storage Commercial Slurry Seed Treatment	Seed treatment	0.003 0.0024 lb ai/ 100 lbs seed EC	[0.003] NS	[1] NS	[1] NS	[1] NS	NA	[10] NS	[10] NS		264-932 Seeding information provide by BEAD.[4] One crop cycle per year.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
TURNIP		✓		Preplant	soil incorporation/ ground boom, handgun	2.3 G, WDG	[4.6] NS	2.3	[2] NS	1	30	24	10		Minimum incorporation: 2 inches.
		✓		Post plant	Soil incorporation/ ground boom, handgun	2.3 G, WDGP	[4.6] NS	2.3	[2] NS	1	30	24	10		Minimum incorporation: 2 inches.
				Total		**2.3**	**4.6**	**2.3**	**2**	**1**	**30**	**24**	**10**		Assumed either a preplant or post plant application. Two crop cycles per year
UTILITIES For use in and around telecommunications, power, utilities and railroad systems equipment: Buried cables, cable television pedestals, cables, pad-mounted electric power transformers, telephone cables, underground				When needed, broadcast	Product container	190.5 G 0.44 lb ai./100 sq ft (see comments)	NS	NS	NS	NS	NS	NS	NS		Applications permitted as needed. Reg. Nos. 13283-14, 13283-17 Broadcast product onto the ground covering the area of the pad location, plus a two-foot perimeter around the outside of the pad location.

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
vaults, telecommunications equipment, power and utilities equipment															
WALNUTS		✓		**dormant/ delayed dormant**; broadcast	Aircraft, airblast	2.0 EC, WDG	2.0	NA	1	NA	14	24	10		62719-301 (12 lb a.i./A)
		✓		**foliar**; broadcast	aircraft, airblast, chemigation	2.0 EC, WDG	4.0	NA	2	NA	14		10		Some labels do not specify retreatment interval.
		✓		foliar; **orchard floors broadcast**	Ground boom, chemigation	4.0 EC, WDG	4.0	NA	1	NA	14		10		
				Total		**4.0**	**10.0**		**4**						Excluding nursery applications; includes dormant, foliar broadcast, and orchard floor. For nursery applications (See general "Fruits" listing)

Table A.5. Summary of Current Chlorpyrifos Usage															
Crop/Site	**Residential**	**Agricultural**	**Forestry**	**Timing; Application Type**	**Method/ Equipment**	**Maximum Single Application Rate by Formulation[1] (lb a.i./A)**	**Maximum Application Rate**		**Maximum Application Number**		**PHI (days)[3]**	**REI (hours)[3]**	**MRI (days)[3]**	**Geographic Restrictions**	**Comments**
							Per Year lb a.i./A	**Per CC[2] lb a.i./A**	**Per Year**	**Per CC[2]**					
WIDE AREA/ GENERAL OUTDOOR TREATMENT For ants and other misc. pests.				when needed, Broadcast	Ground sprayer	0.5084 lb ai/100 gal EC	[1.02] NS	NA	2	NA	NA		NS		66222-19
	✓	✓		when needed, Drench	Drench	1	NS	NA	NS	NA	NA	NS	NS		228-624
						[1] 8.2 lb a.i/100 gal EC	NS	NA	NS	NA	NA		NS		228-625
				Total		[1]	NS	NA	NS	NA	NA				
WHEAT		✓		Slurry Seed Treatment	Seed treatment	0.003 0.0024 lb ai/ 100 lbs seed EC	[0.006] NS	1	[2] NS	1	NA	NA	NA		Seeding information provide by BEAD.[4]
		✓		Foliar, soil treatment	Ground, broadcast	0.5 EC	[8.0] NS	4.0	[2] NS	1	14/ 28		14		PHI: 14 forage or hay, 28 grain or straw
		✓		Post-emergence foliar	Ground, Aerial, Chemigation	1.0 EC	[4.0] NS	2.0	[4] NS	2	14/ 28	24	NS	Only for use in AZ, CA, CO, ID, KS, MN, MO, NE, NM, NV, ND, OK, OR, SD, TX, UT, WA and WY	Label states 1.0 lb ai/A for cereal leaf beetles and then state max rate 0.5 lb ai/A in restriction). Some labels restrict no more than 2 applications per crop/season PHI 14 forage or hay, 28 grain or straw

Table A.5. Summary of Current Chlorpyrifos Usage																
Crop/Site	Residential	Agricultural	Forestry	Timing; Application Type	Method/ Equipment	Maximum Single Application Rate by Formulation[1] (lb a.i./A)	Maximum Application Rate		Maximum Application Number		PHI (days)[3]	REI (hours)[3]	MRI (days)[3]	Geographic Restrictions	Comments
							Per Year lb a.i./A	Per CC[2] lb a.i./A	Per Year	Per CC[2]					
				Total		**[1] 4.0 EC**	[12.006]	**[6.003] 5.0**	[8] NS	[4] 2					MO otherwise 2.0 plus seed treatment
WOOD PROTECTION TREATMENT TO BUILDINGS/ PRODUCTS OUTDOOR				When needed, Wood surface treatment	Low pressure handwand, backback sprayer, paintbrush	16.65 lb/10,000 sq ft 0.17 lb a.i./gal EC	NS	NA	NS	NA	NS	NS	NS		
						0.08 lb ai/gal EC, RTU EC, ME	NS	NA	NS	NA	NS	NS	NS		Apply 1 gal per 100 sq ft of wood

1. EC - emulsifiable concentrate; WDG – water dispersible granular in water soluble packet; WP – wettable power in water soluble packet; B – bait (granular), G – granular; ME – microencapsulated; RTU – ready to use.
2. Reported as per crop cycle or per season
3. PHI – Preharvest interval; REI – reentry interval; MRI – Minimum retreatment interval
4. Becker, J.; Ratnayake, S. Acres Planted per Day and Seeding Rates of Crops Grown in the United States, U.S. EPA OPP/BEAD, 2011; example calculations provided below:
   Beans: 0.00058 lb a.i./lb seed / 960 seeds/lb seed x 418,176 seeds/A [pgs. 19, 81 (beans, succulent)]
   Corn: 0.000625 lb a.i./lb seed / 1,800 seeds/lb seed x 59,739 seeds/A [pgs. 24, 81 (corn, sweet)]
   Cotton: 0.00116 lb a.i./lb seed / 4,500 seeds/lb seed x 85,00 seeds/A [pgs. 13, 81]
   Cucumber: 0.00058 lb a.i./lb seed / 12,000 seeds/lb seed x 80,418 seeds/A [pgs. 25, 81]
   Peas: 0.000625 lb a.i./lb seed / 1,361 seeds/lb seed x 653,400 seeds/A [pgs. 34, 82]
   Pumpkin: 0.00058 lb a.i./lb seed / 1,600 seeds/lb seed x 7,260 seeds/A [pgs. 37, 82]
   Sorghum: 0.001 lb a.i./lb seed / 11,000 seeds/lb seed x 100,000 seeds/A [pgs. 16, 39]
   Triticale: 0.003 lb a.i./100 lb seed / 109 lb seed/A [pg.16]
   Wheat: 0.003 lb a.i./100 lb seed /116 lb seed/A [pg. 16]
   [ ] indicate assumptions that are made when the information is not specified but can be inferred

Appendix 6: Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1; the AHETF database; the Outdoor Residential Exposure Task Force (ORETF) database; the ARTF database; ExpoSAC Policy 14 (SOPs for Seed Treatment); the 2012 Residential SOPs: Lawns/Turf, Outdoor Fogging/Misting Systems; registrant-submitted exposure monitoring studies MRIDs 44180401, 44301301, 44793301, 44829601, 42974501, 43062701, 44748101, 44748102, 46722701, and 46722702; and published literature studies are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency.

Appendix 7: Residential Mosquito ULV Spreadsheets

See attached spreadsheets:

- Appendix 7_1_Adult Worst Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_2_Adult Best Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_3_Child Worst Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_4_Child Best Case Aerial Mosquito ULV applications.xlsx
- Appendix 7_5_Adult Ground Mosquito ULV applications.xlsx
- Appendix 7_6_Child Ground Mosquito ULV applications.xlsx

Appendix 8: Residential Post-Application Golfing Spreadsheet

See attached spreadsheet:

- Appendix 8_Chlorpyrifos Residential Golfer Postapp.xlsx

Appendix 9: Spray Drift Spreadsheets

See attached spreadsheets:

- Appendix 9_1_Adult Drift with MS TTR Data _ 6 lb ai through 3.xlsx
- Appendix 9_2_Adult Drift with MS TTR Data _ 2 lb ai and below.xlsx
- Appendix 9_3_Child Drift with MS TTR Data _ 6 lb ai through 3.xlsx
- Appendix 9_4_Child Drift with MS TTR Data _ 2_3 lb ai through 1_0.xlsx

Appendix 10: Occupational Handler Spreadsheets

See attached spreadsheets:

- Appendix 10_1_Chlorpyrifos Occup Handler Risk Estimates.xlsx
- Appendix 10_2_Occ Seed Treatment.xlsx

Appendix 11: Occupational Post-Application Spreadsheets

See attached spreadsheet:

- Appendix 11_Occupational Postapp.xlsx

EXHIBIT 19

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

PC Code : 059101
DP Barcode: 459269
September 15, 2020

MEMORANDUM

SUBJECT: Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review

TO: Patricia Biggio, Chemical Review Manager
Matthew Manupella, Acting Team Leader
Dana Friedman, Branch Chief
Risk Management and Implementation Branch 1
Pesticide Re-Evaluation Division (7508P)

THROUGH: Dana Spatz, M.S., Chief
Environmental Risk Branch 3
Environmental Fate and Effects Division (7507P)

DANA SPATZ
2020.09.15
20:43:25 -04'00'

FROM: Rochelle F. H. Bohaty, Ph.D., Senior Chemist
Sarah C. Hafner, Ph.D., Chemist
Environmental Risk Branch 3
Environmental Fate and Effects Division (7507P)

ROCHELLE BOHATY Digitally signed by ROCHELLE BOHATY
Date: 2020.09.15 20:38:34 -04'00'

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This memorandum transmits an update to the refined chlorpyrifos drinking water assessment completed in 2016 for registration review, as well as supporting documents and files. This update builds upon the 2016 DWA and focuses on a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. These uses were identified as being high benefit crops to growers by the Biological and Economic Analysis Division in OPP, or the most important of all the currently registered uses by Corteva Agriscience. As in past assessments, this refined assessment considers usage data, upper bound, and average application rates. Furthermore, this update uses updated scenarios (i.e., uses new soil, weather, and crop data), applies new methods for considering the entire distribution of community water systems percent cropped area adjustment factors, integrates state level percent crop treated data, and includes quantitative use of surface water monitoring data.

The exposure estimates reported in this assessment and associated conclusions drawn are solely for those uses listed above. Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).

Chlorpyrifos

Drinking Water Assessment for Registration Review: Update

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September 15, 2020

Abstract

This refined drinking water assessment provides an update to the 2016 drinking water assessment for the registration review of chlorpyrifos. This assessment only evaluates a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. This subset of uses was identified as being the most important of all the currently registered uses of chlorpyrifos.

This assessment utilizes new surface water model scenarios (i.e., soil, weather, and crop data), integrates the entire distribution of community water system percent cropped area adjustment factors, integrates state-level percent crop treated data, and considers the quantitative use of available surface water monitoring data. These methods have recently undergone external peer and public review.

Concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are not likely to exceed the drinking water level of comparison (DWLOC) with or without the retention of the FQPA safety factor for the subset of uses considered. This conclusion is based on upper bound application rates determined from usage data.

Analysis of monitoring data shows that there are several monitoring sites across the United States that could have concentrations higher than the DWLOCs. However, the contribution of other currently registered uses of chlorpyrifos (i.e., uses not considered in this assessment), could not be ruled out, nor could a definitive conclusion be made that the measured concentration data correlated to one of the specific uses evaluated in this assessment.

Executive Summary

This drinking water assessment (DWA) updates and builds upon the 2016 drinking water assessment for chlorpyrifos (USEPA, 2016) completed as part of the registration review process. The focus of this assessment is surface water, as groundwater was determined to not be a potential route of exposure concern in prior assessments. The estimated concentrations from the 2016 DWA for the specific uses considered in this update were used as a gauge for determining the need for refinement.

Exposure estimates for chlorpyrifos and chlorpyrifos-oxon in drinking water sourced from surface water are provided for upper bound and average application rates and typical application timing for a subset of currently registered uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in defined areas of the country (i.e., Hydrologic Unit Code (HUC)-2 regions). These uses encompass a large portion of the total amount of chlorpyrifos applied per year on a national basis, but there is also a lot of chlorpyrifos use that is not captured by these crops, including use on corn, almonds, grapes, peanuts, pecans, and walnuts, for example.

This subset of uses was selected based on discussion of critical uses with the registrant, Corteva Agriscience, and high benefit crops determined by the Biological and Economic Analysis Division (BEAD). As California is in the process of canceling most chlorpyrifos uses, this DWA does not consider use in California (HUC-18), except with respect to an evaluation of the monitoring data. Monitoring data from California reflects historical usage of chlorpyrifos that may also represent uses and environmental conditions relevant to the uses considered in this assessment.

This drinking water assessment integrates three recently developed and externally peer reviewed method improvements for conducting drinking water assessments.

1) ***New surface water model scenarios (i.e., soil, weather, and crop data):*** The Pesticide in Water Calculator (PWC) is a model that uses soil, hydrology, land cover/land use, weather, and waterbody properties to simulate environmental conditions to estimate pesticide concentrations for risk assessment purposes. The development of new PWC scenarios described in the methods document titled, *"Creating New Scenarios for Use in Pesticide Surface Water Exposure Assessments"* (USEPA, 2020) provides an opportunity to clearly and consistently identify field scenario inputs, and to rank the millions of new scenarios by vulnerability, thus providing a better understanding of estimated concentrations relative to environmental conditions and use.

2) ***Use of community water system percent cropped area (PCA) adjustment factors and state level percent crop treated (PCT) data:*** The recently completed methods document titled *"Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment"* (USEPA, 2020) provides an approach to apply use and usage data to further refine estimated drinking water concentration (EDWCs) in higher-tier assessments for agricultural and non-agricultural uses individually or in combinations. The goal of the PCA and PCT refinements is to generate EDWCs that are appropriate for human health risk assessment, but more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations.

3) ***Quantitative use of surface water monitoring data:*** EPA recently evaluated the extent to which existing monitoring data can describe the range of possible pesticide concentrations, using updated tools for monitoring data analysis. The seasonal wave with streamflow adjustment and extended capability (SEAWAVE-QEX) model and sampling bias factors (SBFs) were evaluated for short-term and long-term exposure durations of interest and described in the White Paper titled *"Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments"* and presented to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in November 2019. The goal of this work is to use surface water monitoring data at higher tiers to confidently estimate pesticide concentrations in surface water that may be sourced by community water systems.

A description of how these methods fit into the overall tiered drinking water assessment process can be found in the Framework for Conducting Pesticide Drinking Water Assessments for Surface Water (DWA Framework) (USEPA, 2020).

Both chlorpyrifos and chlorpyrifos-oxon are considered residues of toxicological concern in drinking water in this assessment. Chlorpyrifos-oxon forms from the treatment, e.g., chlorination, of source water containing chlorpyrifos. While chlorination is the primary method of disinfection used in the United States, other methods are used such as chloramines. Generally, alternatives to chlorination are used by systems serving larger populations.

To address the multitude of water treatment possibilities across the country, a bounding approach is used in this assessment to capture the range of potential exposures to chlorpyrifos or chlorpyrifos-oxon in drinking water. To represent those facilities that use disinfectant processes not including free chlorine, 100 percent of the chlorpyrifos entering the facility was assumed to be unchanged in the finished drinking water. Alternatively, to represent those facilities that employ chlorine as a disinfectant, 100 percent of the chlorpyrifos entering the facility was assumed to convert to chlorpyrifos-oxon, which is persistent over typical drinking water treatment distribution times.

The drinking water estimates are compared with four different DWLOCs. The Health Effects Division (HED) provided EFED with drinking water levels of comparison based on 10% red blood cell acetylcholinesterase inhibition for both acute (1-day) and steady state (21-day) exposure. For each of these exposure durations, two DWLOCs are considered, one with, and one without retention of the 10X FQPA safety factor.

Acute DWLOCs were calculated by HED for infants, children, youths, and adult females both with and without the 10X FQPA SF. With the 10X FQPA SF retained, the lowest acute DWLOC calculated was for infants (<1 year old) at 23 ppb chlorpyrifos-oxon. With the FQPA SF removed (FQPA SF of 1X) the lowest acute DWLOC calculated was for infants (<1 year old) at 240 ppb chlorpyrifos-oxon. Steady state DWLOCs were calculated by HED for infants, children, youths, and adult females both with and without the 10X FQPA SF. With the 10X FQPA SF retained, the lowest steady state DWLOC calculated was for infants (<1 year old) at 4.0 ppb chlorpyrifos-oxon. With the FQPA SF removed (FQPA SF of 1X) the lowest steady state DWLOC calculated was for infants (<1 year old) at 43 ppb chlorpyrifos-oxon.

While this drinking water assessment is more refined than the 2016 assessment, it continues to demonstrate that exposure is sporadic, both temporally and spatially. This is supported by both model-estimated concentrations, as well as measured chlorpyrifos concentrations in surface water across the United States.

Modeling results suggest EDWCs of either chlorpyrifos or chlorpyrifos-oxon in raw water (i.e., source water) or finished drinking water are not likely to exceed the DWLOCs for the 11 critical/high benefit uses included in this assessment, with or without the 10x FQPA safety factor. This conclusion only applies to these specific 11 uses in the areas of the country specified. It would be necessary to conduct a new DWA if additional uses were considered. Of note, this assessment does not account for potential residues in drinking water that may result from application on high usage crops such as corn, almonds, grapes, peanuts, pecans, and walnuts, as these crops were not identified by Corteva as critical uses or by BEAD as having high benefit to growers. This assessment also does not account for exposure from non-agricultural uses. If additional crops or non-agricultural use sites are considered, it is expected that model estimated concentration could be above the 10x DWLOC in some areas of the country, primarily driven by the increase in percent cropped area. It is possible with refinement that additional crops or non-agricultural use sites may result in concentrations below the 1x DWLOC; however, additional work would be necessary.

Evaluation of available surface water monitoring data and the application of SEAWAVE-QEX and sampling bias factors suggests chlorpyrifos-oxon concentrations may be above both the 1-day and 21-day DWLOCs with or without the FQPA safety factor. Additional analyses were completed as part of a weight-of-evidence to better understand what uses and environmental conditions are associated with these concentrations, however, the available monitoring data could not be specifically linked to the uses considered in this assessment.

Our analysis shows that the concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are expected to vary across the country with the highest potential for exposure in high use areas in vulnerable (*i.e.*, runoff prone) watersheds. Whether exposure is to chlorpyrifos or chlorpyrifos-oxon is highly dependent on local drinking water treatment processes.

a. Modeling Summary

A summary of the chlorpyrifos-oxon EDWCs resulting from upper bound (descriptions are provided by crop in supporting document provided in **ATTACHMENT 2**) application rates for each refinement step are presented in **Table 1** by 2-digit HUC region. Only chlorpyrifos-oxon EDWCs are provided here as the exposure and risk assessment conclusions are driven by exposure to chlorpyrifos-oxon.

Table 1. Surface Water Sourced Estimated Drinking Water Concentrations Resulting from Different Refinements for a Subset of Upper Bound Application of Chlorpyrifos Uses

2-digit HUC Name Overlapping States[1]	2-digit HUC Uses	Maximum 1-in-10 Year Estimated Chlorpyrifos-oxon Concentrations in Source Surface Water (µg/L)			
		Maximum 2-digit HUC Use Site-Specific Percent Cropped Area[2]		Percent Cropped Area Aggregation[3]	Percent Cropped Area-Percent Crop Treated Aggregation[4]
		1-day Average	21-day Average	21-day Average	21-day Average
Mid-Atlantic VT, NY, PA, NJ, MD, DE, WV, DC, VA	HUC-02 Apple and Peach	1.0	0.8	-	-
South Atlantic-Gulf VA, NC, SC, GA, FL, TN, MS	HUC-03 Cotton, Citrus, Peach, and Soybean	3.1	1.8	-	-
Great Lakes WI, MN, MI, IL, IN, OH, PA, NY	HUC-04 Alfalfa, Sugar beet, Apple, Cherry, Peach, Soybean, and Asparagus	22.8	19.6	3.4	-
Ohio IL, IN, OH, PA, WV, VA, KY, TN	HUC-05 Apple and Soybean	5.3	4.0	-	-
Tennessee VA, KY, TN, NC, GA, AL, MS	HUC-06 Apple	0.4	0.2	-	-
Upper Mississippi MN, WI, SD, IA, IL, MO, IN	HUC-07 Alfalfa, Sugar beet, and Soybean	9.9	7.2	5.4	3.2
Souris-Red-Rainy ND, MN, SD	HUC-09 Alfalfa, Sugar beet, Soybean, Spring Wheat, and Winter Wheat	8.3	5.6	5.2[4]	3.3
Missouri MT, ND, WY, SD, MN, NE, IA, CO, IA, KS, MO	HUC-10 Alfalfa, Soybean, Spring Wheat, and Winter Wheat	5.7	3.6	-	-
Arkansas-White-Red CO, KS, MO, NM, TX, OK, AR, LA	HUC-11 Alfalfa, Soybean, and Winter Wheat	3.9	3.9	-	-
Texas-Gulf NM, TX, LA	HUC-12 Citrus, Peach, and Winter Wheat	1.1	0.7	-	-
Pacific Northwest WA, ID, MT, OR, WY, UT, NV	HUC-17 Alfalfa, Sugar beet, Apple, and Strawberry	8.5	6.1	2.5	-

Green shading indicates concentrations are below the 10x DWLOC (1-day = 43 µg/L and 21-day = 4.0 µg/L) while red shading indicates concentrations are above the 10x DWLOC.
- indicates values are not calculated because the concentrations in the prior step were below the 10x DWLOC.
[1] Sites are listed that include any overlap with the HUC-2 region.
[2] Use site-specific PCA refers to the use of a percent cropped area adjustment factor to adjust EDWCs to account only for the potential use sites (e.g., for example for HUC-03 the PCA is the summation of individual percent cropped area for orchard, cotton, and soybean) within each individual community water system where chlorpyrifos is being considered (see column "2-digit HUC Uses").
[3] PCA aggregation refers to the use of individual percent cropped area adjustment factors to proportionally allocate pesticide residue contribution in the development of EDWCs based on potential chlorpyrifos use sites (i.e., land use data) for individual watersheds. This analysis was done using the model output 1-in-10 year values and does not account for temporal residue contributions.
[4] PCA-PCT aggregation refers to the use of individual percent cropped area adjustment factors to proportionally allocate pesticide residue contribution in the development of EDWCs based on known chlorpyrifos use for individual watersheds. This analysis was done using the model output 1-in-10 year values and does not account for temporal residue contributions.
[5] The use pattern specific PCA is higher (i.e., >1) than all-ag PCA (0.95). Therefore, the use pattern specific PCA is capped at all-ag value and the use pattern PCA should not exceed the all-agricultural PCA. However, when aggregating the individual use residue contributions results, this capping cannot be completed.

In summary, after the first refinement of applying use (usage rates, application dates and retreatment interval) data along with 2-digiti HUC maximum use site-specific percent cropped area (PCA), the EDWCs for upper bound application rates are below both the 1-day and 21-day 1x DWLOCs. However, EDWCs are above the 21-day 10x DWLOC in HUC-04 (considering use only on alfalfa, sugar beet, apple, cherry, peach, soybean, asparagus), HUC-07 (considering use only on alfalfa, sugar beet, soybean), HUC-09 (considering use only on alfalfa, sugar beet, soybean, and spring and winter wheat), and HUC-17 (considering use only on alfalfa, sugar beet, apple, and strawberry). These regions were further refined.

After the second refinement, which includes aggregation of the 1-in-10 year 21-day average concentrations (i.e., portioning the residue contribution from each use), only HUC-07 and HUC-09 have EDWCs greater than the 10x DWLOC. HUC-04 and HUC-17 are no longer considered for further refinement.

The third refinement, which utilized the application of percent crop treated data based on state level usage data in HUC-07 and HUC-09, suggests that concentrations are below the DWLOCs.

The exposure estimates reported in Table 1 and associated conclusions drawn are solely for those uses listed above. Consideration of fewer uses reduces the footprint (i.e., percent cropped area) where chlorpyrifos may be applied. Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).

It should be noted that in some cases the states included (or listed) in a region, as described in Table 1, may not entirely fall within one region. Therefore, the regional conclusions should not be assumed to occur across the entire state, but only part of the state with overlap.

b. Monitoring Summary

SEAWAVE-QEX analysis was completed for 11 sites across the country. SEAWAVE-QEX permits the estimation of pesticide concentrations between sampling events. Estimated chlorpyrifos and chlorpyrifos-oxon concentrations from SEAWAVE-QEX do not exceed the 1- or 21-day 1x or 10x DWLOCs.

Application of SBFs to sites with enough data to support a high confidence analysis indicate that concentrations may be higher than the DWLOCs in HUC-17. Sites with less data suggest concentrations could be higher than the DWLOCs in several HUCs for both the 1- and 21-day and 1x and 10x DWLOC. It should be noted that most available monitoring data for chlorpyrifos do not meet data quantity criteria for use in SEAWAVE-QEX or for the quantitative application of SBFs. Generally, the highest quality and quantity of chlorpyrifos data would be considered historical. The detection frequency for chlorpyrifos has generally gone down in recent years; however, often this is concurrently observed with a reduction in sample frequency, so it cannot be determined if occurrence frequency of chlorpyrifos is going down.

Problem Formulation

a. Background

Over the past 15 years, there have been four assessments of potential chlorpyrifos exposure in drinking water. In the 2001 Interim Reregistration Eligibility Decision (IRED), OPP considered exposure to chlorpyrifos in drinking water[1,2] and recommended the quantitative use of monitoring data to estimate exposure in groundwater. At the time of the IRED, measured chlorpyrifos concentrations in groundwater from termiticide uses (greater than 2000 µg/L) were the primary focus of drinking water exposure. The model groundwater concentrations were orders of magnitude lower than the measured concentrations. The termiticide use was canceled after the IRED.

In 2011, a preliminary drinking water assessment derived EDWCs for several agricultural uses of chlorpyrifos on a national basis and examined available monitoring data (USEPA, 2011). That assessment recommended the use of surface water EDWCs derived from modeling and concluded that a range of agricultural uses could lead to high levels (peak concentrations greater than 100 µg/L) of chlorpyrifos in surface water that could potentially be used by community water systems to supply drinking water. The 2011 assessment also discussed the effects of drinking water treatment on chlorpyrifos. It concluded that once it reaches a drinking water treatment facility, chlorpyrifos can be readily converted to chlorpyrifos-oxon during disinfection processes, primarily through oxidative treatment methods such as chlorination. Therefore, chlorpyrifos and chlorpyrifos-oxon were considered residues of concern in the preliminary assessment to account for the variation of drinking water treatment methods used by community water systems around the country.

The updated 2014 drinking water assessment (USEPA, 2014) considered public comments received following release of the 2011 drinking water assessment. The 2014 assessment presented an approach for deriving more regionally specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos-oxon for two 2-digit HUC regions (**Figure 1**).[3] A 2-digit HUC region is a hydrologically-based area that delineates contiguous drainage areas. There are 18 regions in the lower 48 states, plus 1 additional each for Alaska, Hawaii, and the Caribbean (21 regions total in the U.S.). It also provided several additional analyses that focused on 1) clarifying labeled uses, 2) evaluating volatility and spray drift, 3) revising aquatic modeling input values following updated guidance documents, 4) comparing aquatic modeling and monitoring data, 5) summarizing the effects of drinking water treatment, 6) updating model simulations using current exposure tools, and 7) proposing a strategy to refine the

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[1] U.S. Environmental Protection Agency, Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides, September 28, 2001

[2] Barrett, M, Nelson, H, Rabert, W., Spatz, D. Reregistration Eligibility Science Chapter for Chlorpyrifos Fate and Environmental Risk Assessment Chapter, June 2000

[3] Hydrologic Units Codes are a hierarchical system developed by United States Geological Survey to catalogue hydrological units within the United States. In this system, there are 18 individual HUC-02 regions in the contiguous drainage areas in the United States with an average size of 177,560 mi^2. The U.S. is divided and sub-divided into smaller hydrologic units. These units are arranged within each other and identified by a unique code consisting of two to eight digits based on the levels of classification in the hydrologic unit system. Additional information can be found at https://water.usgs.gov/GIS/huc.html.
Seaber P.R., Kapino, F. P., Knapp, G. L., 1997 Hydrological Unit Maps. W. S. P. United States Geological Survey. March 2007. Available at http://pubs.usgs.gov/wsp/wsp2294/ (Accessed March 5, 2016)

assessment using the drinking water intake percent cropped area adjustment factors. The additional analyses did not change the overall exposure assessment conclusions previously reported in the 2011 DWA.

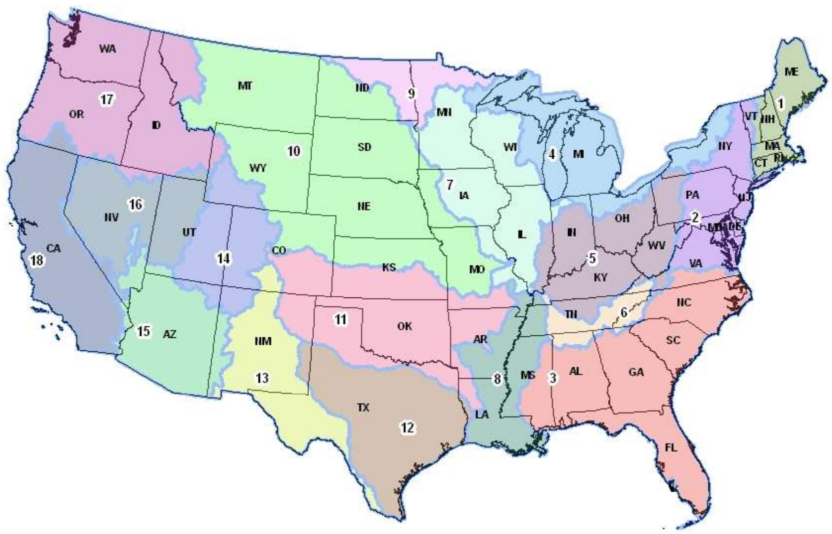


Figure 1. Spatial Distribution of HUC-02 Regions and U.S. State Boundaries

The 2016 DWA (USEPA, 2016) served to combine, update, and complete analysis for all 2-digit HUCs (or regions) presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. The document specifically focused on the exposure estimates for surface water. Urban uses, that had not previously been assessed due to label ambiguities and challenges interpreting the label, were also included. PWC-modeled estimated concentrations indicated that chlorpyrifos and chlorpyrifos-oxon concentrations in drinking water vary over the landscape with potential for localized concentrations to be >100 µg/L for the 21-day average concentration based on maximum use rates provided on the Master Use Summary Table (see **ATTACHMENT 1**). Results were also provided for application rates reflective of typical usage practices, resulting in lower concentrations, though many concentrations are above the current DWLOCs (see **Residues of Concern and Drinking Water Level of Comparison** section beginning on **page 22**).

In addition, a robust statistical analysis of all available surface water monitoring data for chlorpyrifos and chlorpyrifos-oxon was completed as part of the 2016 drinking water assessment. This included data from federal, state, and local agencies, universities, and the registrant.[4] The challenges and uncertainties in evaluating the chlorpyrifos and chlorpyrifos-oxon monitoring data were explained in detail. In summary, the data were determined to be inadequate to characterize the potential short-term exposure to chlorpyrifos and chlorpyrifos-oxon across the landscape. Though the model SEAWAVE-Q and SBFs were used to quantify the potential temporal uncertainty in the available monitoring data (i.e.,

[4] Surface water monitoring programs considered as part of 2016 DWA include Dow Agrosciences California Monitoring Program (DACMP), California Department of Regulation Surface Water Database (SURF), California Environmental Data Exchange Network (CEDEN), Central Coast Water Quality Preservation (CCWQP), Central Valley Irrigated Land Program (ILRP_5) , Central Valley Regional Water Control Board (CV_DNC_BPA), Oregon ELEM (OR ELEM), Registrants Organophosphate Monitoring Study, US EPA Storage and Retrieval Warehouse (STORET), USDA Pesticide Data Program (PDP), USGS National Water Information System (NWIS), USGS National Water Quality Assessment (NAWQA), USGS_EPA Stream Quality Index (USGS_MSQI), USGS State Data, USGS-EPA Pilot Monitoring Program (USGS-EPA reservoir), and Washington State Department of Agriculture (WSDA).

from non-daily sampling) on a site-specific basis, the assessment concluded that concentrations in aquatic systems likely fall within the range of PWC model-estimated concentrations reported in the assessment and could be above the DWLOC discussed in this assessment (see **Residues of Concern and Drinking Water Level of Comparison** section beginning on **page 22**).

b. Assessment Scope

This document provides an update to the refined drinking water assessment completed in 2016. This update integrates three new methods for advancing how EFED conducts drinking water assessments. The three methods include:

1) incorporation of new PWC surface water model scenarios (i.e., soil, weather, and crop data);
2) presentation of the entire distribution of community water systems percent cropped area adjustment factors and integration of state level percent crop treated area data; and
3) quantitative use of surface water monitoring data.

This assessment focuses on a subset of currently registered chlorpyrifos uses. Specifically, this assessment focuses on critical and high benefit uses of chlorpyrifos on alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, wheat, and strawberry in specific 2-digit HUC regions except for HUC-18, -19, -20, and -21. HUC-18 is not considered because California which makes up most of the region is canceling most chlorpyrifos uses. The other HUCs are not typically considered in drinking water assessments. HUCs in the contiguous states are expected to cover these regions -19, -20, and -21 are not expected to have the same agricultural intensity as areas within the contiguous states.

This assessment builds upon prior assessments and begins at the Tier 3 assessment level and proceeds through a Tier 4 assessment level, the most highly refined assessment tier. Based on prior monitoring data analysis conducted as part of the 2016 DWA and preliminary analyses completed as part of this assessment, it was decided that a Tier 4 monitoring data analysis would be beneficial to the assessment and could be informative if additional crops were evaluated. EDWCs are compared to the DWLOC (for more information on the DWLOC see the Residues of Concern and Drinking Water Level of Comparison section on **page 22** on this document).

c. Use Characterization

Chlorpyrifos is an organophosphate used as an insecticide on a wide variety of terrestrial food and feed crops, terrestrial non-food crops, greenhouse food/non-food, and non-agricultural indoor and outdoor sites. Based on an Office of Pesticide Programs Information Network (OPPIN) query (conducted July 2020), there are currently 112 active product labels (76 Section 3s and 36 Special Local Needs), which include formulated products (some with multiple active ingredients) and technical grade chlorpyrifos.

Several updates have been made to the chlorpyrifos registration over the years. For example, in the early 2000s, the registrants voluntarily agreed to eliminate and phase out some uses including eliminating most homeowner uses, as well as use on tomatoes, and restricting use on apples to pre-bloom and dormant applications. In addition, in 2002 label changes were made to include buffer zones to protect water quality as well as several reductions in application rates per season on a variety of crops including citrus and corn. More recent label updates have included spray drift buffers for sensitive sites (e.g., schools) to protect human health. In addition, in the early 2010s a master use summary table was developed in consultation with the technical registrants to ensure consistency across labels and further define the intended use of chlorpyrifos.

1. Master Use Summary Table

The Environmental Fate and Effects Division (EFED) in consultation with the Pesticide Re-evaluation Division (PRD), the Biological and Economic Analysis Division (BEAD), and the Health Effects Division (HED) developed a list of all chlorpyrifos registered uses (see Master Use Summary Table provided in **ATTACHMENT 1**). This summary reflects all currently registered labels and any agreed-upon changes to these labels from the registrants that have not been made to the labels to date.

While the current labels may not reflect all the agreed-upon changes, the registrants agreed to update the chlorpyrifos labels to be reflective of the attached Master Use Summary. Commitment letters from the chlorpyrifos registrants are available online as part of the Biological Evaluation Chapters for Chlorpyrifos ESA Assessment.[5] In general, current single maximum chlorpyrifos application rates do not exceed 4 lb a.i./A nationwide; however, a single chlorpyrifos application of 6 lb a.i./A is permitted on citrus in a limited number of counties in California. Aerial applications are not permitted at rates higher than 2.0 lb a.i./A except for treatment of Asian citrus psyllid (citrus use areas including California, Arizona, Texas, and Florida). In this situation, chlorpyrifos may be applied at a rate of up to 2.3 lb a.i./A by aerial equipment. The maximum annual rate of chlorpyrifos that may be applied to a crop site is 14.5 lb a.i./A for tart cherries.

Chlorpyrifos can be applied in a liquid, granular, or encapsulated form, or as a cattle ear tag or seed treatment. Aerial and ground application methods (including broadcast, soil incorporation, orchard air blast, and chemigation) are allowed. Registered labels for liquid applications (i.e., flowable products) require 25-foot (ground boom and chemigation), 50-foot (orchard air blast), or 150-foot (aerial) no-spray buffer zones adjacent to waterbodies.

Agricultural Use Sites

Currently registered agricultural use sites include: agricultural farm premises (such as, barns, empty chicken houses, dairy areas, calving pens), poultry litter, cattle (impregnated collars/ear tags), alfalfa, orchards [including, almonds, apple, cherries, citrus, figs, filberts, non-bearing fruit and nuts (nursery), grapes, nectarine, peach, pear, pecan, plum/prune, seed orchard trees, and walnut], asparagus, beans, beets (grown for seed), sugar beets, carrots (grown for seed), clover (grown for seed), cole crops, corn (all), cotton, cranberry, cucumber, ginseng (medicinal), grass (forage/fodder/hay), legumes, mint, nursery stock, peanut, peas, pepper, pineapple, pumpkin, radish, rutabaga, sod farms, onions, sorghum, soybean, strawberry, sunflower, sweet potato, tobacco, triticale, turnip, wheat, and tree plantations [including Christmas trees, nursery plantations (conifer and deciduous trees), reforestation programs, conifers, and hybrid cottonwood/poplar].

[5] https://www3.epa.gov/pesticides/nas/final/chlorpyrifos/appendix-1-5.pdf

Non-agricultural Use Sites

Currently registered non-agricultural use sites include: commercial/institutional/industrial (indoor and outdoor – e.g., warehouses, food processing plants, ship holds, railroad cars), golf course turf, greenhouse, households (indoor), mosquito control (outdoor), nonagricultural buildings (outdoor – e.g., fences, construction foundations, dumps), ornamental plants, ornamental lawns, rights-of-way (including road medians), sewer manhole covers and walls, utilities (e.g., power lines, railroad systems, telecommunication equipment), wide area general outdoor use (e.g., for ants and other misc. pests), and wood protection treatment (for outdoor building products).

2. *Usage Data*

Based on usage data provided by BEAD, approximately 7.2 million pounds of chlorpyrifos are used each year for agricultural purposes in the United States (based on yearly averages from 2004 to 2013). Use on corn and soybean make up 20% of the total volume of chlorpyrifos used in the United States each year. However, both crops have low percent (≤5%) crop treated. Crops with relatively high usage of chlorpyrifos (at least 100,000 lbs/year) include alfalfa, almonds, apples, apricots, cotton, grapes, oranges, peanuts, pecans, sugar beets, walnuts and wheat. A large fraction, at least 40%, of the total acreage planted with apples, asparagus, broccoli, onions, and walnuts, is treated with chlorpyrifos. Considering agricultural uses, there has been a general trend of decreased usage per year as shown in **Figure 2**.

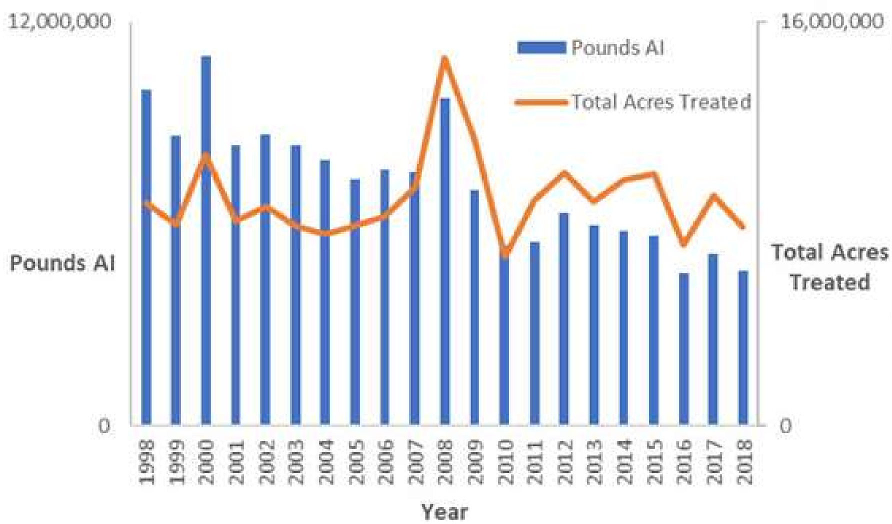


Figure 2. Chlorpyriphos Total Acres Treated and Total Pounds A.I. Applied (1998-2018)[6]

Limited national level chlorpyrifos usage data are available for registered non-crop use sites. These data not summarized here.

Critical Uses

In discussions with Corteva Agriscience, several crops were identified where chlorpyrifos is a critical pest management tool. This includes use of chlorpyrifos to combat alfalfa weevil in alfalfa, scale in citrus, cut

[6] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 1998-2018

worms and lygus bug in cotton, two spotted spider mites in soybean, sugar beet root maggot in sugar beet and Russian wheat aphid in wheat. These uses have been cross walked with 2-digit HUC regions with BEAD's help. A summary of each critical use is provided in **APPENDIX A** and briefly summarized in **Table 2**, while more detailed information from BEAD is provided in **ATTACHMENT 2**. This table notes the only regions identified where the chlorpyrifos use is critical. It is noted that use of chlorpyrifos in California (HUC-18) is not considered in this assessment given the recent regulatory actions the State has taken regarding chlorpyrifos use.

Table 2. Critical (according to Corteva Agriscience) Chlorpyrifos Use Summary

Use	2-digit HUC	Maximum Single Rate (lb a.i./A)	Maximum Annual Rate (lb a.i./A)	Maximum of Average Surveyed Single Application Rate (lb a.i./A)[a]	Maximum of Surveyed Single Application Rate (lb a.i./A)[a]	Average Annual Pounds Chlorpyrifos Applied
Alfalfa	04, 07, 09, 10, 11, 13, 14, 15, 16, and 17	1.0 (l)	5.0	0.6	1.3	600,000
Citrus[b]	03, and 12	6.0 (l)	10.5	2.7	3.0	450,000
Cotton	03	1.0 (l)	3.2	0.2	1.0	70,000
Soybean	03, 04, 05, 07, 09, 10, and 11	2.2 (g)[b]	3.0	0.5	1.0	1,200,000
Sugar beet	04, 07, 09, and 17	2.0 (g)[b]	4.0	1.2	1.5	100,000
Wheat	09, 10, 11, and 12	4.0 (l)	12.0	0.4	0.8	600,000

a. Maximum across the noted 2-digit HUCs. Values for the individual HUCs are provided in **ATTACHEMNT 2**.
b. Includes data for all citrus crops including orange, lemon, and grapefruit.

Data summarized in this table are taken from **ATTACHMENT 2**.
(g) granular
(l) liquid application
1.0 for liquid applications

High Benefit Uses

In addition to the uses that Corteva Agriscience identified as critical, BEAD identified several uses where chlorpyrifos is a high benefit to growers. A high benefit signifies that there are no alternative pesticides available or the alternatives are expensive or not as efficacious for a pest on a specific crop. This includes apple, asparagus, tart cherry, peach, and strawberry. A summary of each critical use is provided **APPENDIX A** and briefly summarized in **Table 3,** while more detailed information from BEAD is provided in **ATTACHMENT 2**. This table notes the only regions identified where the chlorpyrifos use is high benefit to a subset of uses.

Table 3. High Benefit Chlorpyrifos Use Summary

Use	2-digit HUC	Maximum Single Rate lb a.i./A	Maximum Annual Rate lb a.i./A	Maximum of Average Observed Single Application Rate lb a.i./A[a]	Maximum of Observed Single Application Rate lb a.i./A[a]	Average Annual Pounds Chlorpyrifos Applied
Apple	02, 04, 05, 06, 17	2.0 (l)	2.0	1.5	2.8[b]	300,000
Asparagus	04	1.5 (g)	3.0	0.96	1.0	70,000
Tart Cherry	04	4.0 (l)	14.5	1.1[e]	3.0[d,e]	60,000[d]
Peach	02, 03, 04, 12	3.0 (l)	8.0[c]	1.3	3.0	30,000
Strawberry	17	2.0 (l)	4.0	1.24	2.0	<500

a. Maximum across the noted 2-digit HUCs. Values for the individual HUCs are provided in **ATTACHEMNT 2**.
b. 2.0 lb a.i./A is the 90th percentile application rate
c. 8.0 lb a.i./A per year is permitted in Georgia and South Carolina; however, the annual max application rate is 5.5 lb a.i./A in other areas of the county.
d. The maximum rate observed is 3.0 lb a.i./A with the 90th percentile at 2.0 lb/A.
e. Both sweet and tart cherry

Data summarized in this table are taken from **ATTACHMENT 2**.
(l) liquid application, (g) granular

d. Exposure Characterization

1. Conceptual Exposure Model

Chlorpyrifos will initially enter the environment via direct application (e.g., liquid spray and granular) to use sites. It may move off-site via spray drift, volatilization (primarily following foliar applications), and runoff (generally by soil erosion and to a lesser extent dissolution in runoff water). Degradation of chlorpyrifos begins with cleavage of the phosphorus ester bond to yield 3,5,6-trichloro-2-pyridinol (TCP) or oxidative desulfurization to form chlorpyrifos-oxon as shown in **Figure 3.** TCP may be converted to 3,5,6-trichloro-2-methoxypyridine (TMP) also shown in **Figure 3**. Most environmental fate studies (except field volatility and air photolysis studies) submitted to EPA do not identify chlorpyrifos-oxon as a transformation product, yet organophosphates that contain a phosphothionate group, phosphorus-sulfur double bond (P=S), such as chlorpyrifos, are known to transform to the corresponding oxon analogue containing a phosphorus-oxygen double bond (P=O) instead. This transformation occurs via oxidative desulfurization and can occur through photolysis and aerobic metabolism, as well as other oxidative processes. Chlorpyrifos-oxon is considered less persistent than chlorpyrifos and may be present in air, soil, water, and sediment.

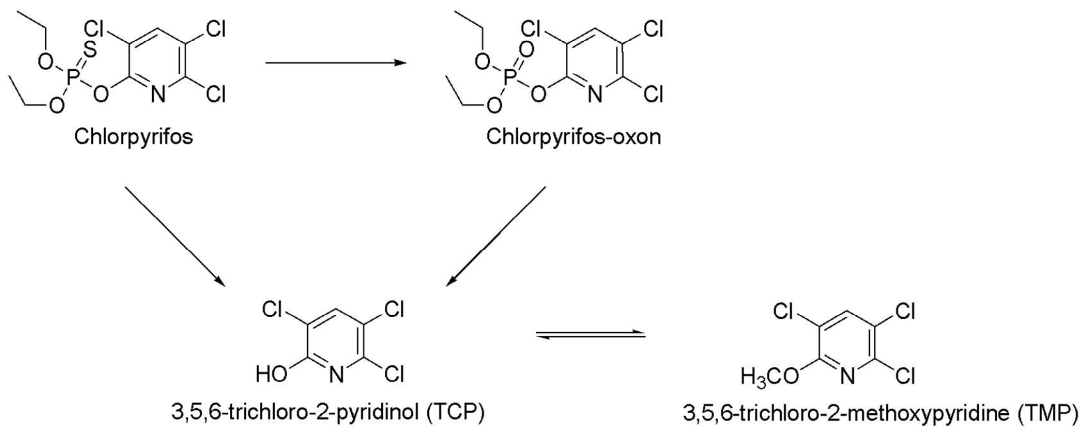


Figure 3. Environmental Transformation of Chlorpyrifos

2. Residues of Concern and Drinking Water Level of Comparison

Chlorpyrifos and chlorpyrifos-oxon are considered residues of toxicological concern for dietary exposure, including drinking water.[7] For this assessment, HED provided four different DWLOCs for both chlorpyrifos and chlorpyrifos-oxon based on 10% red blood cell acetylcholinesterase inhibition for both acute (1-day) and steady state (21-day) exposure. For each of these exposure durations, two DWLOCs are consider one with and one without retention of the 10X FQPA safety factor. This was done because the science addressing neurodevelopmental effects remains unresolved. The DWLOCs for chlorpyrifos are provided in **Table 4.** The DWLOCs for chlorpyrifos-oxon are provided in **Table 5**.[8] The DWLOCs may not be exactly 10-fold apart because the food and residential components of the aggregate exposure assessment completed by HED make up a different percentage of the risk cup depending on whether the 10x FQPA safety is retained or removed.

Table 4. Chlorpyrifos Drinking Water Level of Comparison

Safety Factor	Acute (1-day) µg/L	Steady State (21-day) µg/L
Retained (10x DWLOC)	180	17
Removed (1x DWLOC)	1000	100

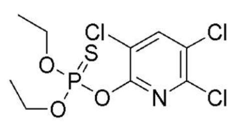
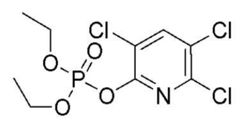
Table 5. Chlorpyrifos-oxon Drinking Water Level of Comparison

FQPA 10x Safety Factor	Acute (1-day) µg/L	Steady State (21-day) µg/L
Retained (10x DWLOC)	23	4.0
Removed (1x DWLOC)	230	43

Physical chemical properties for chlorpyrifos and chlorpyrifos-oxon are provided in **Table 6** (USEPA, 2016). TCP and TMP are not considered residues of toxicological concern based on analysis by HED and, therefore, are not discussed in detail in the remaining sections of this document.

[7] Email from Danette Drew (EPA/HED) to Rochelle Bohaty (EPA/EFED), September 21, 2010.
[8] Email from Kristin Rickard (EPA/HED) to Rochelle Bohaty (EPA/EFED), June 3, 2020.

Table 6. Physical/Chemical Properties of Chlorpyrifos and the Transformation Product of Concern, Chlorpyrifos-oxon

Parameter	Chlorpyrifos	Chlorpyrifos-oxon
IUPAC Name	*O,O*-diethyl o-(3,5,6-trichloro-2-pyridyl phosphorothioate	*O,O*-diethyl O-3,5,6-trichloropyridin-2-yl phosphate Diethyl 3,5,6-trichloro-2,6-pyridin-2-yl phosphate
Chemical Abstracts Service (CAS) Registry Number	2921-88-2	5598-15-2
Chemical Formula	$C_9H_{11}Cl_3NO_3PS$	$C_9H_{11}Cl_3NO_4P$
Smiles	S=P(OC1=NC(=C(C=C1Cl)Cl)Cl)(OCC)OCC	O=P(Oc1nc(c(cc1Cl)Cl)Cl)(OCC)OCC
Chemical Structure		
Molecular Mass (g/mol)	350.57	334.52
Vapor Pressure (Torr, 25°C)	1.87×10^{-5}	6.65×10^{-6}
Henry's Law Constant (atm – m^3/mol)	6.2×10^{-6}	5.5×10^{-9}
Solubility (20°C) (ppm)	1.4	26.0
Octanol-water partition coefficient (Log K_{ow})	4.7	2.89
Table is taken directly from the 2016 DWA (USEPA, 2016)		

It should be noted that an individual would not be exposed to both chlorpyrifos and chlorpyrifos-oxon at the same time at 100 percent of the EDWCs; however, both chemicals could be present in finished drinking water. Moreover, the conversion of chlorpyrifos to chlorpyrifos-oxon in the presence of chlorine may not always be 100 percent. Therefore, an individual would be exposed to both chlorpyrifos and chlorpyrifos-oxon to some degree. For example, an individual could be exposed to 10 percent chlorpyrifos and 90 percent chlorpyrifos-oxon. More discussion is provided in **Drinking Water Treatment Effects** subsection of this document (pg. 26).

3. Environmental Fate

A detailed discussion of the fate and transport of chlorpyrifos and chlorpyrifos-oxon in the environment is provided in the 2016 drinking water assessment. This includes data submitted to the U.S. EPA, as well as open literature data obtained prior to the assessment. Environmental fate parameters for chlorpyrifos are provided in **Table 7** and **Table 8**, respectively. No additional environmental fate data were submitted since the completion of the 2016 drinking water assessment. In summary, chlorpyrifos is expected to be persistent for several months in the environment, with aerobic soil and aerobic aquatic metabolism being the primary routes of transformation. Major routes of dissipation include spray drift, volatilization and runoff via dissolved phase and eroded sediment. Chlorpyrifos-oxon is expected to be more mobile but far less persistent in the environment than chlorpyrifos.

Table 7. Summary of Environmental Fate and Transport Characteristics of Chlorpyrifos

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a] days	Study ID	Study Classification
Laboratory Data				
Hydrolysis half-life (days)	pH 5, 25°C	73	MRID 00155577	Acceptable
	pH 7, 25°C	72		
	pH 9, 25°C	16		
	pH 7, 25°C	81	MRID 40840901	Acceptable
Aqueous photolysis half-life (days)	pH 7	29.6	MRID 41747206	Acceptable
Soil photolysis half-life (days)	--	Stable	MRID 42495403	Supplemental
Air photolysis half-life (hours)	Indirect	2	MRID 48789701	Acceptable
	Direct	6		
Aerobic Soil Metabolism half-life (days) 25 ˚C	Commerce Loam pH 7.4, 0.68% OC	19 (IORE)	Acc. 241547 MRID 00025619	Acceptable
	Barnes Loam, pH 7.1, 3.6% OC	36.7 (IORE)		
	Miami Silt Loam, pH 6.6, 1.12% OC	31.1 (IORE)		
	Catlin Silty Clay Loam, pH 6.1, 0.01% OC	33.4 (SFO)		
	Norfolk Loamy Sand, pH 6.6, 0.29% OC	156 (DFOP)		
	Stockton Clay pH 5.9, 1.01% OC	297 (IORE)		
	German Sandy Loam, pH 5.4, 1.01% OC	193 (IORE)		
	Sandy loam, pH 6.5, 0.8% OC	185 (DFOP)	MRID 42144911	Acceptable
Aerobic Aquatic Metabolism half-life (days) at 25 ˚C	Water, pH 8.1 Sediment, pH 7.7	30.4 (SFO)	MRID 44083401	Supplemental
Anaerobic Soil Metabolism half-life (days) 25 ˚C	Commerce, loam	78 (IORE)	MRID 00025619	Acceptable
	Stockton, clay	171 (SFO) Values represent only anaerobic phase		
Anaerobic Aquatic Metabolism half-life (days) 25 ˚C	Commerce pH 7.4	50.2 (IORE)	MRID 00025619	Supplemental
	Stockton pH 5.9	125 (SFO)		
Field Data				
Terrestrial Field Dissipation half-life (days)	Geneseo, Illinois Silt loam; pH 5.7, 3.1% OC	56	MRID 40395201	Supplemental
	Midland, Michigan Sandy clay loam; pH 7.7, 1.6% OC	33		
	Davis, California Loam; 0.91% OC pH 7.8	46		
Mobility Data				

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a] days	Study ID	Study Classification
Test System Name or Characteristics	**K_d**	**K_{oc}**	**Study ID**	**Study Classification**
Commerce loam	49.9	7300	Acc. 260794	Acceptable
Tracy sandy loam	95.6	5860		
Catlin silt loam	99.7	4960		

a. SFO = Single First Order; IORE = Indeterminate order rate equation; DFOP = Double first-order in parallel; The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the 2[nd] DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*, Health Canada, U.S. Environmental Protection Agency, December 21, 2012. The same model used to estimate the value used to derive a model input, is used to describe the DT_{50} and DT_{90} results.

An **acceptable** study is defined as a study that provides scientifically valid information that is fully documented, and which clearly addresses the study objectives as outlined in the guidelines.
A **supplemental** study provides scientifically valid information that address the study objectives as outlined in the guidelines but deviates from guideline recommendations and/or is missing certain critical data necessary for a complete evaluation-verification.
K_d = adsorption coefficient (mL/g)
Koc = organic carbon normalized adsorption coefficient (mL/g_{OC})

Table 8. Summary of Environmental Fate and Transport Characteristics of Chlorpyrifos-oxon

Parameter	Test System Name or Characteristics	NAFTA Representative Half-life Values (fitting model)[a]		Study ID	Study Classification
Laboratory Data					
Hydrolysis half-life (days)	pH 4, 20°C	38		MRID 48355201	Supplemental
	pH 7, 20°C	5			
	pH 9, 20°C	2			
Air photolysis half-life (hours)	Indirect	11		MRID 48789701	Acceptable
	direct	6			
Aerobic Soil Metabolism half-life (days) 25 ˚C	Missouri Silty clay loam soil (20°C, pH 5.9-6.2)	0.03 (IORE)		MRID 48931501	Supplemental
	Georgia Loamy sand soil (20°C, pH 5.3-5.6)	0.1 (IORE)			
	Texas Sandy clay loam soil (20°C, pH 7.6-7.9)	0.02 (SFO)			
	California Loam soil (20°C, pH 6.1-6.3)	0.06 (IORE)			
Test System Name or Characteristics	**K_f (regressed)**	**K_{foc} µg/g**	**1/n**	**Study ID**	**Study Status**
Tift Sand pH 4.8, 0.61% OC	1.3	270	0.85	MRID 48602601	Supplemental
Hagen Loamy sand pH 5.2, 1.1% OC	2.1	245	0.84		
Ebbinghof Loam pH 5.2, 1.5% OC	4.0	191	0.89		

Tehama Loam pH 5.7, 4.4% OC	4.2	301	0.89		
Chelmorton Silt loam pH 5.9, 2.9% OC	4.3	146	0.88		

a. SFO = Single First Order; IORE = Indeterminate order rate equation; DFOP = Double first-order in parallel; The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the 2nd DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*, Health Canada, U.S. Environmental Protection Agency, December 21, 2012. The same model used to estimate the value used to derive a model input, is used to describe the DT_{50} and DT_{90} results.

An **acceptable** study is defined as a study that provides scientifically valid information that is fully documented, and which clearly addresses the study objectives as outlined in the guidelines.

A **supplemental** study provides scientifically valid information that address the study objectives as outlined in the guidelines but deviates from guideline recommendations and/or is missing certain critical data necessary for a complete evaluation-verification.

%OC = percent organic carbon in the soil K_f = Freundlich adsorption coefficient (µg/g)/(µg/mL)$^{1/n}$
K_{Foc} = organic carbon normalized Freundlich adsorption coefficient (µg/g organic carbon)(µg/mL)$^{1/n}$
1/n = Freundlich exponent

4. Drinking Water Treatment Effects

Because drinking water for a large percentage of the population is derived from community water systems that treat raw water (USEPA, 1989) prior to consumption, the impact of water treatment on pesticide removal and transformation are considered, when possible, in estimating drinking water exposure (USEPA, 2000, 2001, 2011). Community water systems across the national use a wide range of water treatment processes including disinfection, coagulation/flocculation, sedimentation, and filtration (USEPA, 2006). The effect of various processes has been investigated for several pesticides (USEPA, 2011) including chlorpyrifos. These results are detailed in the 2016 DWA.

In summary, in the presence of free chlorine, the most common disinfection process utilized by community water systems, chlorpyrifos transforms to chlorpyrifos-oxon via rapid oxidation by the oxychlorine species. This transformation can yield almost 100% oxon. Reduction of chlorpyrifos in the presence of monochloramines, often used as an alternative to chlorine to avoid transformation biproducts, is low (<10%). Use of monochloramines is more common by community water systems serving larger (>100,001) populations. Once formed as a disinfection by-product, chlorpyrifos-oxon is expected to be relatively stable to drinking water distribution conditions and times (few hours to a few days) with a half-life of 12 days under typical water purification conditions (pH 8) due to stabilization .[9] Very limited data on physical removal processes such as coagulation/flocculation, sedimentation, and filtration are available for chlorpyrifos or chlorpyrifos-oxon. However, such processes, except for granular activated carbon,[10] have been shown to be ineffective for select organic pesticides (USEPA, 2001). Based on the physical-chemical properties of chlorpyrifos and chlorpyrifos-oxon, granular activated carbon likely reduces the amount of both chemicals to some extent. However, data are not available on the removal efficiency for either compound. Use of activated carbon is not a common treatment practice for treatment facilities.

Therefore, to address the multitude of water treatment possibilities, a bounding approach is used in this assessment. That is, to represent those facilities that use disinfectant processes other than free chlorine,

[9] pH 8 and residual chlorine concentration of 1 ppm.
[10] U.S. Environmental Protection Agency. 1998. Small System Compliance Technology List for the Non-Microbial Contaminants Regulated Before 1996. EPA 815-R-98-002.

100 percent of the chlorpyrifos entering the facility was assumed to be unchanged in the finished drinking water. Alternatively, to represent those facilities that employ chlorine as a disinfectant, 100 percent of the chlorpyrifos entering the facility was assumed to convert to chlorpyrifos-oxon.

Analysis

a. Approach

This document provides EDWCs by 2-digit HUC using a bounding approach to address the multitude of drinking water treatment possibilities across the country and potential exposures to chlorpyrifos and chlorpyrifos-oxon in drinking water. This assessment begins at Tier 3 and only considered those uses previously described as being a critical use (CU) or high benefit (HB) and are summarized by 2-digit HUC in **Table 9**. Empty cells indicate that the use is not assessed in the respective HUC. Alfalfa use in HUC-13, 14, 15, and 16 are not modeled in this update because prior estimated concentrations indicate that for usage rates provided by BEAD for this assessment, the estimated concentrations would be below the DWLOCs.

Table 9. Chlorpyrifos Use and 2-digit HUC Region Crosswalk

Name of 2-digit HUC Overlapping States	2-digit HUC	Alfalfa	Apple	Asparagus	Tart Cherry	Cotton	Citrus	Peach	Soybean	Sugar Beet	Wheat, Spring	Strawberry	Wheat, Winter
Mid-Atlantic VT, NY, PA, NJ, MD, DE, WV, DC, VA	02	-	HB	-	-	-	-	HB	-	-	-	-	-
South Atlantic-Gulf VA, NC, SC, GA, FL, TN, MS	03	-	-	-	-	CU	CU	HB	CU	-	-	-	-
Great Lakes WI, MN, MI, IL, IN, OH, PA, NY	04	CU	HB	HB	HB	-	-	HB	CU	CU	-	-	-
Ohio IL, IN, OH, PA, WV, VA, KY, TN	05	-	HB	-	-	-	-	-	CU	-	-	-	-
Tennessee VA, KY, TN, NC, GA, AL, MS	06	-	HB	-	-	-	-	-	-	-	-	-	-
Upper Mississippi MN, WI, SD, IA, IL, MO, IN	07	CU	-	-	-	-	-	-	CU	CU	-	-	-
Souris-Red-Rainy ND, MN, SD	09	CU	-	-	-	-	-	-	CU	CU	CU	-	CU
Missouri MT, ND, WY, SD, MN, NE, IA, CO, IA, KS, MO	10	CU	-	-	-	-	-	-	CU	-	CU	-	CU
Arkansas-White-Red	11	CU	-	-	-	-	-	-	CU	-	-	-	CU

Name of 2-digit HUC Overlapping States	2-digit HUC	Alfalfa	Apple	Asparagus	Tart Cherry	Cotton	Citrus	Peach	Soybean	Sugar Beet	Wheat, Spring	Strawberry	Wheat, Winter
CO, KS, MO, NM, TX, OK, AR, LA													
Texas-Gulf NM, TX, LA	12	-	-	-	-	-	CU	HB	-	-	-	-	CU
Rio Grande CO, NM, TX	13	<[a,b]	-	-	-	-	-	-	-	-	-	-	-
Upper Colorado WY, UT, CO, AZ, NM	14	<[a,c]	-	-	-	-	-	-	-	-	-	-	-
Lower Colorado NV, UT, AZ, NM, CA	15	<[a,d]	-	-	-	-	-	-	-	-	-	-	-
Great Basin CA, OR, ID, WY, NV, UT	16	<[a,e]	-	-	-	-	-	-	-	-	-	-	-
Pacific Northwest WA, ID, MT, OR, WY, UT, NV	17	CU	HB	-	-	-	-	-	-	HB	-	HB	-

a. 2016 drinking water assessment indicates EDWCs will be below the DWLOC.
b. HUC-13: 1.0 lb a.i./A (upper-bound); 2.3 µg/L (no PCA adjustment) chlorpyrifos concentration
c. HUC-14: 1.0 lb a.i./A (upper-bound); 1.6 µg/L (no PCA adjustment) chlorpyrifos concentration
d. HUC-15: 0.75 lb a.i./A (upper-bound) 2.5 µg/L (no PCA adjustment) chlorpyrifos concentration
e. HUC-16: 1.0 lb a.i./A (upper-bound) 1.8 µg/L (no PCA adjustment) chlorpyrifos concentration
\- Use not assessed

Critical use (CU)
High benefit (HB)
< Indicates where concentrations are expected to be below the 10xDWLOC
Empty cells with - indicate that the use is not assessed the respective HUC

The 2-digit HUCs considered in this assessment are shown in **Figure 4**. Regions considered in this assessment are shown in green shading while those not considered are shown in gray shading in **Figure 4**.

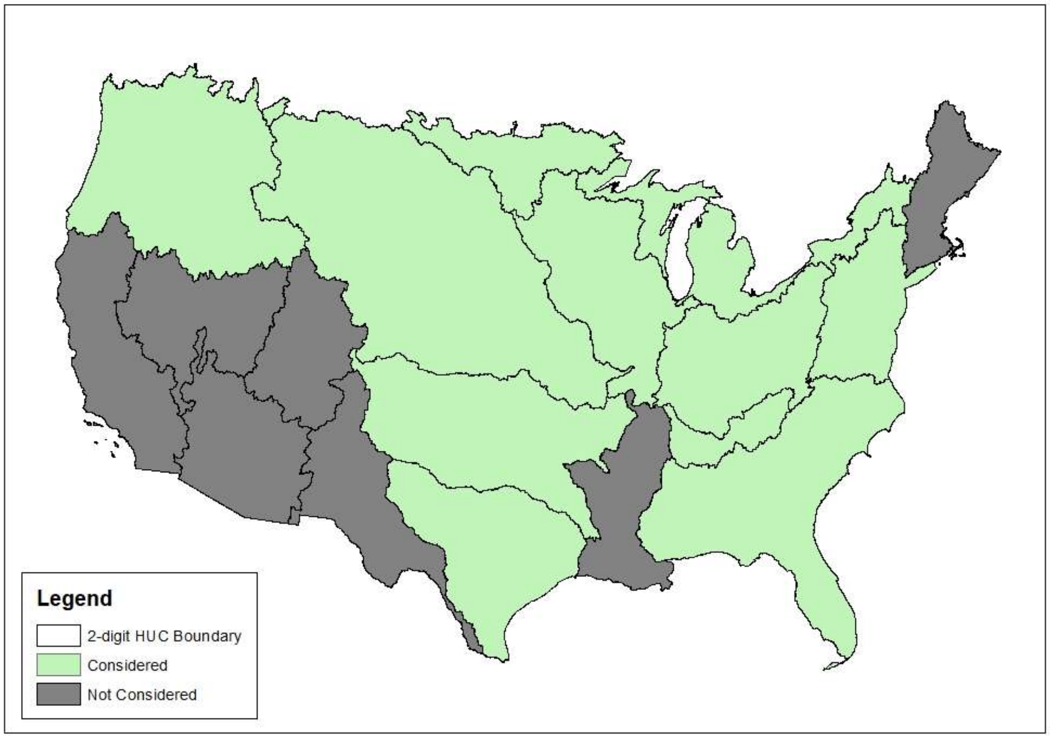


Figure 4. Summary of 2-Digit HUCs with Chlorpyrifos Uses Considered and Assessed in this Assessment

Consistent with the DWA Framework (USEPA, 2019), usage data, regional PCAs, and new methods for considering available surface water monitoring data are utilized. A detailed discussion of the methods and refinement strategies used in this assessment are described in the sections below. The general methods and refinements are well-established and have undergone FIFRA Scientific Advisory Panel (SAP) review or other external review process including formal public comment period and follow currently approved guidance.

b. Model Simulations

1. Pesticide in Water Calculator (PWC)

The Pesticide Root Zone Model (PRZM5) (Young and Fry, 2014) and the Variable Volume Water Model (VVWM) (Young, 2014) are used to estimate pesticide movement and transformation on an agricultural field and in the receiving surface water body (i.e., index reservoir), respectively. These models are linked with a user interface, the Pesticide in Water Calculator (PWC). The PRZM5 and VVWM documentation, installation files, and source code are available at the USEPA Water Models website.[11]

PRZM5 simulates pesticide sorption to soil, in-field decay, erosion, and runoff from an agricultural field or drainage area following pesticide application(s). The VVWM estimates water and sediment concentrations in an adjacent surface water body (i.e., index reservoir) receiving the pesticide loading by runoff, erosion, and spray drift from the field. The index reservoir has dimensions and characteristics

[11] Available: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

based on those of Shipman City Lake — a small, vulnerable midwestern reservoir located in an agricultural setting that was formerly used for source drinking water.[12]

All model simulations were run using the external batch function within the provisional version of PWC (v.1.89) for chlorpyrifos. This version of the model accommodates use of the new scenarios along with new weather files. A final updated version of PWC is scheduled for release in late 2020. Model outputs for chlorpyrifos were compared to the DWLOCs for chlorpyrifos. In addition, the model outputs for chlorpyrifos are converted to chlorpyrifos-oxon equivalents for comparison to the chlorpyrifos-oxon DWLOCs to complete the bounding approach.

2. Scenario Selection

PWC uses soil, hydrology, land cover/land use, weather, and waterbody properties to simulate environmental conditions. Prior to this assessment, a suite of PRZM5 scenarios were used to estimate pesticide concentrations. These scenarios were developed over time by different groups in EFED and for different purposes. As a result, the previous scenarios represented a range of conditions spanning a range of agricultural and non-agricultural pesticide use sites.; however, the percentile of vulnerability for these scenarios is unknown.

To develop scenarios consistently across the landscape, EFED developed a new method to generate PRZM5 scenarios. These scenarios include the use of more recent weather data (1961-2014) (Fry, et. al, 2016). In addition, a process was developed to compare and rank the millions of new scenarios (combinations of soil, land cover, and weather) in order to evaluate relative vulnerability.

New scenarios available at the time of this assessment include: cotton, hay (surrogate for alfalfa), evergreen orchards (for citrus), row and field crop (for sugar beet), soybean, fresh market (for strawberry), spring wheat, and winter wheat based on the regions where these crops are grown and uses considered in this assessment.

The existing scenario for asparagus was updated with new weather data. A new asparagus scenario is not planned as the existing asparagus scenario is suitable for modeling exposure to pesticides asparagus because asparagus largely occurs in a few isolated areas of the country. Furthermore, use of the fresh market scenario is not appropriate as the growth/management practices of asparagus is different from the other vegetables – harvest of the spears occurs before canopy growth starts; the fern canopy continues to grow until frost, when it is removed.

The existing scenarios for apple, cherry, and peach were updated with new weather data and used in this assessment to cover these respective crops, except for peach in HUC-12 (Texas-Gulf) where the evergreen orchard scenario was expected to be a better surrogate than use of the previous GA Peach scenario. a deciduous orchard scenario was not available at the time this assessment was completed.

The new scenarios were created to be the 90th percentile as ranked by the long-term average concentration in the receiving waterbody. Because rankings are sorption-dependent, scenarios were

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[12] See "Development and Use of the Index Reservoir in Drinking Water Exposure Assessments" at http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-and-use-index-reservoir-drinking-water

created for 3 bins of chemicals: those carried primarily by runoff, those carried primarily by erosion, and those carried by both mechanisms. For more information see USEPA (2020b*)

3. *Chemical Specific Input Parameters*

Although limited environmental fate data are available for chlorpyrifos-oxon, the data suggest that in the environment, there is little or no formation of chlorpyrifos-oxon by routes other than photolysis. Therefore, it is only necessary to conduct aquatic modeling for chlorpyrifos. To address the exposure to chlorpyrifos-oxon in drinking water as a result of formation during drinking water treatment with chlorine (described in the *Water Treatment Effects* section of this document) aquatic modeling results for chlorpyrifos can be used to estimate concentrations of chlorpyrifos-oxon (see **Drinking Water Treatment** on **page 35**).

Summaries of the environmental fate input parameters used in the PWC modeling of chlorpyrifos are presented in **Table 10**. These values are the same as those used in the 2016 DWA and more details on the rational for selection is provided in that assessment. Input parameters were selected in accordance with the following EPA guidance documents:

- Guidance for *Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1[13] (USEPA, 2009),
- *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*[14] (NAFTA, 2012; USEPA, 2012c), and
- *Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessmen*t[15] (USEPA, 2013)

[13] http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm (accessed April 11, 2014)
[14] http://www.epa.gov/oppfead1/international/naftatwg/guidance/degradation-kin.pdf (accessed April 11, 2014)
[15] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676 (accessed April 11, 2014)

Table 10. Input Values Used for Tier II Surface Water Modeling Using the PWC and PFAM

Parameter (units)	Value	Source	Comments
Organic-carbon Normalized Soil-water Partitioning Coefficient (K_{OC} (L/kg-$_{OC}$))	6040	Acc. # 260794	The mean K_{oc} value (K_{oc} values = 7300, 5860 and 4960 mL/g_{OC}) is used for modeling.
Water Column Metabolism Half-life or Aerobic Aquatic Metabolism Half-life (days) 25 ˚C	91.2	MRID 44083401	Only one half-life value is available, so this value (30.4 days) is multiplied by 3 to get 91.2 days. This half-life value was not corrected for hydrolysis. Recall the hydrolysis half-life of chlorpyrifos at pH 7 ranged from 72-81 days. Since hydrolysis is likely to be the driver for transformation of chlorpyrifos in aquatic systems, use of aerobic aquatic metabolism half-life of 91.2 days will not result in substantially different model-estimated concentration than if hydrolysis were assumed to be the sole contributor to transformation in aquatic systems.
Benthic Metabolism Half-life or Anaerobic Aquatic Metabolism Half-life (days), 25°C	203	MRID 00025619	The 90th percentile confidence bound on the mean chlorpyrifos half-life value determined following the NAFTA kinetics guidance is 87.6 + [(3.078 x 52.9)/√2)] = 202.7 days.
Aqueous Photolysis Half-life at pH 7 (days) and 40° Latitude, 25 °C	29.6	MRID 41747206	
Hydrolysis Half-life (days)	0	MRIDs 00155577 (Acc. # 260794) and 40840901	Since the aerobic aquatic metabolism half-life value was not corrected for hydrolysis, it is possible that hydrolysis would be double counted in the model simulation. Therefore, hydrolysis is set to 0 (stable) here as it is already accounted for in the aerobic aquatic metabolism study and input parameter.
Soil Half-life or Aerobic Soil Metabolism Half-life (days), 25 °C	170.6	Acc. # 241547 and MRID 42144911	Half-life values of 19, 36.7, 31.1, 33.4, 156, 297, 193, and 185 days are obtained from empirical data following the NAFTA kinetics guidance. The 90th percentile confidence bound on the mean chlorpyrifos half-life value is 118.9 + [(1.415 x 103.3)/√8)] = 170.6 days.
Molecular Weight (g/mol)	350.57	product chemistry	
Vapor Pressure (Torr) at 25 °C	1.87×10^{-5}	product chemistry BC 2062713	
Solubility in Water at 25 °C (mg/L)	1.4	MRID 41829006	The water solubility of chlorpyrifos is reported to be between 0.5-2.0 mg/L for temperatures between 20 – 25 °C. Based on data submitted to EPA, 1.4 mg/L was used in modeling.
Foliar Half-life (days)	0	Default value	
Application Efficiency	0.99 (ground; air-blast) 0.95 (aerial)	Default Values	
Application Drift	See **Table 12**	AgDRIFT modeling based on label restrictions	Labels contain aquatic buffer distances of 25, 50 and 150 ft for ground, airblast and aerial applications.

All PWC model input files, and output files are provided in **ATTACHMENT 3**.

Use Scenarios

Chlorpyrifos-specific modeling scenarios used in this assessment reflect usage data for chlorpyrifos for the critical and high benefit uses based on information provided by BEAD. This includes application rate, method, and timing. **ATTACHMENT 2** includes all the information provided by BEAD for this assessment while **Table 11** provides the application rates modeled by crop at the 2-digit HUC level. Formulation and application methods are considered in the context of the reported usage data when developing use scenarios and multiple scenarios may be modeled. For example, most applications for sugar beet occur by ground with 20% being the highest percentage of survey applications made by air. Furthermore, the maximum average application rate of 1.2 lb a.i./A and the upper bound rate of 1.5 lb a.i./A exceed the maximum permitted application (1 lb a.i./A) for aerial applications and only granular applications are permitted above 1 lb a.i./A. This is due to how usage rates are estimated. For example, usage rates are estimated across all application methods and formulations. In addition, usage rates are not calculated specifically for the critical or high benefit target pest but for all use on the specified critical or high benefit crop. Generally, the usage data would not be robust enough to estimate usage rates for specific target pests.

Table 11. Chlorpyrifos Use Rates Modeled

Use	2-digit HUC	Average Single Application Rate (lb a.i./ acre)	Upper-bound Single Application Rate (lb a.i./ acre)
Critical Uses			
Alfalfa	04	0.25	1.25
	07	0.53	1.00
	09	0.56	1.00
	10	0.50	1.00
	11	0.58	1.00
	13	0.50	1.00
	14	0.6	1.00
	17	0.52	1.00
Citrus	03	1.88	3.0
	12	2.7	3.5
Cotton	03	0.21	0.5
Soybean	03	0.53	1.00
	04	0.41	0.75
	05	0.33	0.75
	07	0.40	1.0
	09	0.33	0.75
	10	0.35	0.75
	11	0.37	0.75
Sugar beet	04	0.50	1.25
	07	1.16	1.50
	09	0.69	1.25
	17	0.66	1.25
Wheat, spring	09	0.36	0.75
	10	0.27	0.75
Wheat, winter	09	0.44	0.75
	10	0.32	0.50
	11	0.39	0.75
	12	0.21	0.75

High Benefit Uses			
Apple	02	1.5	2.0[1]
	04	1.5	2.0[1]
	05	1.5	2.0[1]
	06	1.5	2.0[1]
	17	1.5	2.0[1]
Asparagus	04	0.964	1.0
Tart Cherry	04	1.5	2.0[1]
Strawberry	17	1.24	2.0
Peach	03	1.3	3.0[1]
[1]The BEAD documents (**ATTACHMENT 3**) reported maximum rates; however, when the 90th percentile is lower it was reported. The 90th percentile use rates were used for modeling in this assessment. For peach, the maximum and the 90th percentile were reported to be the same.			

Spray Drift Exposure

Drift fractions used in this assessment for liquid formulation are consistent with those used in the 2016 DWA (USEPA, 2016) and are presented in **Table 12**. Spray drift estimates reflect the most recent offsite deposition guidance (USEPA, 2013a, 2013b) and consider the currently labeled buffer restrictions [25 ft. (ground), 50 ft. (air-blast), and 150 ft. (aerial)] for aquatic water bodies included on all agricultural chlorpyrifos labels. No spray drift is assumed for granular applications.

Table 12. Chlorpyrifos Spray Drift Estimates for Liquid Formulations for Use in PRZM5/VVWM (PWC) Model Simulations

Method	Buffer	Spray Drift Fraction (unitless) Application Method and Buffer	Calculation[1]
Ground	**25 ft**	0.008	Ground: 25 ft. distance to water body from edge of field based on labeled buffer; ASAE Fine to medium/course [$dv_{0.5}$ = 341 µm; labels specify 255-340 µm which is larger than ASAE very fine to fine ($dv_{0.5}$ = 175 µm); high boom; 90th percentile; Index Reservoir - downwind water body width 82 m (fraction applied 0.0061); Streams – 4 m (fraction applied 0.0164); Adjusted Spray drift fraction 0.0061 (spray drift fraction for the Index Reservoir) + [0.0164 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.0079
Air-blast	**50 ft**	0.009	Air-blast: 50 ft. distance to water body from edge of field based on labeled buffer; droplet size not specified; sparse (young, dormant); Index Reservoir - downwind water body width 82 m (fraction applied 0.0056); Streams – 4 m (fraction applied 0.0265); Adjusted Spray drift fraction 0.0056 (spray drift fraction for the Index Reservoir) + [0.0265 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.0086
Aerial	**150 ft**	0.039	Aerial: 150 ft. distance to water body from edge of field based on labeled buffer; ASAE fine to medium ($dv_{0.5}$ = 255 µm; labels specify 255-340 µm); Index Reservoir - downwind water body width 82 m (fraction applied 0.0331); Streams – 4 m (fraction applied 0.0552); Adjusted Spray drift fraction 0.0331 (spray drift fraction for the Index Reservoir) + [0.0552 (spray drift fraction for all Stream) x 0.114 (Surface areas of all streams/surface area of reservoir)] = 0.039
[1] calculation taken from 2014 DWA.			

4. Post-processing or Output Adjustments

Drinking Water Treatment Adjustment Factor

EDWCs for chlorpyrifos-oxon were derived by multiplying the EDWCs for chlorpyrifos by 0.9541 (molecular weight adjustment factor) and 100% to account for the quantitative conversion of chlorpyrifos to chlorpyrifos-oxon during water treatment as well as the stability of oxon in the persistence in residual chlorine.

Percent Cropped Area Adjustment Factors

Community water system (CWS) watersheds large enough to support a drinking water facility rarely consist of a single crop (e.g., apples) or land cover type (e.g., orchards). To account for the variability in use patterns, PCA adjustment factors are used to reflect the percentage of a watershed that is covered by a particular use or land cover type. The application of PCAs has been extensively documented, reviewed, and utilized in drinking water assessments (USEPA, 2014). Prior to 2020, PCA values were only available for seven crops (e.g., soybean) or crop groups (e.g., vegetables) along with all-agricultural and turf, and combinations thereof. For additional information on the development of the CWS PCA values and use as a refinement in DWAs, see *Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update* (USEPA, 2014). PCAs are applied by multiplying the modeled estimated concentration by the PCA fraction that captures all the use sites for the pesticide under evaluation.

In this assessment, the PCAs used do not reflect all currently registered chlorpyrifos uses or those uses provided on the Master Use Summary document. Instead, the PCAs used only reflect the subset of critical or high benefit uses described in the Usage Data Section of this assessment by respective 2-digit HUC. In addition to the previously available PCAs, this assessment also uses the recently developed miscellaneous agricultural (misc-ag) PCA. The misc-ag PCA was developed as an alternative to using the all-ag PCAs when a use site does not fall within the existing crop, crop group, or combination of agricultural PCAs. For more information on the development of the misc-ag PCA see*: Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)*. If more use sites are added (i.e., beyond those considered in this assessment), the PCA used to calculate EDWCs may need to be increased to capture the larger use pattern specific footprint. For example, if non-agricultural uses need to be considered it would be necessary to use a PCA of 1 or add in the non-agricultural PCA depending on the region where the non-agricultural uses need to be considered.

This assessment begins by calculating the maximum use patten specific 2-digit HUC PCAs for each of the respective regions under consideration. Then, if the estimated concentration using the maximum use pattern specific PCA is above the 10x DWLOC, the full distribution of PCAs for the respective region is described. These two steps are described in more detail in the subsections below.

Modeling Refinement 1: Application of Use Pattern Specific PCA

The first refinement of the new drinking water improvement methods includes the use of a use pattern PCA (USEPA, 2020). The use pattern specific PCA is the PCA value for the combination of crops or crop groups specific to the registered uses of the individual pesticide under evaluation. A use pattern specific PCA can be calculated at the national or regional level. For example, in this assessment for HUC-03 where chlorpyrifos use on cotton, citrus, peach and soybean are being considered, the PCA used is the summation of the individual PCAs for cotton, orchards (to cover citrus and peach) and soybean within each individual watershed. While in HUC-04 where chlorpyrifos use on alfalfa, apple, asparagus, cherry, peach, soybean, and sugar beet is under consideration, the PCA used is the summation of misc-ag (to cover alfalfa and sugar beet), orchard (to cover apple, cherry and peach), soybean, and vegetable (to cover asparagus) within each individual watershed. This approach allows for the more accurate EDWC that captures the area of the watershed allocated to the uses under consideration, rather than using the default all-agricultural land PCA, which could encompass more area within the watershed.

For those 2-digit HUCs with concentrations above the 10x DWLOC after consideration of the maximum use pattern, the full distribution of PCA values are then characterized (see following section).

Modeling Refinement 2: Use of the Full Distribution of Watershed PCA Values

The second refinement of the new drinking water improvement methods includes assessing the full distribution of available PCA instead of only using the maximum regional PCA value (USEPA, 2020). EDWCs are calculated for each community water system. The full distribution of PCAs used in this assessment include the majority of the 6,550 CWS drinking water intake (DWI) locations from EPA's Safe Drinking Water Information System (SDWIS) database between the years 1997 and 2004. Of the 6,550 locations, 74% (4,840) had unique, delineated watersheds where PCAs have been calculated. Two of these intakes had watersheds that extend into Canada and, therefore, are not considered in the development of PCAs. In addition to the 4,840, the distribution includes surrogate PCAs (i.e., 12 digit HUC) for a set of community water system drinking water intakes locations that watershed delineation was determined appropriate but had not been validated at the time of the 2014 publication of the percent cropped area adjustment factors for community water systems.

The critical PCA, the ratio between the unrefined EDWC and the DWLOC, is the PCA value that would generate a refined estimated drinking water concentration equal to the DWLOC, was calculated. The critical PCA permits the quick identification of the number (or percentage) of watersheds with PCAs that would results in concentrations above the DWLOC. The critical PCA is used as a benchmark to determine the need to continue to consider additional refinements.

For watersheds with a PCA higher than the critical PCA, the crop-specific footprint (county level acres harvested) overlap is assessed for crops (e.g., cherries or apples) where a crop group (e.g., orchard) PCA is used since a crop-specific PCA is not available for individual crops like cherries and apples available. For more information on the overlap analysis, see the following section. For HUCs where the use-site specific PCA is less than the critical PCA, no further refinement is necessary as the concentrations would be below the DWLOC.

Use Site Overlap Analysis of Watersheds with PCAs Larger than the Critical PCA

Also included in the new drinking water improvement methods is the overlap analysis (USEPA, 2020). PCA values for groups of crops (i.e., orchards, vegetables) are derived from generalized crop data layers based on the National Land Cover Database (NLCD) and Census of Agriculture (Ag Census). Specifically, the calculated PCA is based on the reported acreage of crops/crop groups in a county, as reported in the Ag Census, proportioned to the footprint of agricultural land covers from the NLCD. This approach has the potential to overestimate the percent of a given watershed with the noted use site (e.g., planted with a single crop). For instance, an individual CWS watershed with an orchard PCA of 20% may very well have little or no cherries or apples grown within the watershed. Spatial overlap helps further identify CWS watersheds with potential exposure concerns.

For these analyses, a visual inspection for overlap follows a spatial overlay of the 2007 USDA Census of Agriculture county-level acres harvest data with the watershed or surrogate watershed boundary for community water systems with PCAs above the critical PCA was completed using ArcMap (version 10.5). While there are more recent Census of Agriculture data (i.e., 2012 and 2017) the community water systems PCAs were developed using the 2007 census data. Therefore, for consistency in data sources the 2007 census data were used for the overlap analysis. If any part of the county with reported acres of crop under evaluation overlaps with the community water system under investigation it is considered an overlap for the purposes of this assessment.

For those watersheds with PCA higher than the critical PCA and county overlap, aggregated EDWCs are developed (see following section). Watersheds with no overlap are no longer considered for further refinement.

Development of Aggregated Estimated Drinking Water Concentrations

Another refinement included as part of the new drinking water improvement methods includes calculating EDWCs are based individual use site residue contribution. Prior to this step, EDWCs are based on the highest concentration of all uses modeled within the respective 2-digit HUCs, however, the relative contributions of each modeled use site can be determined by adding the contributing concentrations within each CWS watershed. This is the summation of the crop-specific PCA multiplied by the crop-specific model estimated concentration values for each registered crop or crop group within each watershed.

Aggregated EDWC =
(use pattern 1 individual EDWCs x crop specific PCA) + …
+ (use pattern (1+n) individual EDWCs x crop specific PCA)

Equation 1. Aggregation of Estimating Drinking Water Concentrations

There are two options for doing this aggregation (see the *Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)* for more details. The option used in this assessment, is to aggregate individual PCA adjusted 1-in-10 year estimated concentrations for each use site in a region without regard to timing (e.g., 1-in-10 year EDWCs may come from different calendar days).

Percent Crop Treated Adjustment Factors

In this case, one of new drinking water improvement methods includes the integrating percent cropped treated (PCT) data to adjust estimated concentrations to reflect only those sites which are treated based on available survey data (USEPA, 2020). Use of a PCT further refines the fraction of the area of the respective planted crop area treated with pesticide in a watershed. PCT values are typically aggregated at the state level Chlorpyrifos usage data are summarized in the Science Information and Analysis Branch (SIAB) Use and Usage Matrix (SUUM) which is provided by BEAD. The SUUM reports PCT data based on usage that occurred for a given 5-year range (depending on the crop this spans 2012-2017 or 2014-2018) for chlorpyrifos (Paisley-Jones, 2020). Three statistics for PCT are available for each state and crop combination (where states and crops are surveyed): 5-year average, 5-year minimum and 5-

year maximum annual value. This information is provided in **ATTACHMENT 3**. For chlorpyrifos, only the 5-year maximum annual PCT are considered in this assessment.

The PCT statistics are used to calculate the number of acres treated in each state (referred to as base acres treated). Then the acres treated need to be allocated within each individual community water system watershed. In this assessment, this is done using an upper distribution approach for allocating treated acres within each watershed, described below. A post-processing tool was used to estimate the maximum PCT/upper distribution. For more information on these approaches see: *Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment (USEPA, 2020)*. The files to support this work are provided in **ATTACHMENT 3**.

Upper Distribution: This approach assumes that all the treated acres for a given land cover class in a state can occur within a drinking water watershed boundary, up to the PCA adjusted acreage of the watershed including non-agricultural uses. A graphical depiction is provided in **Figure 5**. In this example, 400 acres (40 green squares) are assumed to be the potential use sites across Colorado. The PCT for Colorado is 10%. Therefore, 40 acres (4 filled green boxes) are treated within Colorado. If these acres are all placed within an individual community water system watershed 4 of the 7 green boxes (potential use sites) within the watershed (orange shape) become filled (as shown in the figure). The 4 green boxes or 40 acres are then divided by the total areas of the community water system watershed (orange shape) to generate the PCA-PCT value for the maximum PCT upper distribution.

Figure 5. Conceptual Illustration of the "Upper" Distribution Method

PCT adjustments can be used to better understand exposure based on historical use, as well as provide a tool to facilitate the interpretation of model estimated exposure results compared to measured exposure concentrations. It should be noted that often watersheds are much smaller than a state. Use of the upper distribution is a conservative approach for allocating acres within a watershed providing an upper bound EDWC.

c. Monitoring Data

There are several challenges with interpreting available surface water monitoring data that may result in underestimating actual concentrations that people may be exposure as a result of consuming surface sourced drinking water. However, tools are available to help account for and describe the uncertainty in the data.

A Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) meeting was held in November of 2019 on Approaches for the Quantitative use of Surface Water Monitoring Data in Drinking Water Assessments. EPA presented the use of the USGS model, the Seasonal Wave with Streamflow Adjustment with Extended Capability (SEAWAVE-QEX), and developed sampling bias factors. Both approaches allow assessors to quantify the uncertainty in available use surface water monitoring data such that the results can be used with reasonable confidence in pesticide drinking water assessments. Additionally, EPA explored presented methods to evaluate the spatial relevancy of monitoring sites and sampling bias factors with respect to vulnerable drinking water locations using quantitative methods such as regression equations, and qualitative methods such as a weight-of-evidence approach. These approaches are detailed in a White Paper. Supporting documents included a Standard Operating Procedure for using SEAWAVE-QEX, a drinking water assessment framework document, and two drinking water assessment case studies. All of these documents, including EPA's response to the SAP comments can be accessed on the docket at EPA-HQ-OPP-2019-0417.

A thorough analysis of available monitoring data for chlorpyrifos and chlorpyrifos-oxon was completed in the 2016 DWA. Based this prior work and preliminary analyses completed as part of this assessment, it was decided that a Tier 4 monitoring data analysis would be beneficial to the assessment and could be informative if additional crops were evaluated. The current assessment focuses on updating the monitoring data analysis based on feedback from the 2019 FIFRA SAP and therefore focuses on monitoring data for chlorpyrifos only, as use of SEAWAVE-QEX on a transformation product was not recommended without further investigation.

The monitoring data considered in this update were primarily data exported from the Water Quality Portal (WQP) downloaded on January 6, 2020, which includes data from NWIS and STORET. Data from Dow Agrosciences (now Corteva Agriscience) California Monitoring Program (DACMP), Washington State Department of Agriculture (WSDA), and the National Center for Water Quality Research (NCWQR) are also considered, as well as the modified chlorpyrifos data sets from the data release files supporting SEAWAVE-QEX (Vecchia and Williams-Sether, 2018). Data from WSDA and NCWQR were obtained recently as part of the preparation for the 2019 SAP and were subject to Quality Assurance/Quality Control (QA/QC) protocols by the organizations that collected the data; these have been provided to EPA and the data are considered reliable.

All monitoring data were analyzed by program and by site-year. To be considered a site-year, there only needs to be one sample taken per year at a given site. A site-year analysis approach was employed because pesticide occurrence depends on spatially specific site conditions including pesticide usage, agronomic practices, soil properties, meteorology, as well as temporally dependent conditions, including pesticide application timing and rainfall occurrence.

These data sources are briefly summarized below with more details provided in the 2016 DWA.

1. Monitoring Program Summary

The *NAWQA* program samples for many pesticides and pesticide transformation products and is larger than any other monitoring program in terms of scope and duration. Sampling sites are distributed across the United States and include a range of site vulnerabilities and waterbody types.

NAWQA is not designed to target a specific pesticide use (i.e., sample timing, frequency, site); however, many sampling sites are in pesticide use areas including agricultural and non-agricultural sites. In general, sample frequencies are sporadic and range from once per year to a couple times per month depending on the site and year.

The *DACMP* included sampling at three locations on the lower reach of Orestimba Creek (California) for one year (May 1, 1996 to April 30, 1997). Daily time-proportional composite samples were collected, along with weekly grab samples. The report included chlorpyrifos use information for fields that drained into the creek or had the potential to contribute spray drift (fields within 305 m buffer on either side of the mid-streamline).

The *WSDA* monitoring programs began sampling salmon-bearing streams in two different Washington State sub-basins in 2003. The program has gradually increased monitoring to 10 different sub-basins throughout the state. Sampling sites are monitored weekly for pesticides during the pesticide use season. While the study does not specifically target pesticide applications, the sampling sites are in agricultural areas with known pesticide use.

The *NCWQR* monitoring program is historically one of the most intensive pesticide sampling programs in the country with sample frequencies ranging from daily to monthly. The most frequent sampling occurs during the spring and summer months. Monitoring sites are in agricultural areas (i.e., corn production) and were established as part of a nutrient and sediment loading monitoring program well before pesticide monitoring began.

2. *Evaluation*

Monitoring data evaluation included in this update builds upon past work including the monitoring data analyses completed to support the 2016 drinking water assessment (USEPA, 2016), as well as work done as part of the 2019 SAP on the quantitative use of surface water monitoring data in drinking water assessments (USEPA, 2019). Prior work indicated that when the uncertainty in having non-daily sampling data for chlorpyrifos is quantified, it is possible concentrations in surface water may occur above the drinking water level of comparisons described in this document. Therefore, consistent with the drinking water assessment framework, Tier 4 tools (SEAWAVE-QEX and pesticide-specific SBFs) are utilized in this assessment.

Several sites from these combined data sources met the criteria for evaluating chlorpyrifos concentrations quantitatively in surface water using SEAWAVE-QEX and SBFs. Both methods were presented as part of the FIRFA SAP on the quantitative use of surface water monitoring data in drinking water assessments (USEPA, 2019). Analyses reported here consider comments received from the Panel. Specifically, this work focuses on addressing the uncertainty in available monitoring data due to non-daily sampling and limited spatial coverage across the landscape by:

1. using SEAWAVE-QEX to estimate chlorpyrifos concentrations between sampling events,
2. deriving and applying SBFs to measured chlorpyrifos concentrations, and
3. employing a weight-of-evidence approach to understand the relevance of sampling sites with respect to potential chlorpyrifos use sites within the watershed.

3. *Interpretation and Extrapolation*

SEAWAVE-QEX

Background

The U.S. Geological Survey SEAWAVE-QEX (Vecchia, 2018) model, a time series regression model run in R statistical computing software (R Core Team, 2017) that interpolates sparse pesticide monitoring data using a daily covariate (e.g., streamflow) to develop daily pesticide chemographs from non-daily sampling data at a specific site, is a tool that can be used to fill in concentration data between sampling events. The model creates multiple, equally probable estimates of daily concentrations (i.e., conditional simulations or chemographs), with each chemograph constrained by the measured input data. Since SEAWAVE-QEX pairs measured concentrations with daily streamflow measurements, the model is able to estimate concentrations that are larger than the measured concentrations, addressing a concern expressed by previous SAPs regarding the consistent underestimation of pesticide concentrations occurring between sampling events (i.e., missing the peak) from other infilling methods.

In addition to multiple estimated chemographs, the model produces a file of diagnostic plots that can be used to determine if the model assumptions were verified (e.g., if the model fit the data appropriately). Refer to the White Paper and the SEAWAVE-QEX SOP for more information on diagnostic plots (USEPA, 2019).

More information on SEAWAVE-QEX and its use in drinking water exposure assessment can be found in the supporting documents for the 2019 FIFRA SAP (USEPA, 2019).

Method

Chlorpyrifos surface water monitoring data for sites in the conterminous United States from the WQP and NCWQR were screened to determine which sites had adequate samples for SEAWAVE-QEX to be used to estimate concentrations between sampling events. This was done by screening available monitoring data to identify sites that met the following criteria:

1. 12 samples per year,
2. detection frequency greater than 25%,
3. minimum of 3 years of data meeting criteria 1 and 2, and
4. daily flow or stage data for the period meeting criteria 1, 2, and 3.

Sites were considered in all 2-digit HUCs for this assessment. While use of these data likely capture labeled and possible cancelled chlorpyrifos uses, all available data were included to capture the range of possible environmental and use conditions that are possible for the uses considered in this assessment. For example, while pecans are not considered in this assessment, chlorpyrifos application to pecans and subsequent occurrence concentrations could be a reasonable surrogate for peaches or other crops grown in the same areas with similar use rates. For this analysis, it is important to have a robust number of site-years to capture the variability in weather and use across years, thus, eliminating sites based on geographical location reduced the confidence in the ability to capture the true range of potential concentrations of chlorpyrifos in source drinking water. Furthermore, environmental variabilities can vary as much within a region as it does across the country.

SEAWAVE-QEX input and output files are provided in **ATTACHMENT 4**. All SEAWAVE-QEX diagnostic plots were evaluated according to the SEAWAVE-QEX Standard Operating Procedure (SOP) and in consultation with the 2019 SAP team. If the model assumptions are not verified by the diagnostic plots, then the data are not used quantitatively. Improvements to the model fits were attempted using options within the SEAWAVE-QEX model, as needed, and may have included: using a different subset of years of data or adding a small constant (e.g., fraction of the LOD) to concentration data for the purposes of model fitting (subsequently removed). This process is detailed further in the SEAWAVE-QEX SOP. When data were available a sensitivity analysis (i.e., using more data than the minimum requirements) was completed.

Confidence in the SEAWAVE-QEX results are noted as high, medium, or low based on evaluation of the diagnostic plots. **SEAWAVE-QEX Results** section summarizes the SEAWAVE-QEX analysis results, while a detailed narrative of each SEAWAVE-QEX analysis by site is provided in **Appendix B.** The narrative includes a discussion of the evaluation of the diagnostic plots including the waveform, sample collection timing, usage data as available, and a description of the watershed and waterbody characteristics. This information is also integrated into the **Spatial** Variability and Relevance Weight-of-evidence analysis.

To use the SEAWAVE-QEX data quantitatively from accepted sites, the maximum of the 99th percentile 1- and 21-day concentrations for each site are compared to the DWLOCs. These summary statistics were derived from calculating 99th percentile 1- or 21-day concentrations of the 100 SEAWAVE-QEX chemographs for each year, then taking the maximum of those 100, 99th percentile concentrations. The maximum of the 99th percentile 1- and 21-day concentrations are chosen to represent the maximum concentration occurring in the waterbody between measurements.

Sampling Bias Factor

Background

While SEAWAVE-QEX provides a way to estimate daily pesticide concentrations from non-daily surface water monitoring data, for many sites, there are not enough monitoring data to use SEAWAVE-QEX. This is because the data are too highly censored (i.e., values below the reporting limit) or there are not enough samples per year or across years. SBFs offer an alternative approach to overcome uncertainty around chlorpyrifos concentrations in source water from non-daily pesticide surface water monitoring data that do not meet the minimum requirements of SEAWAVE-QEX or the SEAWAVE-QEX model fits are not good enough to better understand the potential range of chlorpyrifos concentrations in surface water at that site.

In simple terms, SBFs are multiplicative factors used to calculate an upper level prediction interval (e.g., 95th percentile) on the measured concentration value. By multiplying the SBF and the maximum measured value from the available monitoring data, EPA can derive an upper-bound concentration to address the uncertainty in the measured pesticide concentrations due to infrequent sampling. The development of SBFs is a multi-step process requiring a daily concentration chemograph (i.e., 365 days) and is described in the *Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments* (USEPA, 2019).

Use of SEAWAVE-QEX chemographs to develop SBFs for those sites that meet the criteria (minimum data quantity criteria or flow data) resulting in reasonable model fits expands the ability to develop SBFs for most pesticides, including chlorpyrifos, as daily data often does not exist or is limited.

Method

SEAWAVE-QEX results from sites accepted for quantitative use (i.e., verifying the model assumptions) as described in the **SEAWAVE-QEX Analysis** Section were used to calculate pesticide-SBFs to be applied to other monitoring sites with insufficient data to run in SEAWAVE-QEX. SBFs were developed using a python code named "short term SBF calculator updated July 2020" (included in **ATTACHMENT 4**) and summarized on a site-year basis prior to application. The subsections below describe how SBFs are developed (Process Description) and subsequently applied (Application).

Process Description

The multi-step process for developing short-term SBFs, previously presented to the SAP, which uses a daily concentration chemograph, is detailed in the SAP White Paper (USEPA, 2020) and follows these general steps:

1. The maximum average 1- and 21-day concentration is calculated from the daily pesticide concentration chemograph for each year of available data.
2. Bootstrapped samples are drawn from the daily pesticide concentration data for each year of available data from Step 1. These bootstrapped samples are generated using several sampling frequencies (13, 17, 26, and 52 samples per year using a random sampling strategy.
3. The bootstrapped[16] samples are log-linearly interpolated to generate daily pesticide concentration chemographs.
4. The maximum 1- and 21-day average concentration from the interpolated daily pesticide concentration chemograph for each year of available data is calculated. Residuals of interpolated chemographs are calculated along with root mean square error (RMSE).
5. Steps 2 through 4 are repeated 10,000 times.
6. The 10,000 maximum average concentrations and RMSE for each year are ranked.
7. The ratio of the 5th percentile concentration from the 10,000 bootstrapped samples for each year is compared to the maximum concentration for each year from the input chemograph calculated in Step 1.

When SBFs are developed from daily measured concentration data, there is only one set of SBFs developed – one for each sampling interval and duration of exposure concern. The SBF program provides an output file that contains results for each SEAWAVE-QEX realization across all years of the simulation for each sampling interval and duration of exposure concern. To obtain a single SBF for a site-year, the data must be condensed across SEAWAVE-QEX realizations. For this assessment, the median across years is calculated.

[16] Bootstrapping is any test or metric that uses random sampling with replacement and falls under the broader class of resampling methods.

Application

Sampling Sites with Greater Than or Equal to 13 Samples per Year

The range of SBFs for all sites across the conterminous United States are applied to the available surface water monitoring sites and summarized on a 2-digit HUC basis based on respective sampling number per year (n=13-16, 17-25, 26-52, 52+ samples collected per year) to generate the upper confidence bound on measured concentration. All SBFs generated across the conterminous United States are considered to increase the robustness of the analysis. Having more sites and site years increases the number of SBFs increasing the likelihood of capturing the true range of watersheds and waterbody attributes that exist across the landscape and are represented by community water system watersheds. Even though sites where SBFs were developed fall outside the regions considered in this assessment does not mean that site does not represent areas that fall within the regions (and community water system watersheds) under evaluation. This is particularly important when few acceptable sites are available for SEAWAVE-QEX analysis.

The general equation used to apply sampling bias factor is as follows:

$\hat{Y}$=X*Bias Factor
Where:

$\hat{Y}$ = Estimated chlorpyrifos concentration
X = Chlorpyrifos concentration obtained from monitoring data
Bias Factor = Measured chlorpyrifos concentration / Estimated 5th percentile pesticide concentration estimated from 10,000 simulated chemographs

The 1-day and 21-day sampling bias factor is multiplied by the maximum measured concentration based on the number of samples collected per year to provide the upper confidence bound on the measured value. The statistical implication of the bias factor is that 95% of the time, the bias factor adjusted chlorpyrifos concentrations from monitoring data will be equal to or greater than the true value in the monitoring data. The SBF-adjusted 1- and 21-day upper confidence bound on the measured concentration are compared to the DWLOCs. For site-years where the upper confidence bound for the 21-day average concentration using the maximum single day measured value in the calculation is above the DWLOC, the maximum 21-day average concentration was estimated from the available monitoring data using log-linear interpolation. In the analysis for 21-day average concentrations, the data were analyzed assuming non-detections were equal to ½ limit of quantification (or minimum reporting limit) or the limit of quantification in the log-linear interpolation when less-than values are reported for a sample. This was done as a sensitivity analysis to assess the impact of using different assumptions for the limit of quantification on the calculation of the 21-day average concentration. The 21-day sampling bias factor is then applied to the maximum 21-day average concentration for each site-year.

For any site-year with an SBF-adjusted concentration above the respective DWLOCs, additional analyses are conducted to confirm the appropriateness of the application of the SBFs. These include evaluating sample collection timing and frequency, usage data when available, and a description of the watershed and waterbody characteristics. This information is integrated into a weight-of-evidence analysis (see **Spatial Variability and Relevance Weight-of-evidence**).

Sampling Sites with Less Than 13 Samples Collected per Year

There is a lot of uncertainty in the ability to estimate pesticide concentrations at sites where there are less than 13 samples collected per year. For further characterization, maximum concentrations on a site-year basis are multiplied by the sampling bias factor for sample number 13-16. A count of the number of site-years where SBF-adjusted concentrations are above the DWLOC is reported on a HUC basis. No additional analysis of these sites is provided.

Spatial Variability and Relevance Weight-of-evidence

Background

Monitoring data used in a drinking water assessment should be relevant (i.e., hydrologically connected) to the drinking water intake in pesticide use areas. Evaluating an overlay of the monitoring sites using Geographic Information Systems (GIS) with potential use sites (e.g., cropland data) can provide confidence that the sites are relevant to pesticide use.

Conversely, monitoring sites that are located outside of potential use areas and are not hydrologically connected to these use sites probably will not provide useful information on pesticide concentrations, unless an alternative transport mechanism (i.e., spray drift) can be ascertained. If pesticide usage data are available indicating that the pesticide was applied when monitoring occurred, this adds confidence to the site's spatial relevance.

A lack of monitoring data in a CWS watershed, or the presence of monitoring data in a CWS watershed that is not co-located with potential pesticide use sites, suggest the need for monitoring data in this area or reliance on modeled estimated concentrations. However, additional spatial analysis can be performed to determine if surrogate monitoring sites could be used in lieu of additional monitoring data. If a site has similar or more vulnerable characteristics, such as soil and weather conditions, potential pesticide use patterns and pesticide usage, as areas in the same or another drinking water watershed, then the monitoring data for the site may be of potential use as a surrogate for those areas with missing monitoring data.

Method

GIS was used to determine how relevant monitoring sites are to a CWS intake, as well as determine how similar the SBF watersheds are to CWS watersheds. The weight-of-evidence approach integrates multiple lines of evidence including, chlorpyrifos usage, crop footprints, location of monitoring sites in relation to drinking water intake watersheds, and time of travel to the drinking water intakes, as described below.

Potential Use Sites

Potential use sites are defined in this assessment as alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, wheat, and strawberry in specific 2-digit HUC regions. 2007 USDA Census of Agriculture county-level acres of harvest data are overlaid with monitoring sites to determine if the sites, and the monitoring data, are representative of the uses.

Watershed and Waterbody Properties

Proximity of the site relative to the community water system drinking water intake is determined. Use of lines of evidence, such as hydrologic connectivity and the presence of nearby potential use sites, can add confidence, as the site is connected to the CWS intake and represents an area where the pesticide could be used.

Additionally, how far away the site is from the drinking water intake, how fast the flow of the stream is (i.e., time of travel), and the persistence of the pesticide is also considered. This information provides an approximation of how long the pesticide would take to reach the intake and, along with the pesticide persistence, gives an indication if the pesticide would be expected to persist long enough to reach the intake. If the monitoring site is at the top of the community water system watershed, the monitoring data might not reflect the potential dissipation that could occur before the pulse of flow (i.e., during time of travel) reaches the drinking water intake. This dissipation maybe the results of transformation or dilution, for example. If the monitoring site is near a community water system intake, then there is confidence that it is representative of the community water system.

Use of other lines of evidence, such as the presence of nearby potential use sites, can add confidence, as the monitoring site may represents an area where the pesticide could be used. If a site occurs downstream of a drinking water intake, it should be carefully evaluated, to determine if there are potential sources of pesticide load or dilution between the intake and the monitoring site, there may be uncertainty as to the source of the pesticide and its contribution to drinking water. The closer the monitoring site is to the intake the more confidence the concentrations represent concentrations in source water used for drinking water.

Contributing-area characteristics, such as soil properties, geology, slope, etc., and climatic factors, such as rainfall history and intensity, can provide information on the potential for the pesticide to be in runoff from a treated field. Soil and geology data, obtained from the Soil Survey Geographic Database (SSURGO), as well as the slope, obtained from topographic maps, of the potential pesticide use areas near the monitoring or SBF site can be used to see if the area is conducive to runoff. Likewise, the use of weather data, particularly average daily precipitation data, can be indicative of whether the site is in a wet or dry region and whether the short, intense rain events can generate flashy pesticide peaks. If the potential for runoff and the weather data for the site are like those observed at the potential use sites in the CWS, then there is confidence that the monitoring data may be representative of the CWS. More information on these types of factors can be found in ILSI, 1999.

d. <u>Weight of Evidence</u>

As available, all factors mentioned above are used to determine confidence in the model EDWCs and monitoring data and the representation of the concentrations and impact on drinking water. While analysis of monitoring data inherently considers all uses, this assessment focuses on the relevance of the available data to the uses considered in this assessment. This weighs heavily in the weight of evidence.

Results

a. Modeling

1. *Pesticide Water Calculator*

Application of Use Pattern Specific PCA

As mentioned in the **Post-processing or Output Adjustments** section, the first refinement considered in this assessment is the application of the use pattern specific PCA. Use pattern specific PCA were calculated for each of the 2-digit HUCs considered in this assessment and are specific to the uses considered in this assessment.

Results from PWC are presented in **Table 13** for both chlorpyrifos and chlorpyrifos-oxon resulting from upper bound average rate provided by BEAD after looking at the full distribution of survey results. A description is provided by crop in the supporting document provided by BEAD in **ATTACHMENT 1**. Application of use pattern specific PCAs indicate that the 1-in-10 year 21-day average chlorpyrifos-oxon concentration may be greater than the 21-day 10x DWLOC in four 2-digit HUCs (HUC-04, -07, -09, and -17) for upper bound applications rates. None of the 1-in-10 year 1-day or 21-day average chlorpyrifos-oxon concentrations are higher than the 1x DWLOC. In addition, none of the 1-in-10 year 1-day average chlorpyrifos concentration are greater than the 1-day 10x DWLOC.

Table 13. PCA Adjusted EDWCs for Upper Bound Application Rates of Chlorpyrifos

2-digit HUC	Use Site	2-digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EDWC (cpy)	21-day Model EDWC (cpy)	1-day Model EDWC (cpyo)	21-day Model EDWC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
02	Apple	0.07	127_4_PAappleSTD	10.8	7.6	10.3	7.3	0.8	0.5	0.7	0.5
	Peach			16.2*	11.4*	15.5	10.9	1.1	0.8	1.1	0.8
03	Citrus	0.27	136_4_FL-1421189-7026-72	6.5	3.8	6.2	3.6	1.8	1.0	1.7	1.0
	Peach[b]		216_4_GAPeachesSTD	11.6	6.9	11.0	6.6	3.2	1.8	3.0	1.8
	Cotton		196_4_GA-325617-11261-2	4.9	2.9	4.7	2.8	1.3	0.8	1.3	0.7
	Soybean		221_4_GA-325947-11736-5	11.9	6.8	11.4	6.5	3.2	1.8	3.1	1.8
04	Alfalfa	0.92[d]	2_4_MI-186800-22356-36	2.8	2.1	2.7	2.0	2.6	1.9	2.5	1.8
	Sugar beet		362_4_MI-186667-22116-41	7.2	4.8	6.9	4.6	6.6	4.4	6.3	**4.2**
	Apple[c]		128_4_MIcherrySTD	17.3	14.9	16.5	14.2	15.9	13.7	15.2	**13.1**
	Cherry		134_4_MIcherrySTD								
	Peach			26.0*	22.4*	24.8	21.4	23.9	20.6	22.8	**19.6**
	Soybean		245_4_MI-186667-22116-41	3.9	2.1	3.7	2.0	3.6	2.0	3.4	1.9
	Asparagus		133_4_MIasparagusSTD	3.7	2.1	3.5	2.0	3.4	2.0	3.3	1.9
05	Apples	0.58	129_4_PAappleSTD	9.6	7.2	9.2	6.9	5.6	4.2	5.3	4.0

2-digit HUC	Use Site	2-digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EDWC (cpy)	21-day Model EDWC (cpy)	1-day Model EDWC (cpyo)	21-day Model EDWC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
	Soybean		254_4_OH-198271-18810-5	5.4	3.3	5.2	3.1	3.1	1.9	3.0	1.8
06	Apples	0.02	130_4_NCappleSTD	20.8	13.0	19.8	12.4	0.4	0.3	0.4	0.2
07	Alfalfa	0.90	11_4_MO-2528577-19014-37	7.7	4.5	7.3	4.3	7.0	4.0	6.7	3.8
	Sugar beet		371_4_MN-2423043-23487-41	11.5	8.3	11.0	7.9	10.4	7.5	9.9	**7.2**
	Soybean		263_4_MN-2877271-22781-5	5.6	3.4	5.3	3.2	5.0	3.1	4.8	2.9
09	Alfalfa	0.95[e]	20_4_SD-416559-24423-36	2.0	1.5	1.9	1.4	1.8	1.4	1.7	1.3
	Sugar beet		437_4_ND-2642948-27020-41	9.7	6.5	9.3	6.2	8.7	5.8	8.3	**5.6**
	Soybean		281_4_ND-2571399-26297-5	3.6	2.3	3.4	2.2	3.3	2.1	3.1	2.0
	Spring wheat		473_4_ND-2585363-27001-23	2.9	1.8	2.8	1.7	2.6	1.6	2.5	1.6
	Winter wheat		527_4_ND-341303-27230-24	5.8	3.9	5.5	3.7	5.2	3.5	5.0	3.3
10	Alfalfa	1.0[e]	29_4_IA-404845-19717-37	5.5	3.4	5.2	3.2	5.5	3.4	5.2	3.3
	Soybean		299_4_NE-427060-20409-5	6.0	3.7	5.7	3.5	6.0	3.7	5.7	3.6
	Spring wheat		512_4_ND-339036-26757-22	5.1	3.3	4.9	3.1	5.1	3.3	4.9	3.2
	Winter wheat		536_4_CO-95043-18735-24	3.0	1.8	2.9	1.7	3.0	1.8	2.9	1.7
11	Alfalfa	0.79[e]	65_4_CO-2808264-16377-37	4.1	2.6	3.9	2.5	3.2	2.0	3.1	2.0
	Soybean		335_4_AR-565399-14294-5	3.8	2.3	3.6	2.2	3.0	1.8	2.9	1.7
	Winter wheat		572_4_TX-367160-13558-24	5.2	3.0	5.0	2.9	4.1	2.4	3.9	2.3
12	Citrus[h]	0.18	163_4_TX-367665-6012-72	6.3	3.9	6.1	3.6	1.2	0.7	1.1	0.7
	Peach		163_4_TX-367665-6012-72	5.4	3.3	5.2	3.1	1.0	0.6	0.9	0.6
	Winter wheat		590_4_TX-372533-12603-24	3.9	2.3	3.7	2.2	0.7	0.4	0.7	0.4
17	Alfalfa	0.53	110_4_WA-71453-24575-36	2.4	1.6	2.3	1.5	1.3	0.9	1.2	0.8
	Sugar beet		389_4_ID-79974-21766-41	7.0	4.9	6.7	4.7	3.7	2.6	3.5	2.5
	Apple[c]		131_4_ORappleSTD	9.6	6.2	9.2	5.9	5.1	3.3	4.9	3.1
	Strawberry		353_4_ID-80309-21523-12	16.8	12.1	16.0	11.5	8.9	6.4	8.5	**6.1**

a. Batch run name is truncated (DWA_2020 was removed for reporting purposes).
b. Model run was completed for 2.0 lb a.i./A; however, upper bound rate for peach on a national level is 3 lb a.i./a. Results were multiplied by 3/2.
c. Model run was completed for 2.0 lb a.i./A (maximum rate observed is noted as 3.0 lb a.i./A)
d. Use pattern specific PCA is slightly higher (0.93) than all-ag PCA (0.92). Use pattern specific PCA is capped at all-ag value.
e. Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at all-ag value.
f. Use pattern specific PCA is slightly higher (>1) than all-ag PCA (1.0) Use pattern specific PCA is capped at all-ag value.
g. Use pattern specific PCA is slightly higher (0.96) than all-ag PCA (0.79). Use pattern specific PCA is capped at all-ag value.
h. Model run was completed for 3.0 lb a.i./A and should have been 3.5 lb a.i./A for the upper bound rate. Results were multiple by 3.5/3 to adjust the concentrations.

*****Upper bound rate modeled for apples and cherries is 2 lb a.i./a. The upper bound rate for peach on a national level is 3 lb a.i./a. Results were multiplied by 3/2 to estimated concentrations for peach.
Green shading indicates concentrations below the 10xDWLOC.
Reg shading and bold font indications concentrations above the 10x DWLOC.
Chlorpyrifos (cpy)
Chlorpyrifos-oxon (cpyo)

Subsequent refinements focus on four (i.e., HUC-04, -07, -09, and -17) of the 11 HUC-02 regions considered in this assessment and focus on the 21-day average concentration assuming retention (i.e., 10x) of the FQPA safety factor.

Results for average application rates are provided in **APPENDIX B**.

Use of the Full Distribution of Watershed PCA Values, Critical PCAs, and Percent of Watersheds with PCA Values Larger than the Critical PCAs

Examination of the full distribution of PCAs for HUC-04, -07, -09 and -17 (i.e., those 2-digit HUCs with upper bound application rates resulting in EDWCs above the 21-day 10x DWLOC for chlorpyrifos-oxon) indicate that 232 community water system watersheds may have chlorpyrifos-oxon concentrations above the 21-day 10x DWLOC for upper bound application rates as shown in **Table 14**. This was determined by counting the number of community water systems with PCAs above the critical PCA for each respective region. In addition, **Table 14** provides a count of the total number of community water systems watersheds within each HUC so that the percentage of watershed with concentrations above the DWLOC can also be determined.

Table 14. Full Distribution of Watershed Specific PCA-Adjusted EDWCs for <u>Upper Bound</u> Applications of Chlorpyrifos-oxon

2-digit HUC	Total Community Water System Watersheds	Max[1] 1-in-10 year 21-day Concentration µg/L	Critical 21-day Percent Cropped Area	Number of Community Water Systems with Concentrations Above the 10x 21-day DWLOC	Percent of Community Water Systems with Concentrations Above the 21-day 10x DWLOC	Overlap Counties Crop Acres Community Water System Watersheds (number)
04	196	21.4	0.19	139	71	Yes (several)
07	158	7.9[2]	0.51	79	50	Yes (1)
09	16	5.2	0.67	12	75	Yes (several)
17	343	11.5	0.35	2	<1	-

[1] This column provides the maximum concentration associated with use of the maximum regional use pattern specific PCA. Concentrations would be lower for other community water systems within the 2-digit HUC.
[2] Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at the all-ag value in the prior refinement step; however, when aggregating the individual contributions, the concentration (max=6.1 µg/L) exceeds the prior estimate (max=5.6 µg/L). Therefore, since the model output value is higher for the misc-Ag use site the soybean contribution is low (3%) and a low estimated concentration and wheat falls in the middle, soybean contribution was made zero, and the wheat contribution (PCA) was adjusted down to be the difference in the all-ag and misc-ag. This approach is expected to be conservative yet accounts for the double cropping that is likely occurring in the watershed.
- refinement not considered

There are several community water systems with EDWCs above the 21-day 10x DWLOC in HUC-04, -07, and -09. Only two community water systems in HUC-17 had concentrations above the 10x 21-day DWLOC.[17] Therefore, HUC-17 was not considered for overlap refinements.

The same analysis is provided for average application rates and the results are provided in **APPENDIX B**. The excel file supporting this analysis is provided in **ATTACHMENT 3** (PCA_Analysis subfolder cpy pca_analysis.xlsx).

Overlap analysis of Watersheds with PCAs Larger than the Critical PCA with Use Site Footprint

As described in the **Post-processing or Output Adjustments** section of this document, one of the new refinement methods is to examine the overlap of community water system watersheds with estimated concentrations above the DWLOC with use pattern specific county level acres data. This is done because the PCA values are often calculated for crop groups (e.g., orchards) which contain multiple crops (e.g., citrus, apples, peaches, pecans (USEPA, 2020). Overlap analysis was completed for the community water systems with EDWCs above the critical PCA in HUC-04, HUC-07, and HUC-09. The results are discussed in the subsections below for each of the 2-digit HUCs suspected to have concentrations above the 21-day 10x DWLOC.

<u>HUC-04 (Great Lakes)</u>

Examination of county boundaries with reported acres associated with uses under consideration in HUC-04 suggests overlap with community water systems with PCAs higher than the critical PCA. In this region, chlorpyrifos use on orchard crops (apple, cherry, and peach) result in estimated concentrations above

[17] Concurrent examination of individual community water system watershed PCAs (i.e., aggregation) indicate the concentrations in these two community system watersheds should not be above the 21-day 10 DWLOC. See **ATTACHMENT 3** PCA analysis.

the 21-day 10xDWLOC for chlorpyrifos-oxon. The other uses considered (alfalfa, asparagus, and soybean) have estimated concentrations less than the DWLOC. Further spatial analysis of HUC-04 indicates there are several community water system watershed with use pattern specific PCAs greater than the critical PCA (0.19) for counties reporting acres of either apple, cherry, or peach in 2007 (**Figure 6**). Because there are several watersheds with overlap a count of the number of community water systems with overlap was not done. Instead, this region is considered for additional refinements.

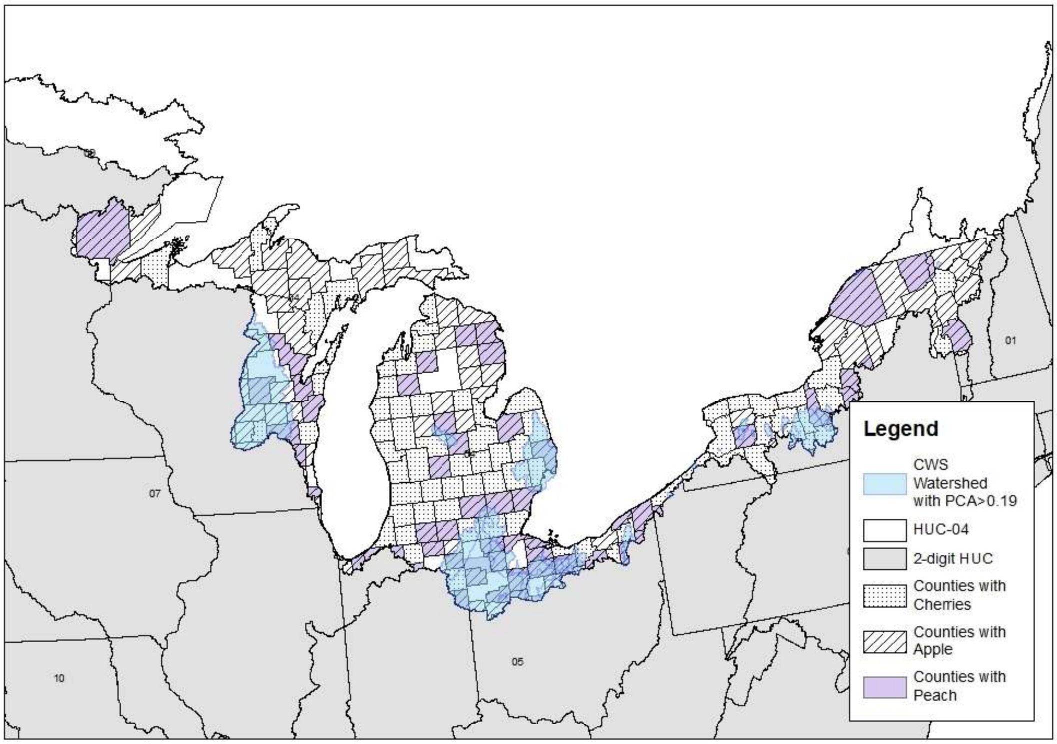

Figure 6. HUC-04 Crop Land Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.19)

HUC-07

Examination of county boundaries with reported acres associated with uses under consideration suggests overlap with community water systems with PCAs higher than the critical PCAs. In this region, chlorpyrifos use on sugar beet is the only use considered in this assessment with estimated concentrations above the 10x DWLOC. The other uses considered (alfalfa and soybean) have estimated concentrations less than for use on sugar beet and the 10x DWLOC. Further spatial analysis of HUC-07 indicates there is only one community water system with a use pattern specific PCA greater than the critical PCA for counties reporting acres of sugar beet in 2007 (**Figure 7**). This watershed (object ID 2703) has a use-site specific PCA of 0.69 (misc-ag PCA of 0.42 + soybean PCA of 0.27). Since there is spatial overlap with at least one community water system in HUC-07 this region is considered for additional refinement.

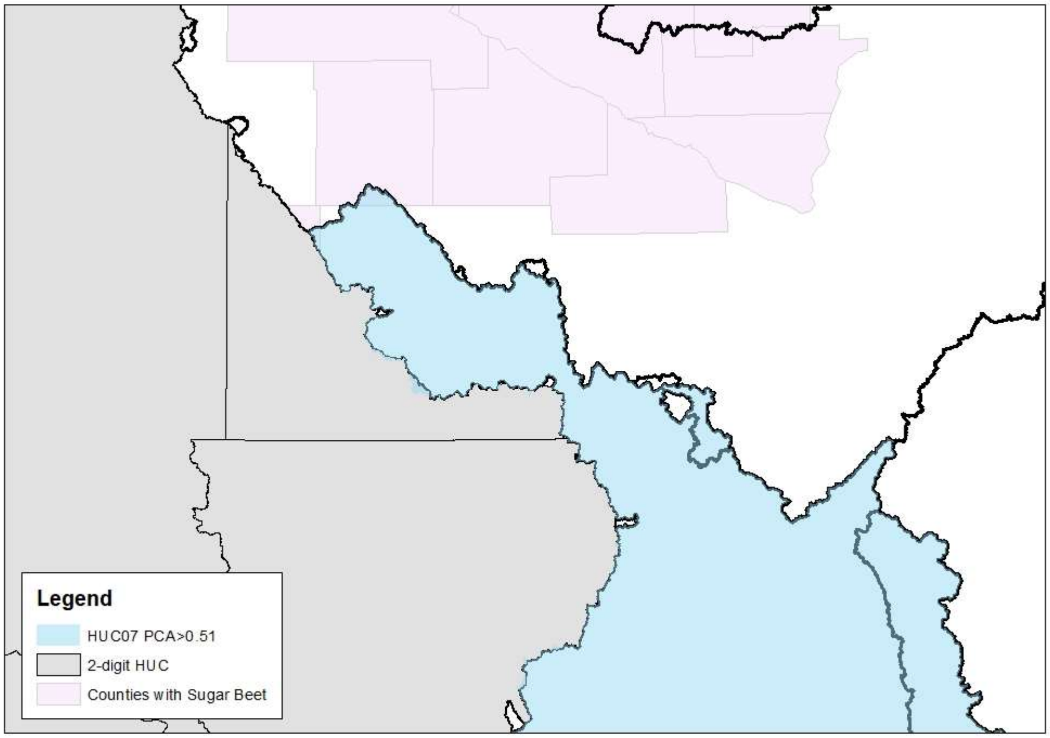

Figure 7. HUC-07 Sugar Beet Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.51)

HUC-09

The same spatial analysis was completed for HUC-09. It showed several community water system with use pattern specific PCAs greater than the critical PCA for counties reporting acres of sugar beet in 2007 (**Figure 8**). Again, chlorpyrifos use on sugar beets results in the highest model output for this region and is the only use with estimated concentrations above the 21-day 10x DWLOC. Since there is spatial overlap between county with acres of sugar beet HUC-09 is considered for additional refinement.

Because there are several watersheds with overlap a count of the community water systems with overlap was not done.

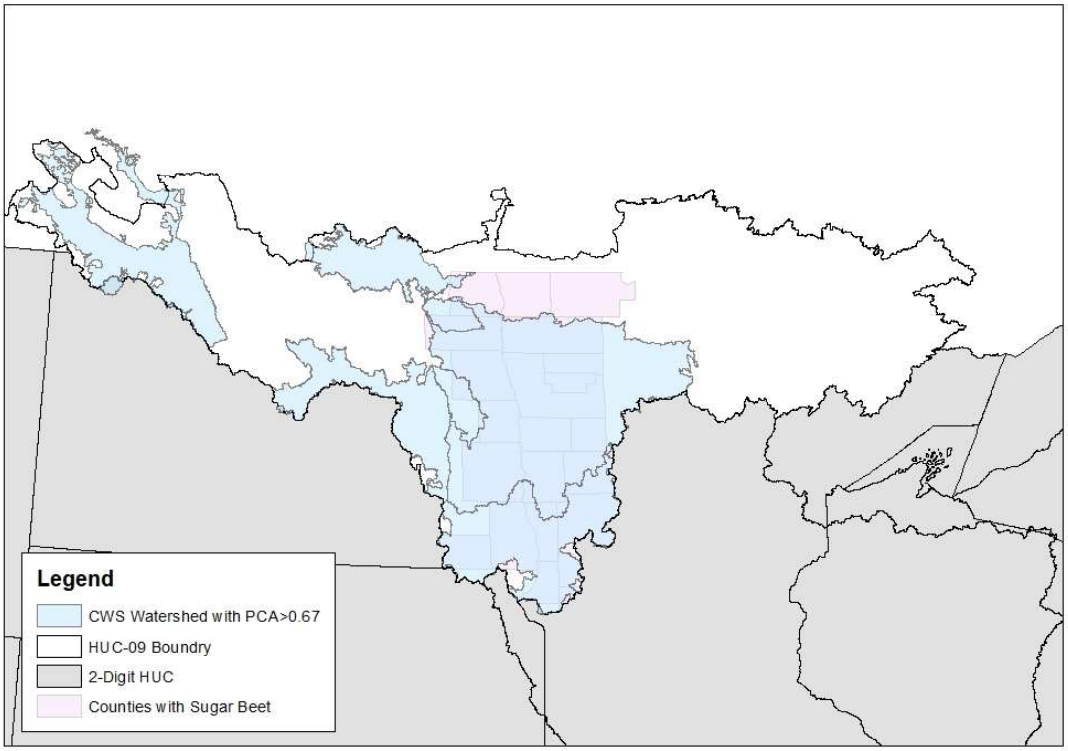

Figure 8. HUC-09 Sugar Beet Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.67)

HUC-17

Examination of county boundaries with reported acres associated with strawberry (2007) in HUC-17 suggests there is no overlap with community water systems with PCAs higher than the critical PCA (**Figure 9**). This region was no longer considered for refinement.

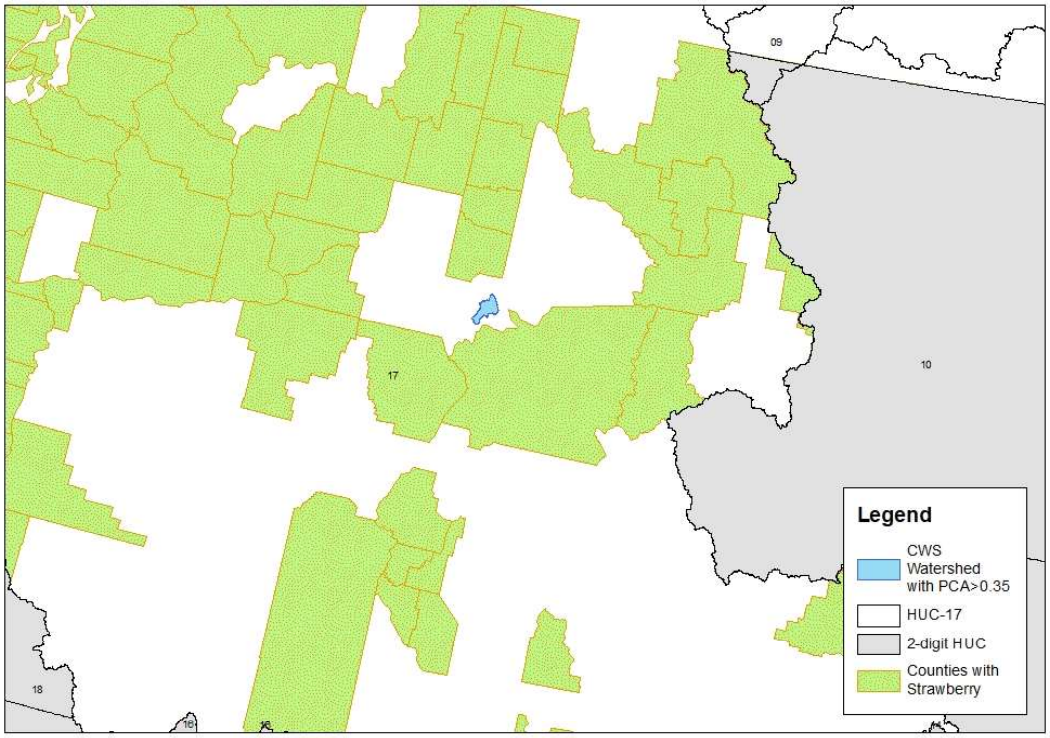

Figure 9. HUC-17 Crop Land Overlap Analysis with Community Water Systems with PCAs Greater than the Critical PCA (0.35)

Development of Aggregated Estimated Drinking Water Concentrations

As described in the **Post-processing or Output Adjustments** section of this document, one of the new refinement methods includes calculating EDWCs based individual use site residue contribution. Prior to this step, EDWCs are based on the highest concentration of all uses modeled within the respective 2-digit HUCs, however, the relative contributions of each modeled use site can be determined by adding (or aggregating) the contributing concentrations within each CWS watershed. This refinement step in this assessment focuses on aggregating 1-in-10 year aggregation.

The aggregated EDWCs reported in this section only represent the uses considered in this assessment and in the regions assessed. If additional uses patterns need to be considered the aggregated concentrations need to be updated to account for the additional exposure resulting from the contribution of additional uses to the overall EDWCs. The results are reported in the subsection below.

1-in-10 year Aggregation

Aggregation of the 1-in-10-year concentrations for community water systems with chlorpyrifos-oxon concentrations estimated to be above the 10x DWLOC indicate that community water systems in HUC-07 and HUC-09 continue to need to be refined as concentration are still estimated to be above the 10x DWLOC for upper bound application rates. Results are presented in **Table 15**. The aggregated concentrations only reflect the uses considered in this assessment and do not account for the temporal contribution of each use.

Table 15. Aggregation of 1-in-10 year PCA-Adjusted 21-day Average EDWCs for Upper Bound Application Rates of Chlorpyrifos

2-digit HUC	Total CWS	Aggregated 1-in-10 year 21-day Average Concentration (cpyo) µg/L	No. of CWS above 21-day DWLOC	Percent of CWS above 21-day DWLOC
04	196	3.4	-	-
07	158	**4.2**[1]	1	<1%
09	16	**6.1**	9	56%

Bold font indicates concentrations above the 10xDWLOC (21-day = 4.0 µg/L)
[1] The watershed (object ID 2703) identified as having overlap with the sugar beet has an aggregated 1-in-10 21-day average concentration of 4.2 ug/L. This value is above the 21-day 10x DWLOC.
- no calculation needed as the concentration is below the 21-day 10x DWLOC.

The watershed in HUC-07 previously identified to have overlap with HUC-09 is a region where the use-site specific PCA is greater than the all-ag, and in the prior step, the use site-specific PCA was capped at the all-ag value as the sum of the individual crop PCA should not exceed the PCA for all cropped land. However, when aggregating concentrations, the individual contributions are adjusted based on the individual crop contributions even if, when combined, the PCAs are greater than the all-ag value. Nevertheless, the maximum aggregated chlorpyrifos-oxon concentration is lower than that calculated concentration reported in the prior step; however, still not below the 21-day 10x DWLOC.

Based on this analysis, one community water system in HUC-07 and 9 in HUC-09 are expected to have concentrations above the 21-day 10x DWLOC. Aggregation of the 1-in-10 year 21-day average concentration does not account for the temporal contribution of residue concentrations in the EDWCs; however, due to the time and tools necessary to aggregate time series data the next refinement considered is percent crop treated.

The same analysis is provided for average application rates. Results are provided in **APPENDIX B**. The excel file supporting this analysis is provided in **ATTACHMENT 3** (PCA_Analysis subfolder cpy pca_analysis.xlsx).

Percent Crop Treated Adjustment Factors

The final new refinement method considered in this assessment includes the calculation of the aggregation EDWCs using percent crop treated data. The maximum PCT is calculated by state for HUC-07 and HUC-09. This information was provided by BEAD. These data were applied using the upper distribution approach for allocating treated acres within each watershed to calculate EDWCs for each individual community water system within the HUC with concentrations above the 10x DWLOC in the prior refinement step. The results for the four approaches are presented in **Table 16**. These results suggest that based on the upper bound application rates all concentrations are expected to be below the 21-day 10x DWLOC; therefore, no additional refinements were considered. The excel file supporting this analysis is provided in **ATTACHMENT 3** subfolder PCA_PCT_Aggregation_Analysis.

Table 16. Full Distribution of Watershed Specific PCA and PCT (all usage)-Adjusted EDWCs for Upper Bound Applications of Chlorpyrifos-oxon

2-digit HUC	Total CWS	Maximum 1-in-10 year 21-day chlorpyrifos-oxon µg/L
		PCA/PCT (max upper)
07	158	0[1]
09	16	3.3[2]

[1] The watershed (object ID 2703) identified as having overlap with the sugar beet was the only watershed in this region considered in this refinement step.
[2] Considers all watershed with use pattern specific PCAs above the critical PCA and not the subset of watersheds with use pattern overlap. This is because the PCT analysis and the overlap analysis were being conducted concurrently. Had a concentration been estimated above the DWLOC the overlap analysis could have been used to refine the estimated concentrations further.

2. Discussion and Conclusions

Using the upper bound application rates provided by BEAD for the high benefit uses identified by Corteva Agriscience and critical uses identified by BEAD, all use site-2-digit HUC region combinations resulted in concentrations below the 10x DWLOC with refinements. The refinements used in this assessment are briefly summarized along with the results below.

Recall, the first refinement considered was <u>application of a use pattern specific PCA</u> to reflect only specific crops within each 2-digit HUC. This refinement identified 4 of the 11 2-digit HUCs as potentially having concentrations above the 21-day 10x DWLOC based on the maximum use pattern specific PCA in each region. However, none of the regions were determined to have concentrations above the 1- or 21-day 1x DWLOC or the 1-day 10x DWLOC.

The second refinement included the use of the full distribution of watershed PCA values and calculation of critical PCAs and percent of watersheds with PCA values larger than the critical PCAs. Examination of the full distribution of community water system watersheds in the regions identified as potentially having concentrations above the 21-day 10x DWLOC indicate that in 3 of the 4 regions there are number of community water systems where chlorpyrifos-oxon concentrations may be above the 21-day 10x DWLOC. The number of community water systems with use-site specific PCAs greater than the critical PCA were reported (**Table 14)**.

Overlap analysis of watersheds with PCAs larger than the critical PCA with use site footprint for uses (e.g., sugar beet, cherries or apples) where a crop group (e.g., misc-ag or orchard) PCA was used to determine overlap with community water systems watersheds. This refinement was useful in HUC-07 and HUC-17. In HUC-07, overlap analysis was used to ruling out all most all the community water systems with PCAs above the critical PCAs. In HUC-17, overlap analysis was not used to rule out community watersheds with PCAs above the critical PCAs because were several counties with acres reported for use sites considered in this assessment that overlapped with community water systems with PCAs greater than the critical PCAs.

Up until this point, concentration estimates relied on use of the single highest modeled estimated across uses within in the 2-digit HUC. Therefore, the development of aggregated EDWCs for each community water system exceeding the 10x DWLOC was done. This was done to allocate individual crop contributions to the EDWCs and develop a refined EDWC.

Percent crop treated adjustment factors were integrated into the exposure estimates for the 1-in-10 year 21-day average concentrations. This analysis indicated that when assuming the maximum percent crop treated over 5-years and allocating the associated acres within each individual community water system the concentrations expected would be below the 21-day 10x DWLOC.

Consistent with previous work, this update suggests the concentrations vary across the landscape and depend on the uses under consideration. The model estimated concentrations are consistent with previous assessments for average and upper bound rates. The impact of using the new scenarios does not substantially change the exposure estimates for chlorpyrifos.

The primary reason why estimated concentrations are below the DWLOC in this assessment is the number of uses considered in the respective regions. Because so many uses are currently registered, past assessments relied on a PCA of 1 because chlorpyrifos is registered for uses that can occur anywhere within a community water system watershed. This assessment, however, focuses only on high benefit and critical uses in specific regions of the country. Importantly, the results of this work do not reflect potential exposure from all currently registered uses. If additional uses were to be considered, this analysis would need to be updated. It is expected that as the number of uses assessed increases, and if application rates are higher than those considered in this assessment, the estimated concentrations will likely be higher than those presented and further refinements would need to be considered.

b. Monitoring

1. General Data Observations

Generally, detections of chlorpyrifos are sporadic with low concentrations. This is expected based on the environmental fate and transport properties (i.e., high sorption), usage data (i.e., applied in response to pest pressure), and low sample frequency. Much of the higher frequency sampled chlorpyrifos data comes from monitoring programs that are older and thus may not represent current use conditions. While these data may not reflect current use scenarios, the data suggest that chlorpyrifos does move to surface water and can be present in concentrations within the range of PWC estimated concentrations, even before adjustment for infrequent sampling. A summary of data accessed through the Water Quality Portal on 01/06/2020 is provided **Table 17**.

Table 17. Summary of Chlorpyrifos Data Accessed via the Water Quality Portal

Source	Number of Samples	Number of Non-detections	Minimum Reported Concentration µg/L	Maximum Reported Concentration µg/L
NWIS	66,345	60,504	0.0009	5.62
STORET	33,975	20,477	2E-07	14.7
Data accessed 1/6/2020				

These data indicate a low over all detection frequency; however, detected concentrations occur at up to 14.7 µg/L.

Surface water monitoring programs typically collect samples on a weekly or biweekly basis, even in programs with a relatively high sampling frequency such as USGS National Water Quality

Assessment (NAWQA) or Washington State Department of Agriculture (WSDA). For example, **Figure 10** shows the range of the number of samples collected per site per year (gray circles) along with the number of sites sampled per year (red dash) for chlorpyrifos (Water Quality Portal accessed 01/06/2020). The gray circles were formatted with transparency so that the darker the circle appears, the larger the number of sites with the same number of samples collected per year.

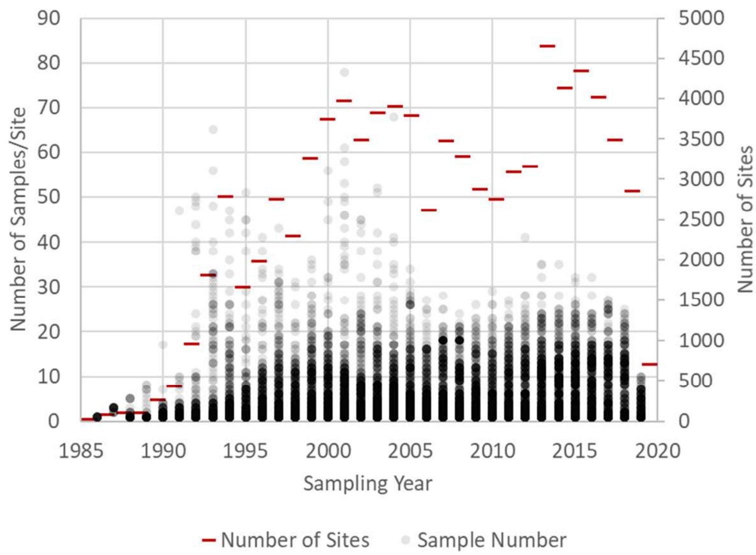

Figure 10. Sampling Quantity Characteristics for Chlorpyrifos Data from the Water Quality Portal

The sample number varies substantially across sites and the number of sites sampled varies by year. **Figure 10** also illustrates a downward trend in the number of sites as well as the number of samples collected at each site in recent years. Most sites have low sample numbers. The most samples collected at a site within a calendar year occurred in 2001 when 78 samples were collected at a monitoring location in San Joaquin River near Vernalis, California (USGS-11303500) with 53 of those samples occurring on different days. Closer analysis of this site shows that 45 samples were collected in the months of January and February. Many of the samples occurred on the same days in January and February.

Sample frequency at other sites and in other years is generally much lower, with the lowest being one sample per year for years that are sampled. **Figure 11** is a histogram showing the number of samples collected in 2016 for chlorpyrifos. Most sites do not have enough samples collected to meet the minimum data requirements for the applications of SBFs (≥ 13 samples/year) or for SEAWAVE-QEX analysis (≥ 12 samples/year with 25% detection frequency for 3 years).

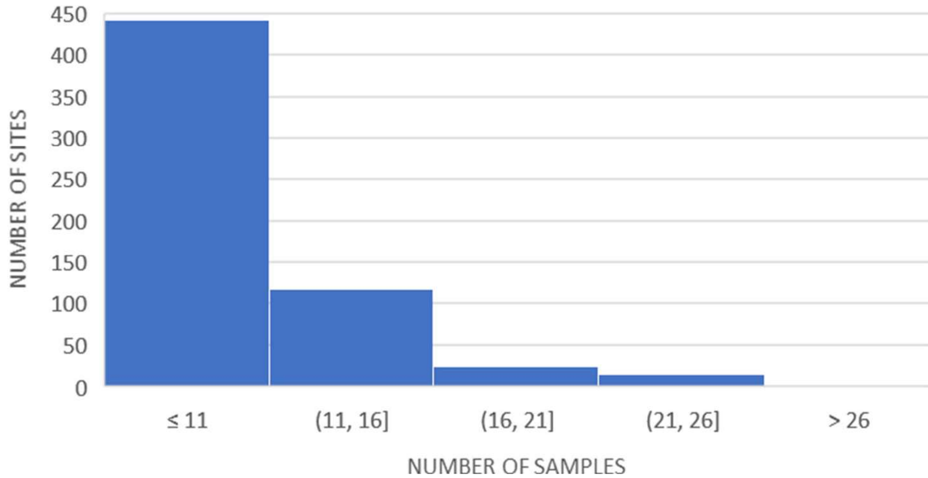

Figure 11. Histogram for Samples in 2016 for Chlorpyrifos (USGS) Across the United States

Further analysis of all years of data reveal that the number of days between sampling events ranged from 1 to 360 days across all years and sites with the average number of days between samples of 1 to 336 days across all site-years.

Analysis of data collected from programs with more frequent sampling suggest that as sample collection increases, the detection frequency also increases. For example, daily composite sampling on Orestimba Creek had detection frequencies between 42-52% for chlorpyrifos.

Sampling frequency should be considered in the context of use information, as an increase in the number of samples collected at an individual location where use is infrequent or absent, or during times of the year when applications or runoff events are not expected to occur, may reduce detection frequencies, as well as reduce the likelihood of measuring peak concentrations.

Most of the data in the Water Quality Portal come from grab samples. A grab sample is defined as an individual aliquot or volume of water collected over a short period of time (<15 minutes). For example, scooping up water in a cup, bottle or bucket. In contrast, a composite sample consist of a collection of several individual discrete samples taken at regular intervals over a period, usually 24-hours.

While differences in surface water concentrations can result from differences in the sampling design, frequency, and/or sample number with respect to the peak concentration on a daily time step, potential variation in concentrations may also occur over the course of a day for chlorpyrifos **Figure 12** shows measured chlorpyrifos concentrations from the Rock Creek sampling site from NCWQR. it is possible that daily grab samples can miss measuring peak concentrations on days which the sampling occurs. Grab samples are currently the most common sampling method within the available data sources.

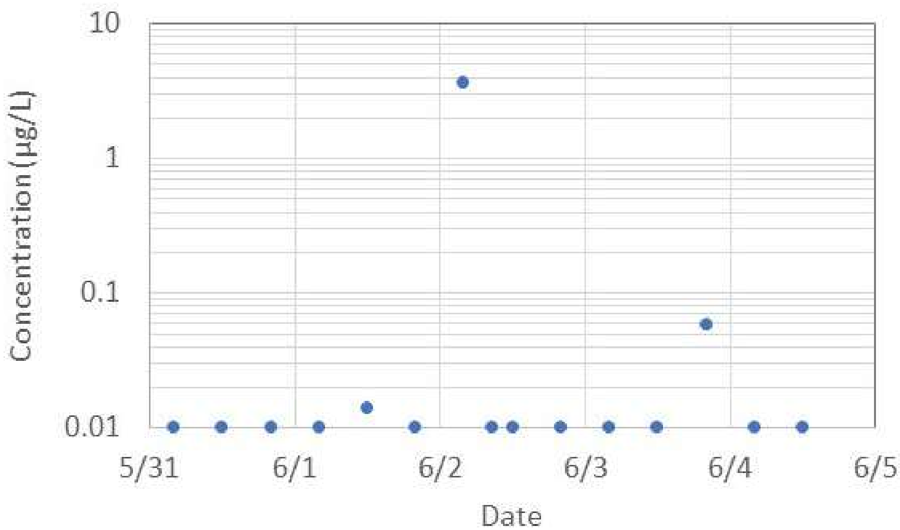

Figure 12. Pesticide Concentration Variation Over a Daily Time Step for Rock Creek (NCWQR)

Therefore, data need to be evaluated on a site-specific basis as the sampling frequency may impact the interpretation of the data. In many cases, there is not enough data either on an annual, multi-year, or multi-site basis to reliably estimate pesticide concentrations for short-term exposure estimates.

Several tables summarizing available surface water monitoring data, including more regionally-specific and site-specific summaries are provided in **APPENDIX C** and **Attachment 4**.

2. Data Interpretation and Extrapolation

SEAWAVE-QEX Results

Of the many sites with chlorpyrifos samples in the WQP datasets, 13 sites were determined to satisfy the model assumptions (see White Paper Chapter 3 and the SEAWAVE-QEX SOP for more information on satisfying model assumptions). However, upon further evaluation, two sites were excluded from quantitative analysis due to indications in the flow data that suggest the sites may not have year-round flow; however, the analysis of these sites is also included in **APPENDIX C**. A map of the sites considered for SEAWAVE-QEX analysis is presented in **Figure 13**. This map illustrates the need to consider all SEAWAVE-QEX sites across the contiguous states to capture as much of the range chlorpyrifos use conditions. For example, there are no SEAWAVE-QEX sites in HUC-10 or -11 and in most others HUCs there is only one SEAWAVE-QEX site.

Figure 13. Monitoring Sites Meeting the SEAWAVE-QEX Data Quantity Criteria

Figure 14 describes the sampling quantity characteristics for the final 11 SEAWAVE-QEX sites, showing both the number of samples at each site (y-axis) and the number of sites sampled each year (z-axis). However, data used in SEAWAVE-QEX spans from 1987-2012 as other years may not have met the minimum SEAWAVE-QEX criteria. These years may represent use patterns that are no longer registered as well as uses not considered in this assessment. Of the sites flagged for use in SEAWAVE-QEX based on the minimum criteria, recent years (e.g., after 2012) generally have less monitoring and/or lower detection frequencies. The reduced detection frequency could be the result of reduced sampling frequency in more recent years, changes in use in the early 2000s, and/or timing of sampling.

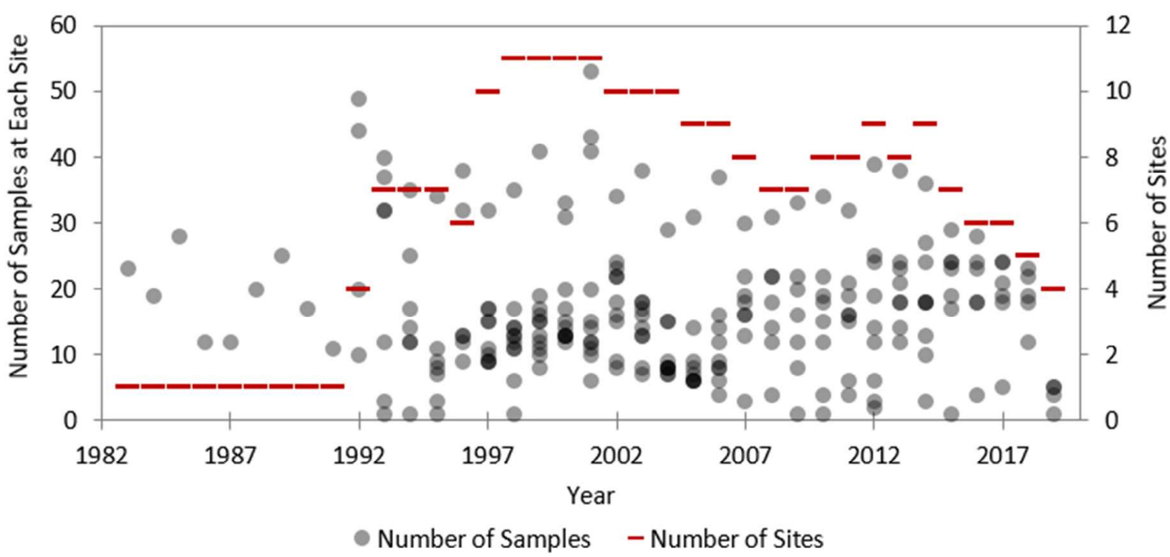

Figure 14. Sampling Quantity Characteristics for Chlorpyrifos Data for Sites Meeting the SEAWAVE-QEX Data Quantity Criteria

As observed in **Table 18** for several sites, the maximum measured concentration is lower than the reported censoring limit during other sampling events. For example, for USGS-01654000, the maximum measured concentration was 0.041 µg/L in 1994, but the reporting limit ranged from 0.0037 µg/L up to 0.0586 µg/L (i.e., greater than 0.041 µg/L) from 1994 to 2014. Reporting limits often vary between sampling events and descriptions included in the WQP are not always clear. For chlorpyrifos, which has relatively low measured concentrations that are of importance, these database issues create more uncertainty in the monitoring data. Additionally, a high censoring limit relative to measured concentrations may adversely affect the SEAWAVE-QEX output, which takes the censoring limit into account. This is because SEAWAVE-QEX randomly assigning values below the censoring limit. Therefore, a randomly high value may be selected that does not correspond with a flow event. However, not all high censoring limits occurred in years that were included in the SEAWAVE-QEX analysis.

Table 18. Summary of Monitoring Sites with Acceptable SEAWAVE-QEX Models

USGS Site No.	2-digit HUC (State)	Max Measured Conc. µg/L (Year)	Max Censoring Limit µg/L (Year)	Years Used in SEAWAVE-QEX	Final Simulation Filename (Confidence[1])	SEAWAVE-QEX Est. 1-day Conc. (µg/L)[2]	SEAWAVE-QEX Est. Est. 21-day Conc. (µg/L)[2]
01654000	02 (VA)	0.041 (1994)	0.0586 (2014)	1994-2000	cpy_1 (m)	0.026-0.060	0.011-0.036
02174250	03 (SC)	0.338 (2005)	0.02 (1999)	1996-2008	cpy_7 (m)	0.088-0.50	0.055-0.25
02335870	03 (GA)	0.034 (1993)	0.5 (2001)	1993-2000	cpy_2 (l)	0.022-0.085	0.013-0.041
03353637	05 (IN)	0.11 (1996)	0.3 (1993)	1992-1996	cpy_1 (m)	0.13-0.24	0.046-0.11
04193500	04 (OH)	0.0299 (1996)	0.21 (1998)	1996-2007	cpy_4 (l)	0.077-2.1	0.049-1.4
08057200	12 (TX)	0.0549 (2000)	0.025 (2016, 2017)	1998-2002	cpy_6 (h)	0.022-0.058	0.010-0.027
11274538	18 (CA)	0.3 (1992)	0.025 (2016)	1992-2010	cpy_4[3] (l)	0.48-2.1	0.20-1.1
11303500	18 (CA)	0.079 (1993)	0.025 (2016)	1994-2012	cpy_2 (h)	0.024-*0.073*	0.016-0.043
14211720	17 (OR)	0.0137 (2007)	0.013 (2006)	1997-2007	cpy_1 (m)	0.015-0.029	0.011-0.019
04208000	04 (OH)	0.5 (1988)	0.12 (2012-2014)	1987-1991	cpy_2 (m)	2.9-12.7	1.3-4.7
11447360	18 (CA)	0.0445 (1997)	0.02 (1998, 2002, 2005)	1997-2008	cpy_3 (n/a[4])	n/a	n/a
14201300	17 (OR)	0.401 (1995)	0.02 (2004)	1993-2018	cpy_1 (n/a[4])	n/a	n/a
03612500	05 (IL)	0.01 (2005, 2008-2010, 2013)	0.038 (1992)	1992-2000	cpy_6 (l)	0.031-0.35	0.021-0.23

[1] Confidence categories are: h=highest, m=medium, l=lowest
[2] Range of the yearly maximum of the 99^{th} percentile concentration
[3] Additional data from Dow (now Corteva Agriscience) for 1996-1997 was included with the USGS site data for Orestimba Creek.
[4] Site excluded based on seasonal streamflow variation (i.e., intermittently flowing).
Italic font notes concentration measured is higher than summary statistic pulled from the SEAWAVE-QEX simulation.

Confidence in the SEAWAVE-QEX results are noted as high (h), medium (m), or low (l) (see **Table 18**). Reasoning based on goodness of fit of the diagnostic plots for these qualifiers are detailed in **APPENDIX C** on a site-by-site basis. For all sites except USGS-11303500, the highest 1-day estimated concentration was greater than the maximum measured concentration. For USGS-11303500, the SEAWAVE-QEX estimate was up to 0.073 µg/L while the maximum measured concentration was 0.079 µg/L. More than half of the sites have a single broad seasonal wave, likely because of either uses occurring year-round, applications occurring at different times across multiple years, and sporadic detections or a combination. Use of SEAWAVE-QEX may not be suitable for some pesticides with sporadic occurrence and low seasonality (e.g., not consistent use patterns at certain times of the year) as observed at these sites. To date, EPA's evaluation of SEAWAVE-QEX has focused on pesticides with strong seasonality (i.e., atrazine, metolachlor) and was limited geographically as the data used in the evaluation was from the NCWQR for sites in Ohio (tile drained). Even chlorpyrifos sites that had more seasonality in the data have shallow seasonal waves, suggesting that the monitoring analysis is not likely underestimating concentrations due to low seasonality.

Figure 15. Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites summarizes several properties from the landcover data of the final 11 sites used quantitatively from SEAWAVE-QEX (National Land Cover Database reported in StreamCat). The graphed landcover data shown in **Figure 16** may not add up to 100% due to other contribution of other landcovers not presented. To determine the relevance of these monitoring sites to chlorpyrifos uses, landcover characteristics were examined. The 11 sites represent a mixture of urban environments with high percentages of impervious surfaces and agriculturally relevant sites, such as cropland and hay.

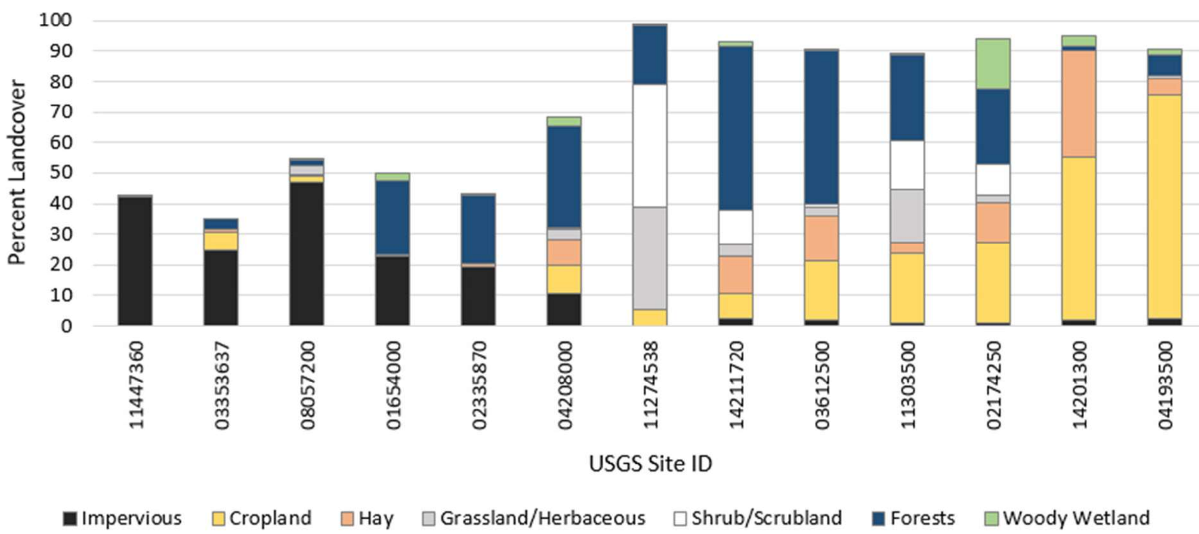

Figure 15. Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites

Figure 16 and **Figure 17** below provide a summary of the 1- and 21-day estimated concentrations derived for each site-year from SEAWAVE-QEX. Note that one site (USGS-04208000) has the highest estimates of any other, from 1987-1991. These are also the oldest sampling data included and may represent uses that are no longer registered. Based on the StreamCat landcover data (Hill et al., 2016) (**Figure 15.** Summary of Site Landcover Characteristics for Final SEAWAVE-QEX Sites), the site is not substantially different from other sites with similar amounts of impervious surfaces and cropland; however, the gage station for the site is shared with the NCWQR Cuyahoga sampling site, and it is known that these are influenced by tile drainage. This is also true of USGS-04193500 (Maumee River), which includes higher concentrations than most other sites from 1996-2007. USGS-11274538 (Orestimba Creek) also stands out as having higher concentrations than most sites from 1992-2010.

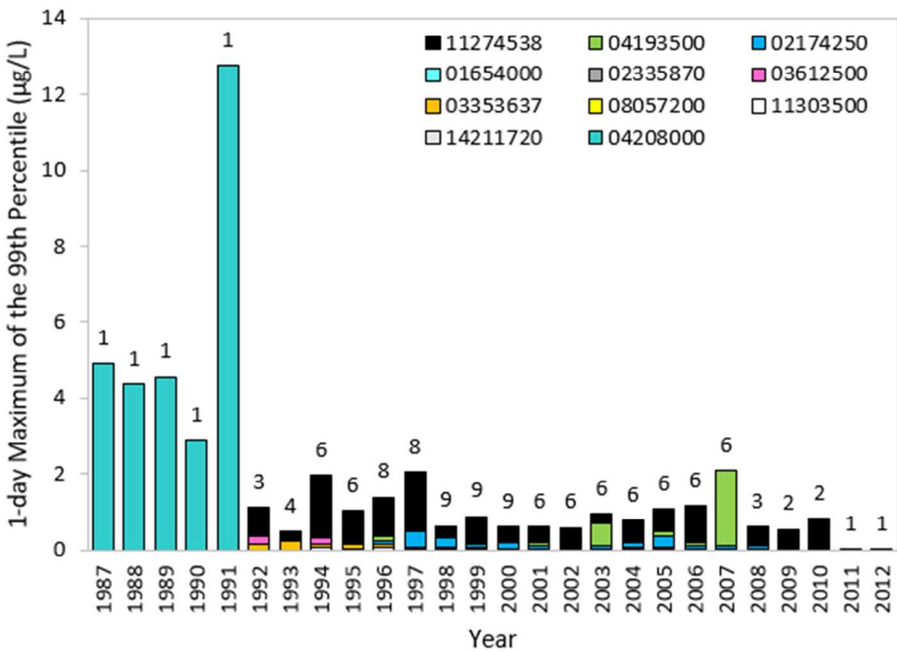

Figure 16. Summary of SEAWAVE-QEX 1-day Maximum of the 99th Percentile Chlorpyrifos Concentrations for Each Site (data labels are number of sites per year)

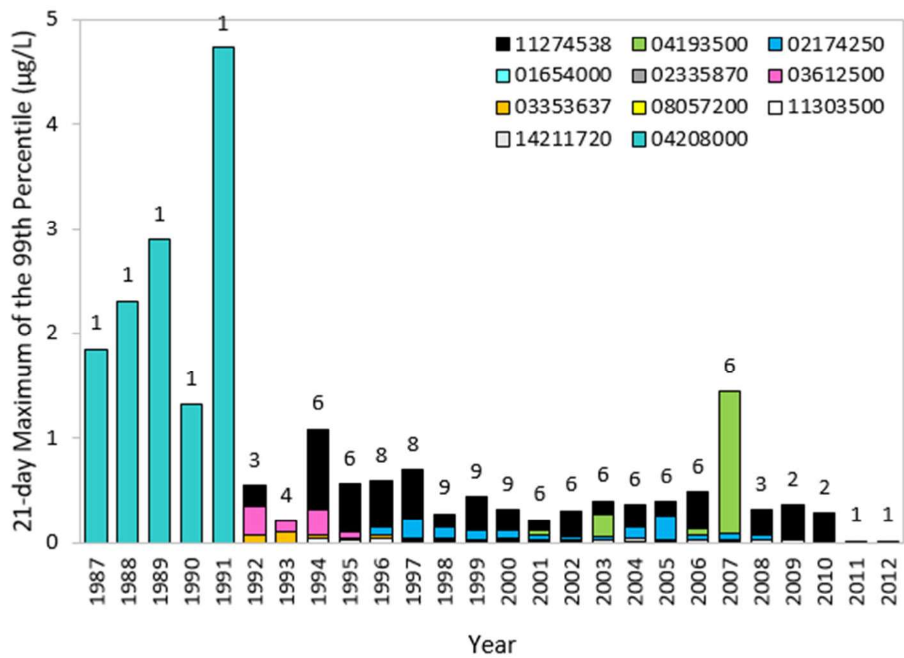

Figure 17. Summary of SEAWAVE-QEX 21-day Maximum of the 99th Percentile Chlorpyrifos Concentrations for Each Site (data labels are number of sites per year)

Sampling Bias Factors Development

SBFs were developed for 110-site years (11 sites) for estimating the upper bound confidence intervals on the 1- and 21-day average concentrations. The results are shown in **Figure 18** and **Figure 19**, respectively. The entire distribution of SBFs within each sampling frequency (e.g., 13-16 samples/year) was used to assess the potential concentrations across time and across the landscape. The maximum SBFs for 52, 26, 17, and 13 samples per year are 11, 23, 29, and 55, respectively, for estimating the 1-day average concentration and 4, 6, 8, and 12, respectively, for estimating the 21-day average concentration. These SBFs are much lower than SBFs developed for chlorpyrifos presented to the FIFRA SAP in November 2019. This is because only a subset of the SEAWAVE-QEX simulations were determined to be adequate for the development of SBFs based on feedback from the SAP panel.

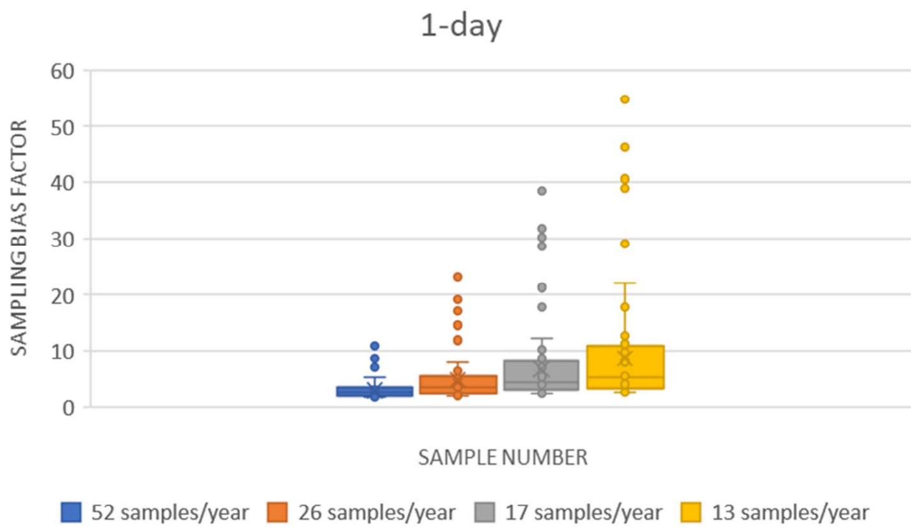

Figure 18. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across All Sites

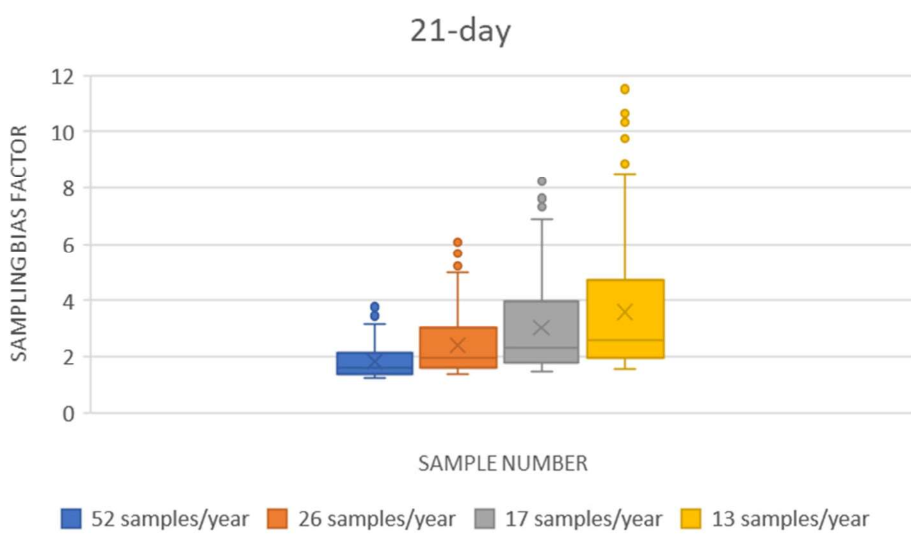

Figure 19. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across All Sites

Additional analysis of the developed SBFs revealed that SBFs varied more across sites than across years for most sites. **Figure 20** and **Figure 21** show the variability in the SBFs for 1- and 21-day across sites, respectively. However, there are a few sites where the SBFs notably varied across years. These sites include USGS-02174250 (Cow Castle Creek near Bowman, SC), USGS-0420800 (Cuyahoga River at Independence, OH), and USGS-11274538 (Orestimba Creek near Crows Landing, CA).

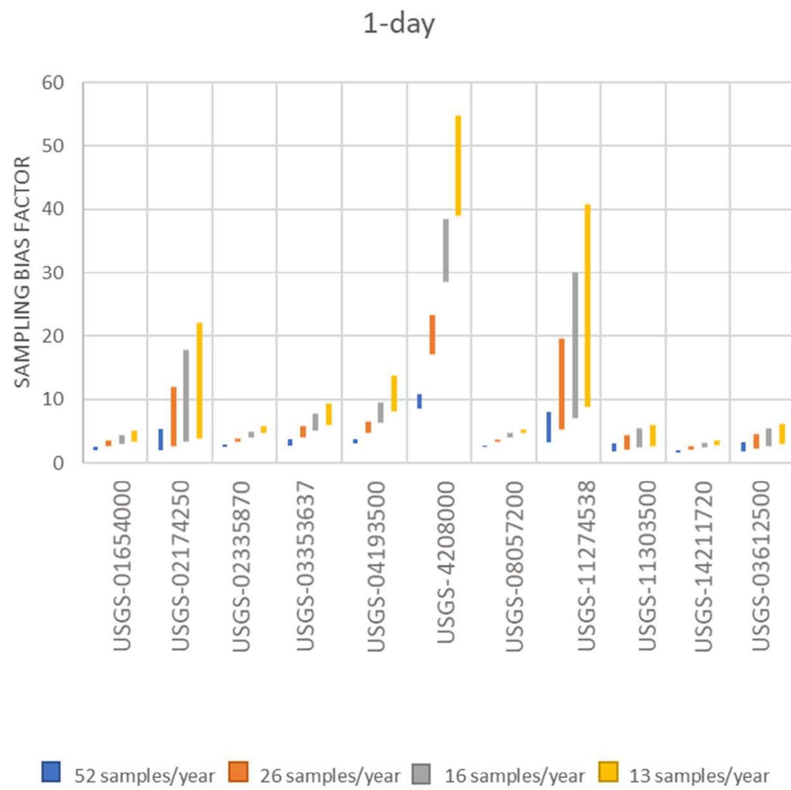

Figure 20. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration by Site

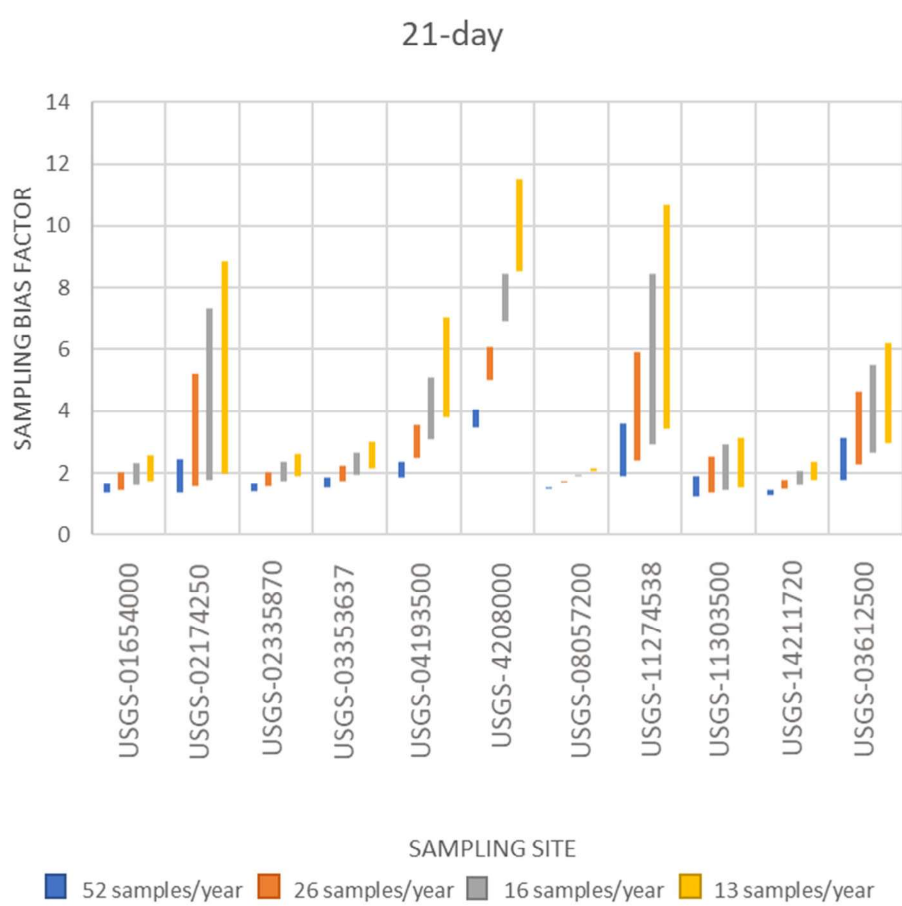

Figure 21. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration by Site

Further analysis of the sites indicates that:

For USGS-02174250, the large range and higher SBFs are due to a measured concentration in 2005 that resulted in much higher SBFs for 2005 than calculated for other years and sites. SBFs ranged from 2.0 to 2.9 for 52+ samples per year, 2.6 to 3.9 for 26-51 samples/year, 3.3 to 4.9 for 17-25 samples/year and 3.8 to 6.0 for 13-16 samples/year for estimating the upper bound concentration on the 1-day average for all years excluding 2005. In comparison, SBFs for 2005 are 5.3, 11.9, 17.8, and 22.2, for the corresponding sampling number.

For USGS-04208000, the large range and higher SBFs are observed for years 1987 through 1991. The SBFs are consistently high ranging from 9 to 11 for 52+ samples per year, 17 to 23 for 26-51 samples/year, 29 to 38 for 17-25 samples/year and 39 to 55 for 13-16 samples/year for estimating the upper bound concentration on the 1-day average concentration and 4 to almost 12 for 52+ samples per year and 13-16 samples/year, respectively, for 21-day average concentration.

For USGS-11274538, the larger range and higher SBFs are observed for 1996 and 1997. Again, the higher SBFs observed for this site are driven by a measured concentration. In addition, 1996 and 1997 had the most sampling data (i.e., daily) across years at this site and across sites.

This analysis, for USGS-11274538, suggests that for other years or other sites where peak occurrence concentration may have gone unmeasured, the SBFs may not capture the true range of potential chlorpyrifos concentrations. This is likely due to the sporadic application of chlorpyrifos and wide potential application window. In addition, chlorpyrifos is not observed to be persistent at a given point (e.g., sampling site) in a waterbody due to stream flow. Chlorpyrifos concentrations are driven by pulse inputs due to application or high runoff events. As discussed in the SEAWAVE-QEX section, the use patterns of chlorpyrifos and pulse inputs cause broad, shallow seasonal waves in SEAWAVE-QEX and fewer estimates of the pulse (peak) concentrations.

Figure 22 and **Figure 23** show the variability in the SBFs for 1- and 21-day across time, respectively. The number and specific sites where SBFs are calculated each year is different. The difference in sites is expected to be the primary contributor to the differences in magnitude of SBFs calculated across years.

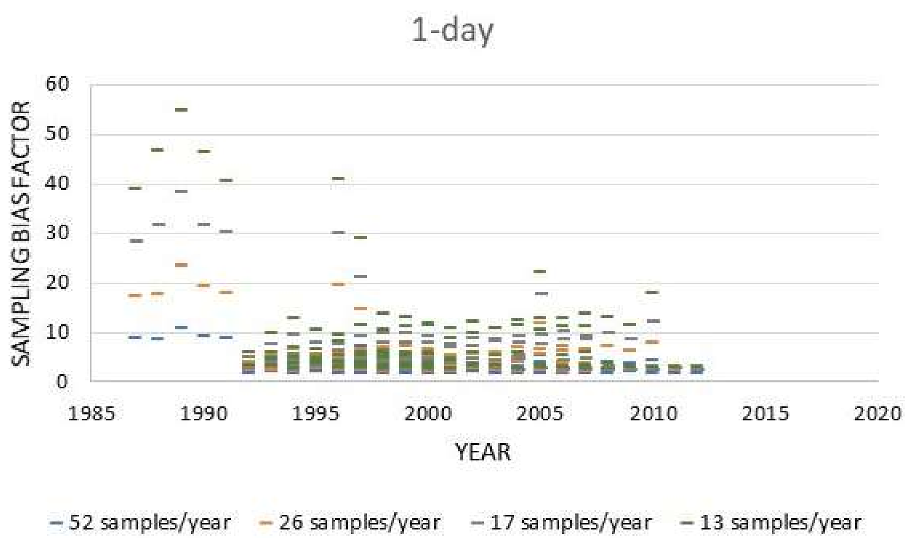

Figure 22. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across Years

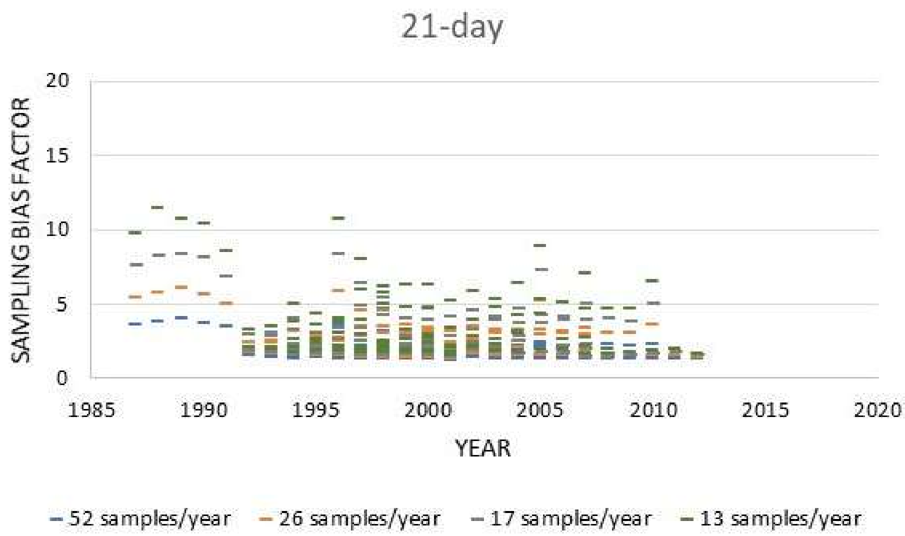

Figure 23. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across Years

Given that the use profile for chlorpyrifos changed in the early 2000s (see Use Characterization page 17 for more information), SBFs developed for 2005-2012 (post-registration review label changes) are presented in **Figure 24** and **Figure 25** for estimating the upper bound confidence interval on the 1- and 21-day average concentration.

The maximum SBFs for 52, 26, 17, and 13 samples per year are 5, 12, 18, and 22, respectively, for estimating the 1-day average concentration and 2, 5, 7, and 9 for estimating the 21-day average concentration, respectively. While these SBFs were developed based on data that likely better reflect current use, the data only represent 23-site years (5 sites) as compared to 110 site-years (11-sites) considering all available SBFs. Therefore, the abbreviated time span is not expected to represent a robust number of site-years to capture the range of potential chlorpyrifos concentrations in surface water. The 2012 FIFRA SAP suggested that 100 site years of data would be enough to capture a range of weather and site conditions.

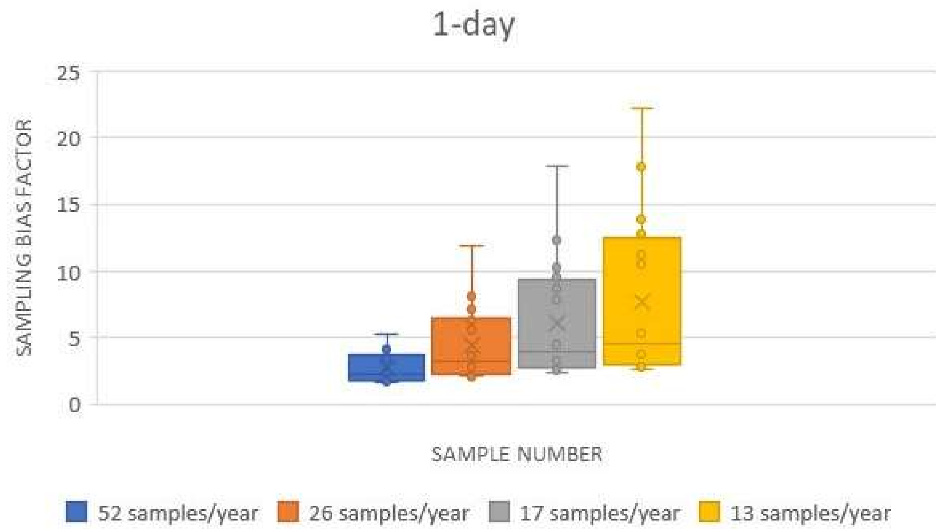

Figure 24. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 1-day Concentration Across All Sites (2005-2012)

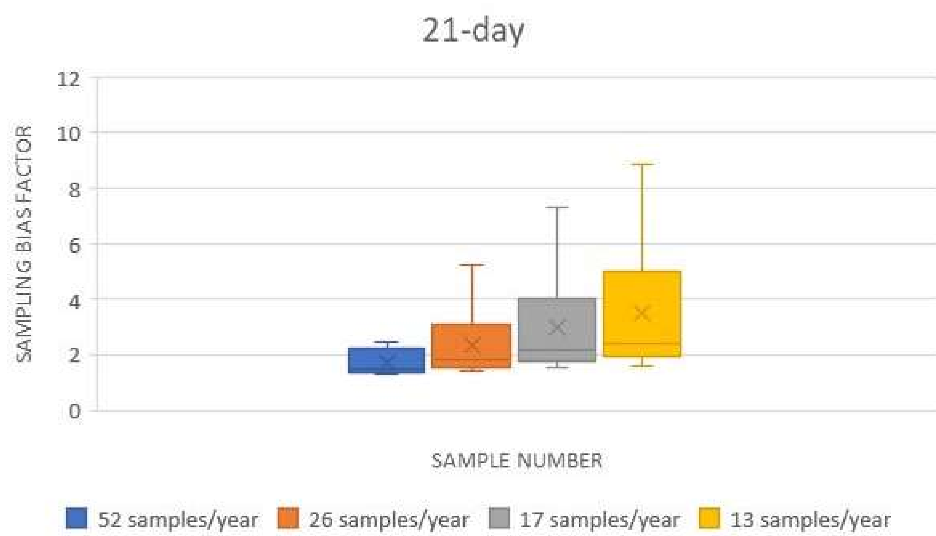

Figure 25. Chlorpyrifos Sampling Bias Factors for Estimating the Upper Bound Confidence Interval on the 21-day Concentration Across All Sites (2005-2012)

Sampling Bias Factors Application

Sampling Sites with Greater Than or Equal to 13 Samples per Year

SBFs for 1987-2012 (all years) and 2005-2012 (post-registration review label changes) are presented in **Table 19**. While there is a 2x difference in the 1-day SBFs for the two different periods of time the difference in 21-day SBFs is not that different especially when considering the 12-16 per year sampling category. Most chlorpyrifos data fall within the 12-16 per year sampling category or in the less than 13 sampling category. Therefore, to capture the most variability across time and space all SBFs years were considered and applied based on the number of samples per year for all site-years of data from the Water Quality Portal with greater than or equal to 13 samples per year (**Table 19**). A sensitivity analysis using the SBFs for the abbreviated time period was also completed. The results for the sensitivity analysis were not notably different.

Table 19. Maximum Sampling Bias Factors

Sample Number	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor
	1-day		21-day	
52+	10.9	5.3	4.0	2.4
26-51	23.3	11.9	6.1	5.2
17-25	38.5	17.8	8.4	7.3
13-16	54.8	22.2	11.5	8.9

SBFs adjusted concentrations (i.e., the upper confidence bound) that are above the 10x DWLOC for 1-day or 21-day average concentration based on the maximum SBFs are shown in **Table 20** and **Table 21**, respectively. There are 7-site-years (4 sites in HUC-17) where concentrations may be above the 10x DWLOCs (1-day) using the maximum SBFs across all years. Considering only bias factors developed for years 2005-2012 (i.e., post label modifications) results in 4-site years (3-sites) where concentrations may be above the 10x DWLOC. There are 8-site-years (5 sites in HUC-17) with concentrations above the 10x DWLOCs (21-day) using the maximum SBFs across all years. Considering only SBFs developed for years 2005-2012 results in 5-site years (3-sites) where concentrations may be above the 10x DWLOC. The sites where concentrations may be above the DWLOC are consistent across the exposure duration of concern. The site-years of data resulting in potential concentration above the 10x DWLOC were collected in the mid-2000s to as recent as 2018, post label changes. Therefore, these sites would be expected to represent uses currently permitted on chlorpyrifos labels. For site OREGONDEQ-34235-ORDEQ, the highest concentration is for a censored value; however, this assumption has not been confirmed.

Table 20. Summary of Monitoring Sites with Sampling Bias Factor Adjusted Chlorpyrifos Concentrations Above the 1-day 10x DWLOC (24 μg/L)[1]

Monitoring Site	Year	Number of Samples	Detection Range (μg/L)	Range of Detection Limits (μg/L)	Maximum 1-day Sampling Bias Factor Adjusted Maximum 1-day Chlorpyrifos Concentration (μg/L)	Maximum 1-day Sampling Bias Factor Adjusted Maximum 1-day Chlorpyrifos-oxon Concentration (μg/L)
OREGONDEQ-32010-ORDEQ	2005	15	0.033-0.49	0.023-0.026	26.9	**25.7**
	2009	14	0.0618 - 0.6494	0.038-0.079	35.6	**34.0**
OREGONDEQ-32068-ORDEQ	2007	14	0.026 - 2.4	0.024-0.03	131.5	**125.5**
	2015	15	0.125 - 1.77	0.021 - 0.0865	97.0	**92.5**
	2016	13	0.039 - 0.722	0.0214 - 0.023	39.6	**37.8**
OREGONDEQ-32069-ORDEQ	2007	13	0.04 - 1.3	0.025 - 0.03	71.2	**67.9**
OREGONDEQ-34235-ORDEQ	2018	13	0.0591	0.0213-2.72[2]	74.5	**71.1**

Bold font Indicates concentration above the 10x DWLOC.
[1] The source water concentration of chlorpyrifos necessary to result in the chlorpyrifos-oxon concentration in drinking water following conversion during treatment was back calculated from the DWLOC for chlorpyrifos-oxon using a molecular weight adjustment factor (DWLOC/0.9541) (23 μg/L/0.9541) = 24 μg/L
[2] value is a censored concentration.

Table 21. Summary of Monitoring Sites with Sampling Bias Factor Adjusted Concentrations Above the 21-day 10x DWLOC (4.2 µg/L)[1]

Monitoring Site	Year	Number of Samples	Detection Range (µg/L)	Range of Detection Limits (µg/L)	Maximum 21-day Sampling Bias Factor Adjusted Maximum 1-day Concentration (µg/L)[2]	21-day Interpolated Concentration (µg/L)[2]	Maximum 21-day Sampling Bias Factor Adjusted Maximum Estimated 21-day Concentration (µg/L)
					1987-2012		1987-2012
OREGONDEQ-32010-ORDEQ	2005	15	0.033-0.49	0.023-0.026	**5.6**	0.14 (0.14)	1.6 (1.6)
	2009	14	0.0618 - 0.6494	0.038-0.079	**7.5**	0.14 (0.02)	1.6 (0.2)
OREGONDEQ-32068-ORDEQ	2007	14	0.026 - 2.4	0.024-0.03	**27.6**	1.7 (2.7)	**19.3 (19.3)**
	2015	15	0.125 - 1.77	0.021 - 0.0865	**20.4**	0.66 (0.63)	**7.6 (7.3)**
	2016	13	0.039 - 0.722	0.0214 - 0.023	**8.3**	0.57 (0.57)	**6.5 (6.5)**
OREGONDEQ-32069-ORDEQ	2007	13	0.04 - 1.3	0.025 - 0.03	**15.0**	0.42 (0.41)	**4.8 (4.7)**
OREGONDEQ-34235-ORDEQ	2018	13	0.0591	0.0213-2.72[3]	**15.6**	1.4 (0.7)	**16.4 (8.2)**
OREGONDEQ-37639-ORDEQ	2014	14	0.0274-0.395	0.0212 – 0.0862	**4.5**	0.22 (0.20)	2.5 (2.3)

[1] The source water concentration of chlorpyrifos necessary to result in the chlorpyrifos-oxon concentration in drinking water following conversion during treatment was back calculated from the DWLOC for chlorpyrifos-oxon using a molecular weight adjustment factor (DWLOC/0.9541) (4 µg/L/0.9541) = 4.2 µg/L

[2] The 1-day max concentration multiplied by the 21-day sampling bias as a surrogate from to estimate the upper bound 21-day average concentrations.

[3] 21-day average concentration was estimated using log-linear interpolation. Interpolated 21-day concentration using the detection limit was calculated using the detection limit, bracketed values include use of ½ the detection limit.

value is a censored concentration (i.e., below the minimum reporting limit)

Bold font Indicates concentration above the 10x DWLOC.

Watershed characteristics for these sampling sites are provided in **Figure 26**. All the sampling sites are in HUC-17 with sampling data collected by the Oregon Department of Environmental Quality. An overlap of the sampling site locations with counties associated with cropped acres for the use sites considered in this assessment is provided in **Figure 27**. Only three blue dots are visible on the map due to scaling as there are multiple sampling sites in proximity to one another (OREGONDEQ-32068-ORDEQ is near OREGONDEQ-32069-ORDEQ and OREGONDEQ-34235-ORDEQ is near OREGONDEQ-37639-ORDEQ).

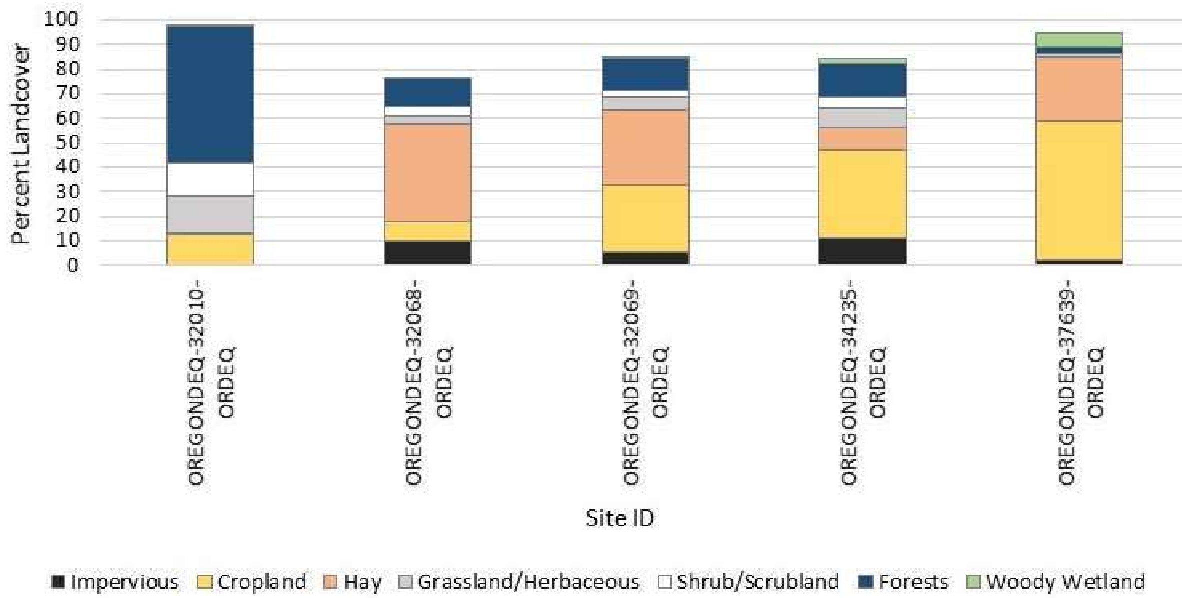

Figure 26. Summary of Site Landcover Characteristics for Sampling Sites with Sampling Bias Factor Adjusted Concentrations above 10x DWLOCs

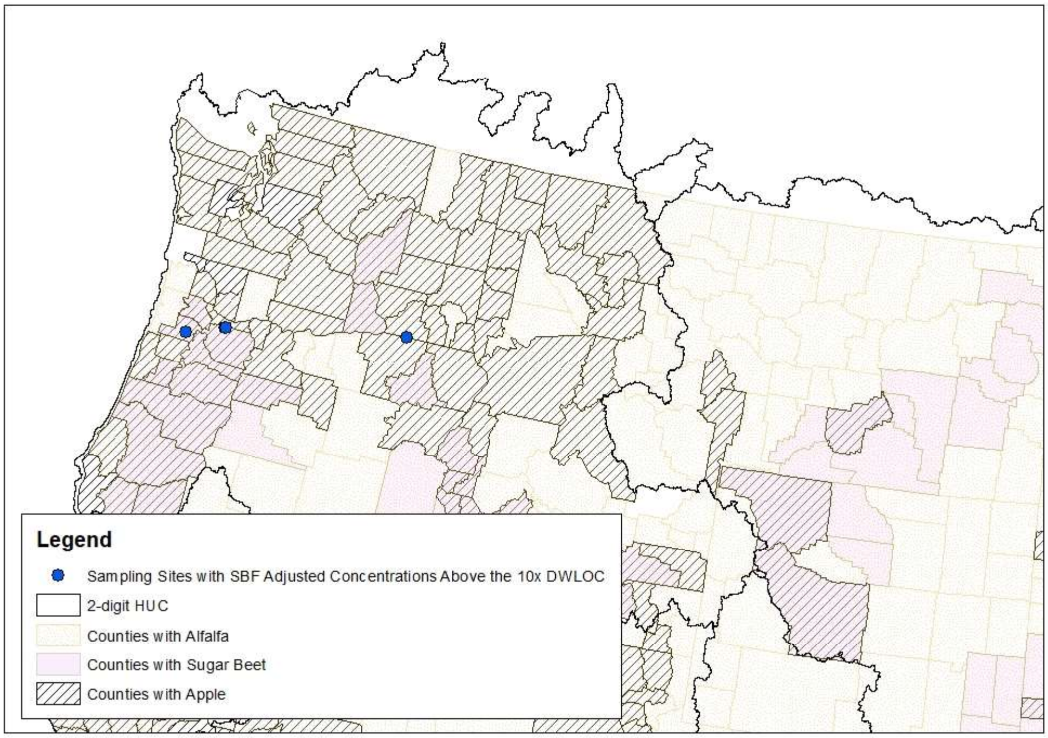

Figure 27. Summary of Site Landcover Characteristics for Sampling Sites with Sampling Bias Factor Adjusted Concentrations above 10x DWLOCs

Four of the sites have overlap with counties with all four uses (alfalfa, apple, strawberry and sugar beet) considered in this assessment in HUC-17 (**Figure 27**). These sites are in western Oregon. The occurrence timing is sporadic April through October. This suggest that there are likely multiple chlorpyrifos uses leading to occurrence in surface water within and across years. The other site OREGONDEQ-32010-ORDEQ is in eastern Oregon. This site overlaps with counties with three (alfalfa, apple, and strawberry) of the four uses considered in this assessment. For this site, chlorpyrifos is detected in surface water in March and April suggesting an early season dormant application such as to a tree fruits including apple, a use considered in this assessment. However, it cannot be determined if other uses are contributing.

Additional characterization of these sites is provided in **APPENDIX C.**

Sampling Sites with Less Than 13 Samples per Year

Sites with greater than 13 samples per year are appropriate for consideration quantitatively in DWAs, however, there is the potential that pesticide concentrations, from monitoring sites not meeting the criteria, could be higher and could lead to an underestimation of exposure in drinking water. Therefore, sampling data from sites where less than 13 samples per year are examined. Concentration data for these sites indicates there are several sites in several HUCs that may have concentrations above the 1-day and 21-day 10xDWLOC and a few sites that may have concentrations above the 1- and 21-day 1x DWLOC. There is overlap with the regions considered in this assessment (i.e., HUCs 03, 04, 06, 07, 08, 10, 12, 15, and 17.

Table 22 highlights the regions where concentrations may occur above the various DWLOCs. In addition, **Table 22** provides the total number of samples that suggest concentrations are above the respective DWLOCs. Additional characterization of these sites is provided in **APPENDIX C**.

Table 22. 2-digit HUC Summary of the Number of Sites with Potential Concentrations Above the DWLOCs

2-digit HUC	Max Measured Value	Site-Years			
		>1-day 10xDWLOC[1]	>21-day 10xDWLOC[2]	>1-day 1xDWLOC[3]	>21-day 1xDWLOC[4]
01	1.3	1	1		
02	0.2				
03	1.5	16 (1)	33 (4)		
04	0.8	3	3		
05	0.2				
06	1.5	6	10 (1)		
07	1.1	4 (1)	6 (1)		
08	1.7	1	1		
09	0.2				
10	14.7	1	2	1	1
11	0.2				
12	2.2	2	2		
13	0.2				
14	0.2				
15	0.6	1	1		
16	0.02				
17	3.3	4	6		
18	8.9	37 (13)	47 (18)	2	3
19	-				
20	0.9	1	1		
21	0.04				
Total Sites		76	113	3	4
Total Site-Years		119	165	3	4

1. 1-day chlorpyrifos-oxon 10x DWLOC = 23 µg/L; 1-day SBF = 54.8; reference concentrations >0.42 µg/L
2. 21-day chlorpyrifos-oxon 10x DWLOC = 4.0 µg/L; 21-day SBF = 11.5; reference concentrations >0.35 µg/L
3. 1-day chlorpyrifos-oxon 1x DWLOC = 230 µg/L; 1-day SBF = 54.8; reference concentrations >4.2 µg/L
4. 21-day chlorpyrifos-oxon 1x DWLOC = 43 µg/L; 21-day SBF= 11.5; reference concentration >3.7 µg/L

Bracketed values indicate the number of sites with multiple years where concentrations may be above the respective DWLOCs.
Gray shading indicates HUCs considered in the modeling analysis of this assessment.
SBF based on 13 samples per year was used although the same number may be much lower.

c. Weight of Evidence

Model estimated concentrations as well as measured concentrations of chlorpyrifos were evaluated to determine whether monitoring data suggested a potential DWLOC exceedance for either chlorpyrifos or chlorpyrifos-oxon (following drinking water treatment), with the lines of evidence described in **Table 23**.

Model estimated concentrations indicate that for the subset of assessed uses concentrations of chlorpyrifos and chlorpyrifos-oxon are not expected to be above the DWLOCs with or without the retention of the FQPA safety factor.

However, monitoring data suggest that in some areas of the country concentrations may exceed the DWLOC with and without the FQPA safety factor when all uses currently registered are considered since available monitoring data represent usage of chlorpyrifos. When considering the data with more than 13 samples per year, five sites all in HUC-17 indicated a potential for DWLOC exceedances. This is based on the application of sampling bias factors.

When considering the data with fewer than 13 samples per year, several sites indicated a potential for concentrations to be above the DWLOC. In one region, concentrations may exceed the 1x 1- and 21-day DWLOCs. Further analysis of sites with concentrations that could be higher than the DWLOCs could not definitively determine that the measured concentration was the results of a use or combination of uses considered in this assessment (i.e., the 11 critical or high benefit uses). It is possible that if more frequent monitoring data were available these conclusions could change.

Table 23. Lines of Evidence Used to Quantify and Characterize Potential Exposure to Chlorpyrifos and Chlorpyrifos-oxon

Lines of Evidence	
	Modeling
PWC Modeling	All uses and regions assessed are below DWLOCs. Some regions required a high-level of refinement. • **HUC-02 (apple and peach):** concentrations below DWLOCs based on upper bound application rates • **HUC-03 (cotton, citrus, peach, and soybean):** concentrations below DWLOCs based on upper bound application rates • **HUC-04 (alfalfa, sugar beet, apple, cherry, peach, soybean, and asparagus):** PCA aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-05 (apple and soybean):** concentrations below DWLOCs based on upper bound application rates • **HUC-06 (apple):** concentrations below DWLOCs based on upper bound application rates • **HUC-07 (alfalfa, sugar beet, and soybean):** PCA-PCT aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-09 (alfalfa, sugar beet, soybean, spring wheat, and winter wheat):** PCA-PCT aggregated concentrations below DWLOCs based on upper bound application rates • **HUC-10 (alfalfa, soybean, spring wheat, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-11 (alfalfa, soybean, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-12 (citrus, peach, and winter wheat):** concentrations below DWLOCs based on upper bound application rates • **HUC-17 (alfalfa, sugar beet, apple, and strawberry):** PCA aggregated concentrations below DWLOCs based on upper bound application rates

Monitoring	
SEAWAVE-QEX	Concentrations are not expected to exceed the DWLOC for 11 sites dispersed across the country.
Sampling Bias Factors	Monitoring data in HUC-17 indicate that concentrations could be above 10x DWLOC. These monitoring sites are in areas where the crops considered in this assessment are grown. However, there is also expected to be other crops where chlorpyrifos is applied and the contribution of these uses to the measured concentrations cannot be precluded.
Sites <13 Samples/year	This dataset had the highest detected concentration (14.7 μg/L) across the sample number categories and is predicted to have the lowest probability of capturing upper-bound concentrations. Nevertheless, there are several sites across the country that indicate concentrations may exceed the 1x and 10x DWLOCs including in regions assessed in this assessment. This suggests that current usage of chlorpyrifos could lead to concentrations above the DWLOCs.
Monitoring in Major Usage Area	There is limited data (i.e., low sample frequency and a low number of sites) in many areas of the locations and across years.
Uncertainty	The major uncertainty in understanding the monitoring results is an understanding of the usage data in relation to where and when monitoring occurred and how those relate to the uses under consideration in this assessment.

1. *HUC-02 (apple and peach)*

Upper bound use rates used in this assessment were from national level data supplied by BEAD several years ago. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs for chlorpyrifos use on apple and peach in HUC-02.

Monitoring data where the uncertainty could be quantified were limited. There was only 1 SEAWAVE-QEX site in HUC-02, which indicated concentrations were below the DWLOCs. Application of SBFs also indicated concentrations are likely below the DWLOCs in this region; however, sample frequency is generally low thus higher occurrence concentration likely occurred.

2. *HUC-03 (cotton, citrus, peach, and soybean)*

Upper bound use rates used in this assessment were from national level data for peach supplied by BEAD several years ago while usage data for cotton, citrus, and soybean were provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs for chlorpyrifos use on cotton, citrus, peach, and soybean in HUC-02.

Monitoring data where the uncertainty could be quantified were limited. There were only 2 SEAWAVE-QEX sites in HUC-03, which indicated concentrations were below the DWLOCs. These sites are in the northern portion of the region and does not capture the citrus growing area within the region. Application of SBFs suggested that concentrations maybe above the 10x DWLOCs in this region. Cotton, peach, and soybean are grown through the region and likely overlap with some of the sites where potential exceedance are possible. Generally, sample frequency is low in this region limiting the ability to confidently estimate concentration in the region from available monitoring data.

3. HUC-04 (alfalfa, sugar beet, apple, cherry, peach, soybean, and asparagus)

Upper bound use rates used in this assessment were from national level data for apple, cherry and peach supplied by BEAD several years ago while usage data for alfalfa, sugar beet, soybean and asparagus were provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs following aggregation using available PCAs. This is primarily driven by the low overlap of orchard acres with community water system watersheds.

Monitoring data where the uncertainty could be quantified were limited. There were only 2 SEAWAVE-QEX sites in HUC-04, which indicated concentrations were below the DWLOCs. These sites are in northern Ohio. The monitoring sites fall in areas where alfalfa, apple, peach, and soybean. The SEAWAVE-QEX sites are not in areas where sugar beet, cherry, or asparagus are grown. Application of SBFs suggested that concentrations maybe above the 10x DWLOCs in this region. This region has high frequency monitoring data includes those supported by NCWQR. Again, these high frequency sampling sites do not coincide with sugar beet, cherry, or asparagus growing areas.

4. HUC-05 apple and soybean

Upper bound use rates used in this assessment were from national level data for apple supplied by BEAD several years ago while usage data for soybean was provide at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were limited. There was only 1 SEAWAVE-QEX site in HUC-05, which indicated concentrations were below the DWLOCs. This site falls withing a country with reported acres of soybean; however, there is no reported acreage of apples in the county where the sampling site falls. Application of sampling bias factor suggested that concentrations do not exceed the DWLOCs in this region. However, this region generally has low frequency monitoring data.

5. HUC-06 apple

Upper bound use rates used in this assessment were from national level data for apple supplied by BEAD several years ago. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs suggest there are sites that could exceed the 10x DWLOC. These sites overlap with counties reporting acres of apples. This region generally has low frequency monitoring data.

6. HUC-07 alfalfa, sugar beet, and soybean

Upper bound use rates used in this assessment were from usage data for alfalfa, sugar beet, and soybean provide at a state-level. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs based on PCA-PCT aggregation, the highest level of model refinement used in this assessment.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs suggest there are sites that could exceed the 10x DWLOC. These sites overlap with counties reporting acres of apples. This region generally has low frequency monitoring data.

7. HUC-09 Alfalfa, Sugar beet, Soybean, Spring Wheat, and Winter Wheat

Upper bound use rates used in this assessment were from usage data for alfalfa, sugar beet, soybean spring wheat, and winter wheat were provided at a state-level. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs based on PCA-PCT aggregation, the highest level of model refinement used in this assessment.

Monitoring data where the uncertainty could be quantified were not available for this region. Application of SBFs did not lead to the identification of sites that could have concentrations above the DWLOCs. However, generally this region has a low frequency monitoring data.

8. HUC-10 Alfalfa, Soybean, Spring Wheat, and Winter Wheat

Upper bound use rates used in this assessment for alfalfa, soybean, spring wheat and winter wheat were provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. This region has the highest single measured concentration of chlorpyrifos (14.7 µg/L). Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC and 1x DWLOC. This is primarily driven by the one high detection. Generally, this region has a low frequency monitoring data.

9. HUC-11 Alfalfa, Soybean, and Winter Wheat

Upper bound use rates used in this assessment for alfalfa, soybean, and winter wheat were provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs.

Monitoring data where the uncertainty could be quantified were not available for this region. This region has the highest single measured concentration of chlorpyrifos (14.7 µg/L). Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC and 1x DWLOC. This is primarily driven by the one high detection. Generally, this region has a low frequency monitoring data.

10. HUC-12 Citrus, Peach, and Winter Wheat

Upper bound use rates used in this assessment for citrus, peach, and winter wheat were provided at a state-level and are based on more recent data. Modeling suggests concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs. Recall, that at the time of this assessment a new model scenario was not available for deciduous orchards. Therefore, the evergreen orchard scenario was used. The impact on estimated concentrations is not known.

Monitoring data where the uncertainty could be quantified were not available for this region. There was only 1 SEAWAVE-QEX site in HUC-12, which indicated concentrations were below the DWLOCs. This site falls withing a county with reported acres of peach and wheat. However, this site does not cover areas where citrus is grown. Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC.

11. HUC-12 Alfalfa, Sugar beet, Apple, and Strawberry

Upper bound use rates used in this assessment for alfalfa, sugar beet was provided at a state-level and are based on more recent data. Modeling suggest concentrations for chlorpyrifos and chlorpyrifos-oxon are below the DWLOCs following aggregation using available PCAs. Application of SBFs indicate that this region could have sites that exceed the 10x DWLOC.

Monitoring data where the uncertainty could be quantified were not available for this region. There was only 1 SEAWAVE-QEX site in HUC-17, which indicated concentrations were below the DWLOCs. There are five sites in Oregon with enough sampling to have confidence in the prediction intervals to have confidence in the SBF-adjusted concentrations. In some cases, concentrations above the 10x DWLOC were estimated to occur over multiple years. Furthermore, these estimates were all estimated to occur after the labels for chlorpyrifos were updated in the mid-2000s. These sites were determined to be relevant to community water systems as all the sites were upstream with a short travel time to the often less than a day. These sites were in areas where may different chlorpyrifos uses could be occurring includes those considered in this assessment for HUC-17.

12. Other Considerations

One major uncertainty in understanding the monitoring results is the uncertainty in the usage data, which is only available at the state level for a limited number of use patterns. Additionally, how the monitoring relates to the usage in time and space is not readily available. This makes it extremely difficult to determine if any of the reported exceedance may have been the result of one of the uses considered in this assessment. Therefore, the results of this assessment indicate that it is important to consider all potential use sites when estimating potential exposure in drinking water.

Another major uncertainty is that in general sampling frequency for chlorpyrifos has tapered off over the last decade as well as detection frequency. It is unknow if the lack of sampling is contributing to the reduced detection frequency or if detection frequencies are decreased. Likely both are contributing factors. Often reduced testing lead to reduced detection frequency unless sampling is specifically started to use.

Higher SBFs were driven by measured concentrations value input into SEAWAVE-QEX. This generally resulted in tighter confidence bounds around the measured concentration; however, the ability of SEAWAVE-QEX to capture the peak occurrence concentration for a sporadically used pesticide is questionable. Furthermore, when more frequent data were input into SEAWAVE-QEX higher concentrations were estimated. Therefore, when infrequently sampling data are input into SEAWAVE-QEX it is possible that concentrations as well as SBFs developed from the resulting chemographs underestimate the potential range of concentrations occurring in the environment. It is possible that SBFs are underestimated for chlorpyrifos in this assessment and the exposure potential underestimated. More frequency data would help address this concern.

Chlorpyrifos-oxon concentrations in drinking water are primarily driven by chlorpyrifos concentrations in source water. In source water chlorpyrifos is stable compared to chlorpyrifos-oxon. Once formed during drinking water treatment chlorpyrifos-oxon has increased stability (t ½= 12 days) under drinking water conditions compared to environmental conditions. This suggests that chlorpyrifos -oxon is stable during the expected range of distribution times which can be a few hours to several days.

Conclusions

This assessment focuses on a subset of currently registered chlorpyrifos uses – alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat in specific areas of the country. This subset of uses was identified as being the most important of all the currently registered uses of chlorpyrifos. This assessment utilized new surface water model scenarios (i.e., soil, weather, and crop data), integrates the entire distribution of community water system percent cropped area adjustment factors and integrates state-level percent crop treated data, and considers the quantitative use of available surface water monitoring data.

Concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water are not likely to exceed the drinking water level of comparison (DWLOC) with or without the retention of the FQPA safety factor for the subset of uses considered. This conclusion is based on upper bound application rates for the subset of assessed uses. Furthermore, a thorough analysis of monitoring data was completed and indicates that there are several monitoring sites across the United States that could have concentrations higher than the DWLOCs (with and without the retention of the FQPA safety factor). However, the contribution of other currently registered uses of chlorpyrifos (i.e., uses not considered in this assessment) could not be ruled out, nor could a definitive conclusion be made that the measured concentration data correlated to one of the specific uses evaluated in this assessment.

References

Aulenbach, B.T., Buxton, H.T., Battaglin, W.T., and Coupe R.H., 2007, Streamflow and nutrient fluxes of the Mississippi-Atchafalaya River Basin and subbasins for the period of record through 2005: U.S. Geological Survey Open-File Report 2007-1080

Bohaty, R. Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment, June 20, 2011, PC Code: 059101; DP Barcode: 368388, 389480

Fry, M. M., Rothman, G., Young, D. F., Thurman, N., Daily Gridded Weather for Pesticide Exposure Modeling, Environmental Modelling & Software, August 2016, https://doi.org/10.1016/j.envsoft.2016.04.008

Hill, Ryan A., Marc H. Weber, Scott G. Leibowitz, Anthony R. Olsen, and Darren J. Thornbrugh, 2016. The Stream-Catchment (StreamCat) Dataset: A Database of Watershed Metrics for the Conterminous United States. Journal of the American Water Resources Association (JAWRA) 52:120-128. DOI: 10.1111/1752-1688.12372.

Paisley-Jones, C., Chlorpyrifos (059101) National and State Summary Use and Usage Summary, April 1, 2020.

U.S. Environmental Protection Agency. Chlorpyrifos Refined Drinking Water Assessment for Registration Review, April 14, 2016, PC Code: 059101; DP Barcode 432921.

U.S. Environmental Protection Agency, Office of Pesticide Programs. The Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Food Quality Protection Act (FQPA) Drinking Water Assessment, October 25, 2001.

U.S. Environmental Protection Agency, Assessment of pesticide concentrations in drinking water and water treatment effects on pesticide removal and transformation, FIFRA Scientific Advisory Panel Meeting September 26-29, 2000.

U.S. Environmental Protection Agency. 1989. Technologies for Upgrading Existing or Designing New Drinking Water Treatment Facilities. EPA/625/4-89/023.

U.S. Environmental Protection Agency, 2006 Community Water System Survey.

U.S. Environmental Protection Agency, *Progress Report on Estimating Pesticide Concentrations in Drinking Water and Assessing Water Treatment Effects on Pesticide Removal and Transformation: A Consultation.* FIFRA Scientific Advisory Panel Meeting, Sept 29, 2000; SAP Report No. 2001-02 February 12, 2011.

U.S. Environmental Protection Agency, Estimating Field and Watershed Parameters Used in USEPA's Office of Pesticide Programs Aquatic Exposure Models, Sept 2020.

U.S. Environmental Protection Agency, Creating New Scenarios for Use in Pesticide Surface Water Exposure Assessments, Sept 2020.

U.S. Environmental Protection Agency, White, K., Khan, F., Peck, C., Corbin, M. Guidance on Modeling Offsite Deposition of Pesticides via Spray Drift for Ecological and Drinking Water Assessments, December 19, 2013.

U.S. Environmental Protection Agency, Office of Pesticide Programs. The Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Food Quality Protection Act (FQPA) Drinking Water Assessment, October 25, 2001.

Vecchia, A.V., and Williams-Sether, T., 2018, Data Files to Support SEAWAVE-QEX Model for Simulating Concentrations of Selected Pesticides in the Continental United States, 1992-2012: U.S. Geological Survey data release, https://doi.org/10.5066/F7NV9H50.

Young, D.F. and Fry, M.M., 2014. A Model for Predicting Pesticide in Runoff, Erosion, and Leachate: User Manual, U.S. Environmental Protection Agency, Washington, DC. USEPA/OPP 734F14002.

Young, D. F., 2014. The Variable Volume Water Model, U.S. Environmental Protection Agency, Washington, DC. USEPA/OPP 734F14003.

APPENDIX A. Summary of Uses Considered

Critical Uses

Alfalfa

Use of chlorpyrifos to treat alfalfa weevil was identified as one of the most critical uses by Corteva Agriscience. Analysis completed by BEAD indicates that chlorpyrifos is only used on alfalfa in HUC-04, -07, -09, -10, -11, -13, -14, -15, -16, and -17. Application rates for alfalfa weevil larvae and adults are permitted between 0.47-0.94 lb a.i./A (Lorsban Advance Reg. No. 62719-591). This falls within the reported use range for chlorpyrifos use on alfalfa. Usage data across all regions with reported use, suggest that only one of the four permitted applications occurs per year in alfalfa. Most applications are applied by ground equipment; however, in some regions, such as HUC-14, almost half of the applications are made by aerial equipment. Generally, applications to treat alfalfa weevil occur mid-April through early June depending on the 2-digit HUC region.

Citrus – Oranges, Lemons, and Grapefruit

Since the introduction of the Asian citrus psyllid (ACP) to the continental U.S. in 1998, chlorpyrifos has become one of several insecticides used to control this pest, which transmits the incurable citrus greening disease, or Huanglongbing. Use of chlorpyrifos to treat scale insects[18] was identified as one of the most critical uses by Corteva Agriscience. While growers report the use of chlorpyrifos against scale insects over the largest area in HUC-12, usage of chlorpyrifos in HUC-03 against scale is over a much smaller area compared to ACP and citrus rust mites. Application timing and information focused on the most significant use. An analysis completed by BEAD indicates that (outside California) chlorpyrifos is only used on citrus in HUC-03 and HUC-12. Usage data suggest only one chlorpyrifos application occurs per year on average, and that most applications occur via ground equipment. The average application rate is 2.7 lb/A, while the upper bound application rate is 3.5 lb/A. Applications to treat ACP and citrus rust mite occur in early May in HUC-12, while applications targeting ACP, citrus rust mite and scales occur in early June in HUC-03.

Cotton

Chlorpyrifos is used against cotton aphid, silverleaf whitefly, and stinkbugs (various species) (**ATTACHMENT 2**). Analysis recently completed by BEAD indicates that chlorpyrifos is only used on cotton in HUC-03. Label rates for cotton are permitted at up to 1.0 lb/A three times per year. The average rate of chlorpyrifos made to cotton is 0.21 lb/A, with an upper bound application rate of 0.50 lb/A, with 99% of all application occurring via foliar ground spray. Usage data suggest that two applications of chlorpyrifos occur per year in cotton. Using the state of Georgia to represent use of chlorpyrifos on cotton in HUC-03, BEAD suggests the first application of chlorpyrifos occurs on May 20 with the second application occurring on June 30.

Soybean

Use of chlorpyrifos to treat two-spotted spider mites was identified as one of the most critical uses by Corteva Agriscience. An analysis completed by BEAD indicates that chlorpyrifos is only used on soybean

[18] Exclude California red scale (California and Arizona). California recently cancelled almost all chlorpyrifos use.

in HUC-03, -04, -05, -07, -09, -10, and -11. Application rates for two-spotted spider mites are permitted between 0.23-0.47 lb/A (Lorsban Advance Reg. No. 62719-591). This falls within the reported average use range for chlorpyrifos use on soybean. Usage data across all regions with reported use suggest only one application of chlorpyrifos occurs per year on soybean. Most applications are made by ground equipment, except in HUC-10, where about half of the applications are made by air. Generally, applications that are made to treat two-spotted spider mites occur in early to mid-July, depending on the region.

Sugar beet

Use of chlorpyrifos to treat sugar beet root maggot was identified as one of the most critical uses by Corteva Agriscience. Analysis completed by BEAD indicates that chlorpyrifos is only used on sugar beet in HUC-04, -07, -09, and -17. Applications rates for sugar beet root maggot larvae and adults are permitted between 0.23-0.94 lb/A (Lorsban Advance Reg. No. 62719-591) and 2.0 lb/A (Lorsban 15G). Average application rates range from 0.5 to 1.16 lb a.i./A with upper-bound rates ranging between 1.25-1.5 lb a.i./A. Usage data across all regions with reported use, suggest only one application occurs per year in sugar beet. Both at-plant and foliar applications are reported. Most applications are applied by ground equipment. The highest percent of application applied by air is 20% for HUC-17. Generally, applications to treat sugar beet root maggot occur in June for foliar applications. Soil applications are noted to occur earlier in the season – roughly 1.5 months.

Wheat

Use of chlorpyrifos to treat Russian wheat aphid was identified as one of the most critical uses by Corteva Agriscience. However, there are multiple species of aphids present in wheat (wheat aphid complex), and Russian wheat aphid is not necessarily the most targeted species in all states. Russian wheat aphid and other species in the wheat aphid complex can affect both spring and winter wheat. An analysis completed by BEAD indicates that chlorpyrifos is only used on spring wheat in HUC-09 and -10 and on winter wheat in HUC-09, -10, -11, and -12. Applications rates for all aphids are permitted between 0.23-0.47 lb a.i./A (Lorsban Advance Reg. No. 62719-591). Average application rates range from 0.21 to 0.44 lb a.i./A for winter wheat with upper-bound rates ranging between 0.5 to 0.75 lb a.i./A. Usage rates are similar for spring wheat. Usage data across all regions with reported use, suggest only one application occurs per year in wheat. Most applications are applied by ground equipment. The highest percent applied by air is 41% for HUC-10. Applications begin as early as April and extend through June depending on the region.

High Benefit Uses

Apple

The use of chlorpyrifos on apples is a high benefit in HUC-02, -04, -05, -06, and -17 for the control of scale insects. Chlorpyrifos applications up to 3 lb a.i./A are permitted on apples with no more than 2 lb a.i./A permitted as a dormant/delayed dormant application (no in season applications are allowed). The majority (95%) of applications are applied by ground equipment. The average application rate is 1.5 lb/A (USEPA, 2013). The maximum rate observed is 2.8 lb/A with the 90th percentile at 2.0 lb/A. Average number of applications is 1.2. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Asparagus

A high benefit use of chlorpyrifos identified by BEAD is managing cutworms in asparagus in HUC-04. All applications are expected to occur via ground equipment. Application rates are permitted up to 1.5 lb a.i./A for granular applications and up to 1.0 lb a.i./A for liquid applications. Based on usage data, only one application is expected to occur each year, either once in the spring or once in the fall. Spring applications are soil directed while fall applications are foliar. The average application rate is 0.96 lb a.i./A with the maximum observed application rate of 1.0 lb a.i./A. Only about 7% of applications are made at a lower rate of 0.5 lb a.i./A.

Cherry

The use of chlorpyrifos to control borers that damage tart cherry in HUC-04 is considered a high benefit use. Single application rates on cherries are permitted at up to 4.0 lb a.i./A, with maximum annual rates of 4.5 lb a.i./A for sweet cherries and 14.5 lb a.i./A for tart cherries. The majority (98%) of applications are applied by ground equipment. The average application rate is 1.5 lb/A (USEPA, 2013). The maximum rate observed is 3.0 lb/A with the 90th percentile at 2.0 lb/A. Average number of applications is 1.1. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Peach

The use of chlorpyrifos to control borers that damage peach trunks is a high benefit in the southeastern United States (HUC-02, 03, 04, and 12). Chlorpyrifos applications up to 3 lb a.i./A are permitted on peaches with no more than 2 lb a.i./A permitted as a dormant/delayed dormant application. The majority (95%) of applications are applied by ground equipment. The average application rate is 1.3 lb/A (USEPA, 2013). The maximum rate observed is 3.0 lb a.i./A with the 90th percentile at 2.0 lb/A. Average number of applications is approximately one per year. This usage information is based on data provided by BEAD in 2012 and covers usage between 2006-2010 (USEPA, 2012).

Strawberry

A critical use of chlorpyrifos identified by BEAD is to treat garden symphylans and strawberry crown moth[19] in strawberry in HUC-17, specifically in Oregon. A single application at up to 2.0 lb a.i./A is permitted with a maximum annual rate of 4.0 lb a.i./A. All applications are expected to occur via ground equipment to the soil. Only one application is expected to occur each year. The average application rate is 1.24 lb a.i./A with the maximum observed application rate of 2.0 lb a.i./A. Usage data are based on data from 2011 to 2015. Insecticide usage has not been surveyed in Oregon since 2015.

[19] http://storage.dow.com.edgesuite.net/dowagro/chlorpyrifos/Who_needs_chlorpyrifos_and_why_(by_crop).pdf accessed June 23, 2020.

APPENDIX B. Results for Average Application Rates

Results from PWC are presented in

Table 24 for both chlorpyrifos and chlorpyrifos oxon for average application rates. This table only presents results for the four 2-digit HUCs (HUC-04, -07, -09 and -17) where the upper bound EDWCs are above the 10x DWLOC. Application of PCAs indicates that only the 1-in-10 year 21-day average chlorpyrifos-oxon concentration may be greater than the 10x DWLOC in two 2-digit HUC regions (HUC-04 and -07) for average applications rates. It should be noted in using this approach, there are four regions where crop specific PCAs are greater than the all-agricultural PCA. This is due to how the misc-Ag value is calculated to account for the potential double cropping. In these situations, the use pattern specific PCAs are capped at the all-Ag PCA.

Table 24. PCA Adjusted EDWCs for Average Application Rates of Chlorpyrifos

2-digit HUC	Use Site	2-Digit HUC Maximum Use Pattern Specific PCA	Batch Run ID[a]	1-day Model EEC (cpy)	21-day Model EEC (cpy)	1-day Model EEC (cpyo)	21-day Model EEC (cpyo)	Adj 1-day EDWC (cpy)	Adj 21-day EDWC (cpy)	Adj 1-day EDWC (cpyo)	Adj 21-day (cpyo)
				µg/L							
04	Alfalfa	0.92[b]	608_4_MI-186800-22356-36	1.3	1.0	1.2	1.0	1.2	0.9	1.2	0.9
	Sugar beet		1016_4_MI-186667-22116-41	2.8	1.9	2.7	1.8	2.6	1.7	2.5	1.7
	Apple		734_4_MIcherrySTD	13.0	11.2	12.4	10.7	11.9	10.3	11.4	**9.8**
	Cherry		740_4_MIcherrySTD	13.0	11.2	12.4	10.7	11.9	10.3	11.4	**9.8**
	Peach		740_4_MIcherrySTD	9.5*	8.28*	9.1	7.9	8.8	7.5	8.3	**7.2**
	Soybean		851_4_MI-188235-22121-5	2.1	1.2	2.0	1.1	2.0	1.1	1.9	1.0
	Asparagus		739_4_MIasparagusSTD	3.6	2.1	3.4	2.0	3.3	1.9	3.1	1.8
07	Alfalfa	0.90	617_4_MO-2528577-19014-37	4.1	2.3	3.9	2.2	3.7	2.1	3.5	2.0
	Sugar beet		989_4_MN-2423043-23487-41	8.9	6.4	8.5	6.1	8.0	5.8	7.7	**5.5**
	Soybean		869_4_MN-2877271-22781-5	2.2	1.4	2.1	1.3	2.0	1.2	1.9	1.2
09	Alfalfa	0.95[c]	626_4_SD-416559-24423-36	1.1	0.9	1.0	0.9	1.1	0.8	1.0	0.8
	Sugar beet		1043_4_ND-2642948-27020-41	5.4	3.6	5.2	3.4	5.1	3.4	4.9	3.2
	Soybean		887_4_ND-2571399-26297-5	1.6	1.0	1.5	1.0	1.5	1.0	1.4	0.9
	Spring wheat		1079_4_ND-2585363-27001-23	1.4	0.9	1.3	0.9	1.3	0.8	1.3	0.8
	Winter wheat		1133_4_ND-341303-27230-24	3.4	2.3	3.2	2.2	3.2	2.1	3.1	2.0
17	Alfalfa	0.53	717_4_WA-71453-24575-36	1.3	0.9	1.2	0.9	0.7	0.5	0.6	0.4
	Sugar beet		1007_4_ID-79974-21766-41	3.7	2.5	3.5	2.4	1.9	1.3	1.8	1.3
	Apple		737_4_ORappleSTD	7.2	4.7	6.9	4.5	3.8	2.5	3.7	2.4
	Strawberry		966_4_ID-80309-21523-12	10.4	7.5	9.9	7.2	5.5	4.0	5.3	3.8

a. Batch run name is truncated (DWA_2020 was removed for reporting purposes).
b. Use pattern specific PCA is slightly higher (0.93) than all-ag PCA (0.92). Use pattern specific PCA is capped at all-ag value.
c. Use pattern specific PCA is higher (>1) than all-ag PCA (0.95). Use pattern specific PCA is capped at all-ag value.

*Average rate modeled for apples and cherries is 1.5 lb a.i./a. The upper bound rate for peach on a national level is 1.1 lb/a. Results were multiplied by 1.1/1.5 to estimated concentrations for peach.
Green shading indicates concentrations below the 10xDWLOC.
Reg shading and bold font indications concentrations above the 10x DWLOC.
Chlorpyrifos (cpy)
Chlorpyrifos-oxon (cpyo)

Examination of the full distribution of PCAs for HUC-04 and -07 (i.e., those 2-digit HUCs with average application rates resulting in EDWCs above the 10x DWLOC) indicate that there are 138 CWS watersheds where chlorpyrifos-oxon concentrations could be above the 10x DWLOC (**Table 14**).

Table 25. Full Distribution of Watershed Specific PCA-Adjusted EDWCs for Average Applications of Chlorpyrifos-oxon

2-digit HUC	Total CWS	Max 1-in-10 year 21-day (cpyo) µg/L	Critical 21-day PCA (cpyo)	No. of CWS above 21-day DWLOC (percent)
		Average Application Rates		
04	196	10.7	0.37	79 (40)
07	158	6.1	0.66	49 (31)

The prior analysis for the average application rates indicates there could be concentrations above the 10x DWLOC for HUC-04 and HUC-07. However, aggregation of the 1-in-10 year concentrations indicates that concentrations in HUC-04 are not expected to be above the 21-day 10x DWLOC. Therefore, aggregation of concentrations in only HUC-07 was completed for the average application rates.

Aggregation of the 1-in-10-year concentrations for watersheds in HUC-07 indicate that two CWS watersheds could have concentrations above the 10x DWLOC for average application rates. Results are presented in **Table 26**.

Table 26. Aggregation of 1-in-10 year PCA adjusted 21-day Average EDWCs for Average Application Rates of Chlorpyrifos-oxon

2-digit HUC	Aggregated 21-day (cpyo) µg/L	No. of CWS above 21-day DWLOC	Total CWS	Percent of CWS above 21-day DWLOC
07	4.1	2	158	1

Appendix C. Monitoring Data Analysis Technical Chapter

a. Introduction

This technical chapter is intended to supplement the drinking water assessment by providing the technical details of the analysis and interpretation of the available monitoring data considered quantitively and summarized in the drinking water assessment. Each subsequent subsection is dedicated to an individual sampling site. Depending on what analysis was done for the site each section may include: 1) site characterization based on size and landcover percentages of the National Land Cover Database for 2006 as reported in StreamCat 2) SEAWAVE-QEX analysis, 3) sampling bias factor development and 4) sampling bias factor application. For example, a summary of the available monitoring data for each site, procedures for fitting SEAWAVE-QEX, and description of the diagnostic plots from the final fit are provided for each site. In addition, developed SBFs are presented and described.

SEAWAVE-QEX Analysis

For SEAWAVE-QEX analysis, surface water monitoring sites were screened for potential use in SEAWAVE-QEX based on the minimum requirements of the model. A Microsoft Access query was used to determine which sites might be able to run in SEAWAVE-QEX (Access file is provided in **ATTACHMENT 3**). The tool searched for sites that met the minimum criteria (at least 3 years with 12 or more samples with a 25% detection frequency), which included comparing the results column with the detection limit column, as often data in the WQP are not properly identified as being detected or below the detection limit. The sites that remained were evaluated for use in SEAWAVE-QEX.

Sites that could not be successfully used in SEAWAVE-QEX are summarized in **Table 27** One site did not have accompanying flow data and two sites could not be confidently simulated by the model as model assumptions were not verified. Two additional sites were successfully run in SEAWAVE-QEX but a surface-level analysis of the streamflow data and how it is used in SEAWAVE-QEX for these sites indicated that the sites may not be appropriate to use quantitatively. Monitoring data from the 11 remaining sampling sites run in SEAWAVE-QEX were deemed acceptable for quantitative use based on goodness-of-fit criteria described in the model's Standard Operating Procedure (SOP; USEPA, 2019). The model fit was optimized for each site as needed by changing the years included in the analysis or adding a small constant to the concentration values within SEAWAVE-QEX. These sites are detailed in the following section along with the 11 sites selected for quantitative analysis.

Table 27. Summary Table of Sites Not Included in SEAWAVE-QEX Analysis

USGS Site ID	Site Name	No or limited flow data	Model assumptions not verified	Site not applicable	Comment
06800000	Maple Creek near Nickerson, NE		X		Estimated maximum concentration above blue boxes, large 2x SSD. Tight residuals. CTS maxed out and correlogram is too low (overestimating).
08364000	Rio Grande at El Paso, TX		X		Flow data not available at USGS but found data from the International Boundary and Water Commission.

USGS Site ID	Site Name	No or limited flow data	Model assumptions not verified	Site not applicable	Comment
					However, correlogram often missing from diagnostic plot at lower sampling times (e.g., 5-day).
11273500	Merced R A River Road Bridge near Newman, CA	**X**			No flow data found.
11447360	Arcade Creek near Del Paso Heights, California			**X**	Intermittently flowing site (see description below)
14201300	Zollner Creek near Mt. Angel, OR			**X**	Intermittently flowing site (see description below)
SSD standard deviation					

Sampling Bias Factor Development

Using the chemographs from the SEAWAVE-QEX analysis, short-term pesticide-specific SBFs were developed for chlorpyrifos for application to monitoring data that did not meet the SEAWAVE-QEX criteria. This was done using Python code (ncg_merg.py), a Python integrated development environment (IDE) (Spyder 3.7), and the methods described in Chapter 4 of the White Paper for the 2019 FIFRA SAP. Short-term SBFs are developed for all sites where model assumptions were satisfied for SEAWAVE-QEX (i.e., 11 sites) as data are only available to calculate SBFs for a limited number of sites.

Sampling Bias Factor Application

SBFs for 1987-2012 (all years) and 2005-2012 (post-registration review label changes) were applied based on the number of samples per year for all site-years of data from the Water Quality Portal with greater than or equal to 13 sampled per year (**Table 28**).

Table 28. Maximum Sampling Bias Factors

Sample Number	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Fact	Maximum 1987-2012 Sampling Bias Factor	Maximum 2005-2012 Sampling Bias Factor
	1-day		21-day	
52+	10.9	5.3	4.0	2.4
26-51	23.3	11.9	6.1	5.2
17-25	38.5	17.8	8.4	7.3
13-16	54.8	22.2	11.5	8.9

b. Detailed Site Analysis

1. USGS-11303500

Site and Sampling Characterization

USGS site 11303500 (San Joaquin River near Vernalis, California) has a 13,844 mi^2 (35,855 km^2) watershed in HUC 18. The watershed for the collection site has 22% cropland along with a high percentage of natural areas (e.g., grasslands, forests, shrubs), as shown in **Figure 28.** Watershed Landcover Characteristics of Sampling Site USGS-11303500 . This sampling site is upstream of several community water systems drinking water intakes with a time of travel of less than a day to each intake, implying that the site is relevant to community water systems in the area. Additionally, the site may be representative of other agricultural areas that affect CWS, as it is downstream of many other intakes with travel times ranging from 2 to 8 days.

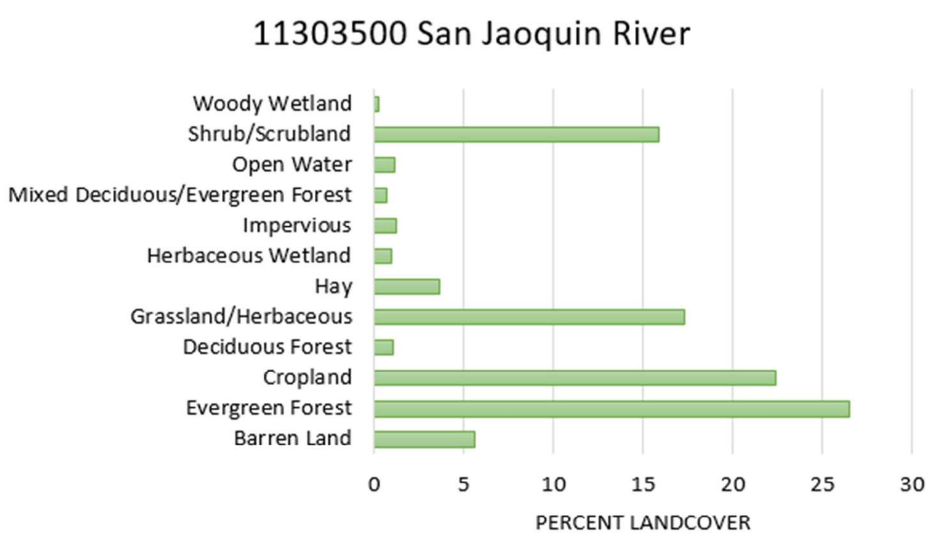

Figure 28. Watershed Landcover Characteristics of Sampling Site USGS-11303500

This site had a total of 190 chlorpyrifos detections out of 528 samples over 27 years between 1992 and 2019. Only 12 years of data have at least 12 or more samples and a detection frequency greater than 25%, as shown in **Table 29**. **Table 29** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 29. Data Summary for USGS-11303500

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	20	16	80%			
1993	37	23	62%			
1994	17	12	71%	✓	4	✓
1995	9	4	44%	✓	1	✓
1996	0	—	—	✓	—	✓
1997	11	6	55%	✓	0	✓
1998	12	3	25%	✓	0	✓
1999	12	1	8%	✓	0	✓
2000	31	23	74%	✓	10	✓
2001	53	31	58%	✓	14	✓
2002	22	9	41%	✓	2	✓
2003	17	7	41%	✓	0	✓
2004	8	5	63%	✓	0	✓
2005	6	1	17%	✓	0	✓
2006	8	3	38%	✓	0	✓
2007	22	9	41%	✓	0	✓
2008	22	14	64%	✓	0	✓
2009	22	0	0%	✓	0	✓
2010	22	4	18%	✓	0	✓
2011	21	7	33%	✓	0	✓
2012	25	9	36%	✓	1	✓
2013	21	0	0%			
2014	18	1	6%			
2015	23	0	0%			
2016	28	1	4%			
2017	21	0	0%			
2018	19	1	5%			
2019	1	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1994-2012 were used as SEAWAVE-QEX inputs. Expanding the years to include 1992 and 1993 was explored, however, the best fit was determined to be for the period from 1994 to 2012 with default SEAWAVE-QEX parameters.

The 80% confidence bounds on the estimated maximum for each year are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. Only two years (1995 and 2004) have 80% confidence bounds that overlap with the highest measured concentration from 1994-2012 (0.05 µg/L), occurring in 2004. One other higher concentration was measured in 1993, 0.079 µg/L, a year that was not included in the final run. When running 1992-2012, there is less confidence in the normality of the residuals than when running from 1994-2012. Additionally, the high concentration in 1993 is not used by SEAWAVE-QEX due to the automatic sample spacing and higher frequency sampling occurring immediately before. The model gives a single shallow seasonal wave with a season spanning from early January to early October and few concentrations outside of the 2SSD bounds, which span less than an order of magnitude. Adjusted concentrations do not have much trend over time and have a significant (α=0.05) negative correlation with MTFA and significant positive correlation with STFA. The normalized residuals are centered on zero with one residual skewing very positive in 2004, likely corresponding with the large measured concentration in that year. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function with a CTS of 9 days.

Table 30 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 30. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-11303500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1994	0.073	0.043
1995	0.047	0.030
1996	0.054	0.035
1997	0.050	0.029
1998	0.031	0.016
1999	0.031	0.018
2000	0.042	0.023
2001	0.041	0.021
2002	0.043	0.028
2003	0.037	0.022
2004	0.065	0.042
2005	0.051	0.031
2006	0.026	0.017
2007	0.041	0.021
2008	0.034	0.021
2009	0.033	0.018
2010	0.031	0.017
2011	0.025	0.016
2012	0.024	0.017

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 29** and **Figure 30**, respectively. All the 1-day and 21-day SBFs figures have the same x- and y-axis scales to permit evaluation of the differences in magnitude of the values across sites and years. These figures show the variation in SBFs derived across the years where data are available to develop SBFs based on the number of samples collected (13-16 samples/year, 17-25 samples/year, 26-51 samples/year and 52+ samples per year). Recall, the median SBF is calculated across the 100 SEAWAVE-QEX chemographs. All SBFs associated data files are provide in **ATTACHMENT 4**.

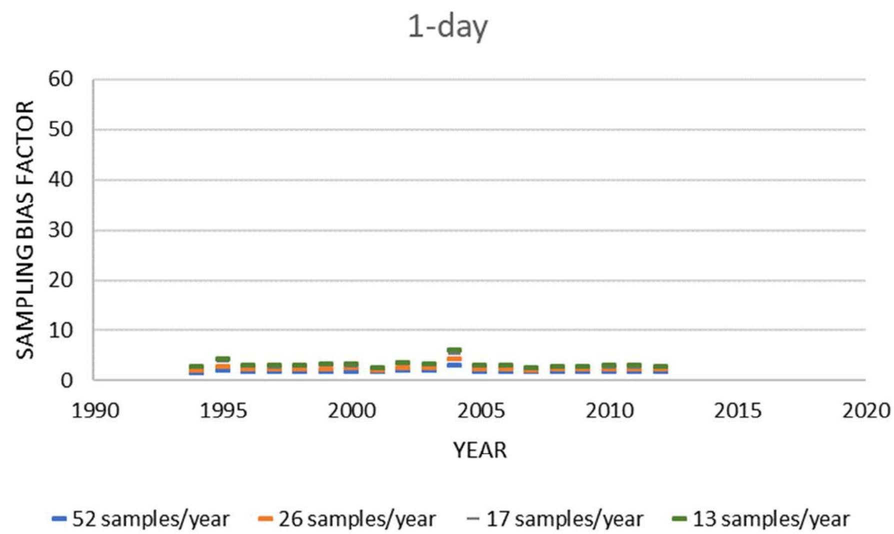

Figure 29. USGS Site 11303500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-11303500 for estimating the upper confidence interval on the 1-day average concentration except for two years, 1995 and 2004. SBFs for all sample number categories are below 4 for the upper confidence interval on the 1-day average concentration. The SBFs for 1995 and 2004 are noticeably higher than other years, SBFs are roughly 6 or below for all sample categories.

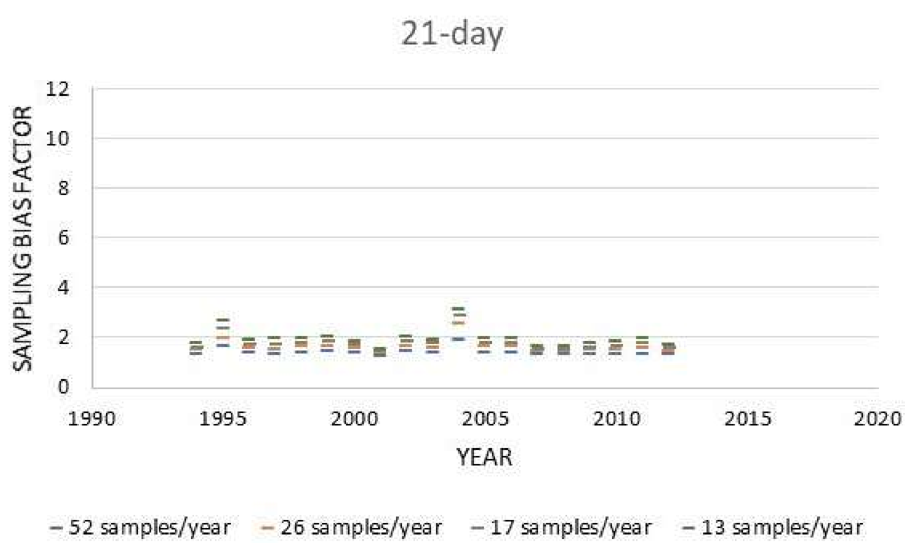

Figure 30. USGS Site 11303500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

A similar, consistent trend is observed for the SBFs for estimating the upper confidence interval on the 21-day average. SBFs for all sample number categories are below 2 for all years except 1995 and 2004. For these years, the maximum SBFs is below 4.

2. *USGS-08057200*

Site and Sampling Characterization

USGS site 08057200 (White Rk Ck at Greenville Ave, Dallas, TX) is in a 73.5 mi^2 (190 km^2) urban watershed in Hydrologic Unit Code (HUC) 12. The watershed landcover is 47% impervious surfaces and only 2% cropland (**Figure 31. Watershed Landcover Characteristics of Sampling Site USGS-08057200**). A spatial overview shows the sampling location is next to a golf course and recreational facility. The sampling location is upstream of two drinking water intakes with a 9 to 11 day time of travel from the sampling site to the intakes.

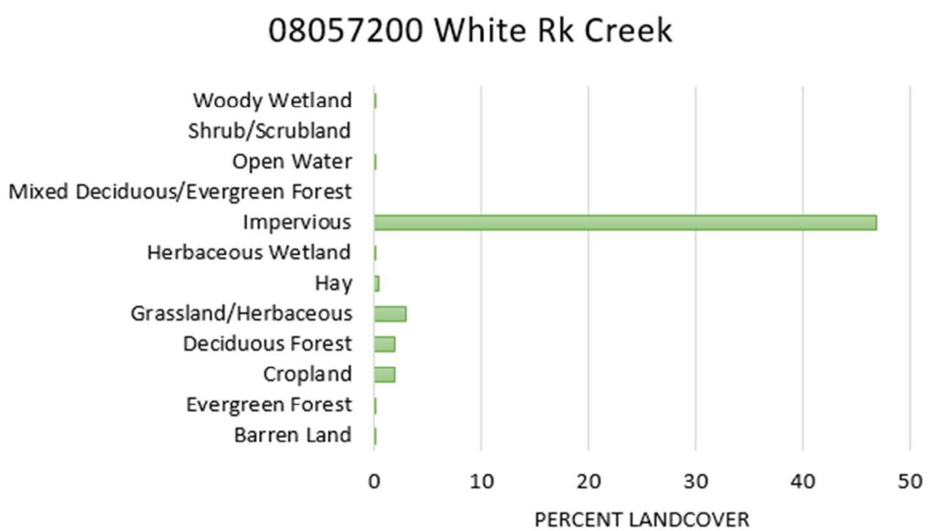

Figure 31. Watershed Landcover Characteristics of Sampling Site USGS-08057200

This site has a total of 63 chlorpyrifos detections out of 351 samples over 22 years between 1995 and 2019 (**Table 31**). Only 4 years of data (1998-2001) have at least 12 samples and a detection frequency greater than 25%, which were used as SEAWAVE-QEX inputs. **Table 31** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 31. USGS-08057200 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1995	7	7	100%			
1996	0	—	—			
1997	9	8	89%			
1998	17	12	71%	✓	0	✓
1999	17	9	53%	✓	1	
2000	15	12	80%	✓	6	
2001	12	4	33%	✓	0	✓
2002	24	3	13%	✓	3	
2003	18	1	6%			
2004	9	2	22%			
2005	6	1	17%			
2006	8	0	0%			
2007	16	2	13%			
2008	4	0	0%			
2009	16	0	0%			
2010	4	0	0%			
2011	16	1	6%			
2012	6	0	0%			
2013	23	0	0%			
2014	24	0	0%			
2015	24	1	4%			
2016	24	0	0%			
2017	24	0	0%			
2018	23	0	0%			
2019	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The site has an incomplete flow record through the years that meet the minimum requirements for use in SEAWAVE-QEX (1998-2001). The discharge data for these years is shown in black in **Figure 32**, which has short gaps in the flow, particularly in the year 2000. There was a drought in the summer of 2000 which may influence the amount of sampling done. The impact of missing days of flow results from the MTFA in SEAWAVE-QEX. For a given time step, the MTFA is calculated using covariate data from the preceding 30 days, so that a day of missing flow can result in many days of missing MTFA calculations and therefore no concentration output. The days for which there is no SEAWAVE-QEX output is shown in orange in **Figure 32**.

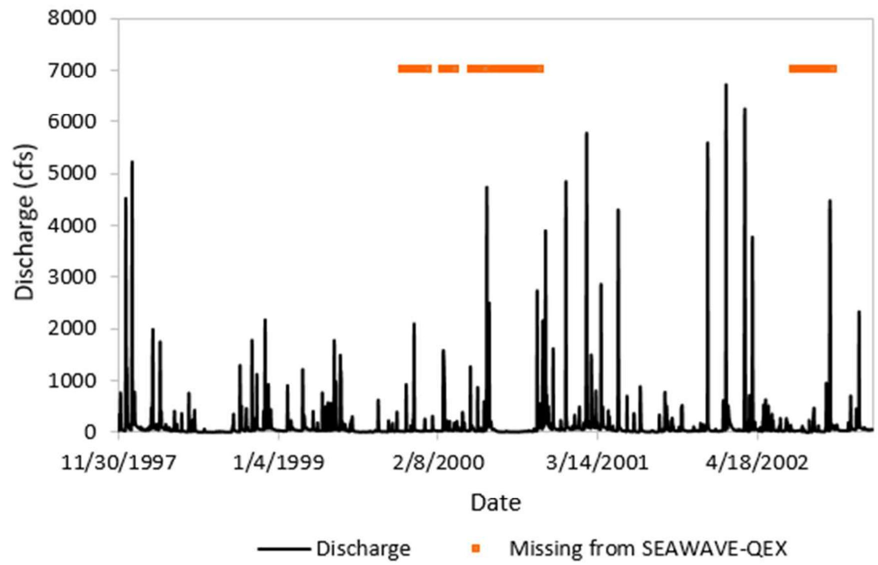

Figure 32. Discharge and Gage Height (unadjusted) Data for USGS-08057200 from 1998-2002

Using SEAWAVE-QEX on only the years 1998-2001 resulted in a poor empirical correlogram at short sampling intervals (i.e., the 5-day bar is absent from the diagnostic plot). An additional run was attempted by including the year 2002 with 13% detection. Although it does not meet the detection frequency criteria, the addition of the year 2002 resulted in a better model fit and allowed for the site to be included. The best fit was determined to be from 1998 to 2002 without modification of the default SEAWAVE-QEX parameters. The highest measured concentration at this site was 0.0549 µg/L in 2000.

The resulting diagnostic plots show 80% confidence bounds on the estimated maximum for each year well below 0.1 µg/L spanning less than an order of magnitude (**Figure 33**). There is a single a shallow wave with a season late September to late June with a short “off-season” of lower measured concentrations. All but one measured concentration fall within the 2x seasonal standard deviations (2SSD) bounds on the model (i.e., the data fall between the dashed lines on **Figure 34**), which span much less than an order of magnitude in size. There is a significant (α=0.05), slightly negative correlation of adjusted concentration with MTFA and a weakly positive correlation with STFA. The adjusted concentrations trend slightly downward over time and the normalized residuals center around zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function with a CTS of 4.2 days. All other model assumptions are satisfied (all diagnostic plots are provided in **ATTACHMENT 4**).

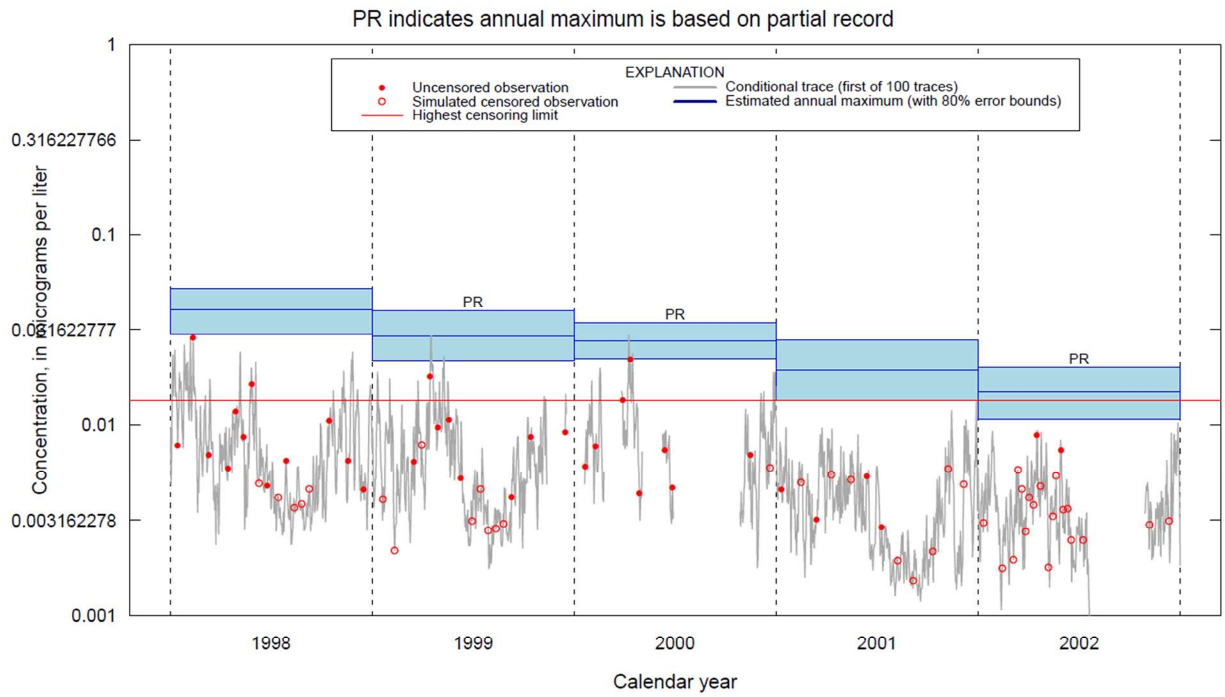

Figure 33. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-08057200

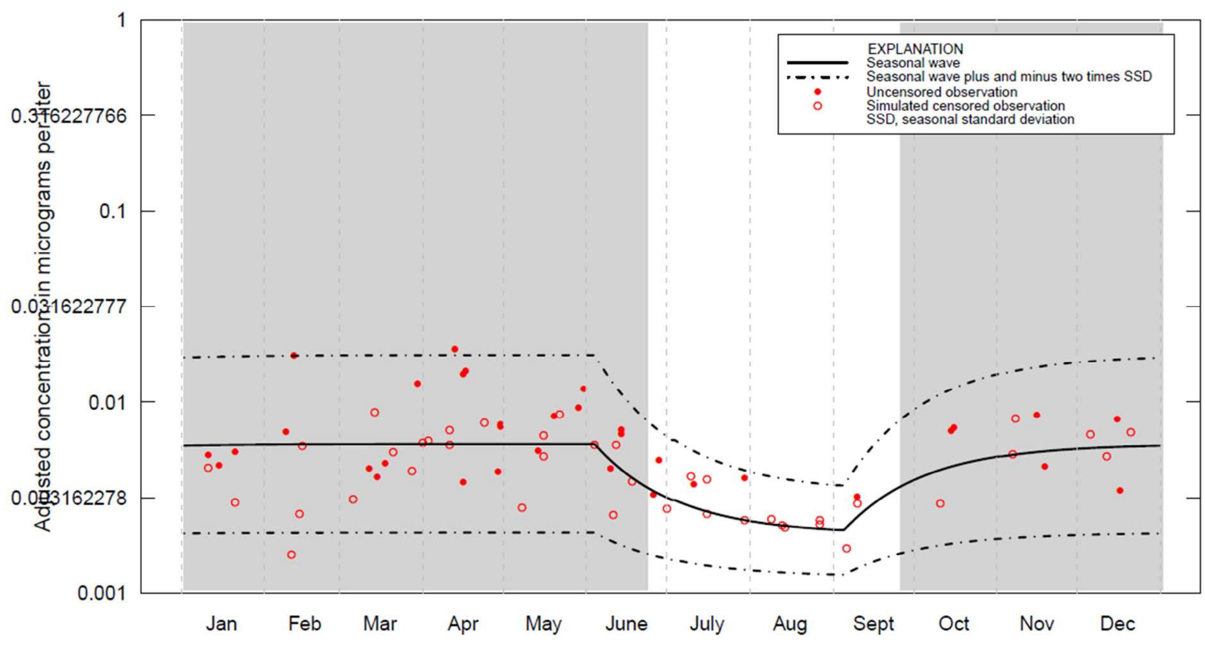

Figure 34. SEAWAVE-QEX Seasonal Wave Model for USGS-08057200 (Diagnostic Plot 2)

The resulting chemographs from this model were used to describe the estimated concentrations at site 08057200 by calculating the maximum of the 99th percentile 1- and 21-day concentrations. **Table 32** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 32. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-08057200

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1998	0.06	0.03
1999	0.03	0.02
2000	0.03	0.03
2001	0.03	0.02
2002	0.02	0.01

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 35** and **Figure 36**, respectively. Again, these figures show median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category. Only two years of the SEAWAVE-QEX output could be used for calculating SBFs due to periods of missing flow. Years with a partial flow record cannot produce daily concentration estimates for periods of the year when the flow is missing. More than two years were simulated in SEAWAVE-QEX; however, due to missing flow in the data (-9 reported in output files for those days with missing flow) the additional years were excluded from the SBF development.

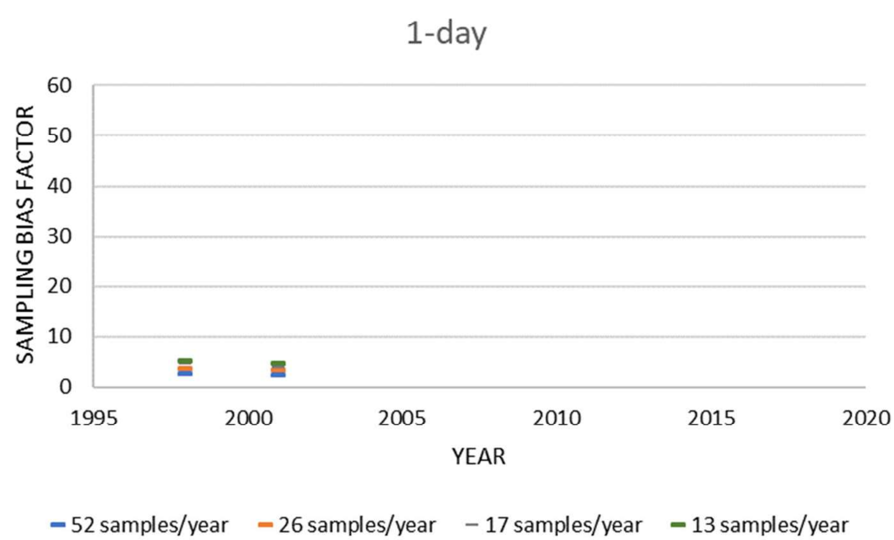

Figure 35. USGS Site 08057200: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

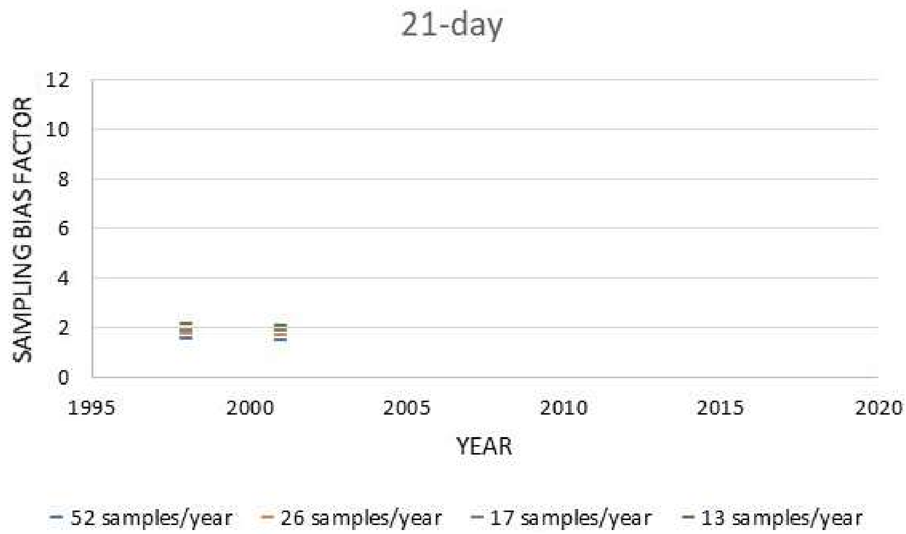

Figure 36. USGS Site 08057200: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

The SBFs are roughly equal for the two years where SBFs could be developed. SBFs for all sample number category are below 6 for estimating the upper confidence interval on the 1-day average and are roughly 2 or below for estimating the upper confidence interval on the 21-day average.

3. USGS-01654000

Site and Sampling Characterization

USGS site 01654000 (Accotink Creek near Annandale, VA) falls within a 24 mi^2 (62.3 km^2) urban watershed in HUC 02 with land use acreage comprising of <1% cropland, 23% impervious surfaces, and 23% deciduous forest (**Figure 37.** Watershed Landcover Characteristics of Sampling Site USGS-01654000). Although this watershed does not supply source drinking water, it is possible that this site is representative of other areas relevant to drinking water intakes that have similar watershed characteristics and chlorpyrifos use.

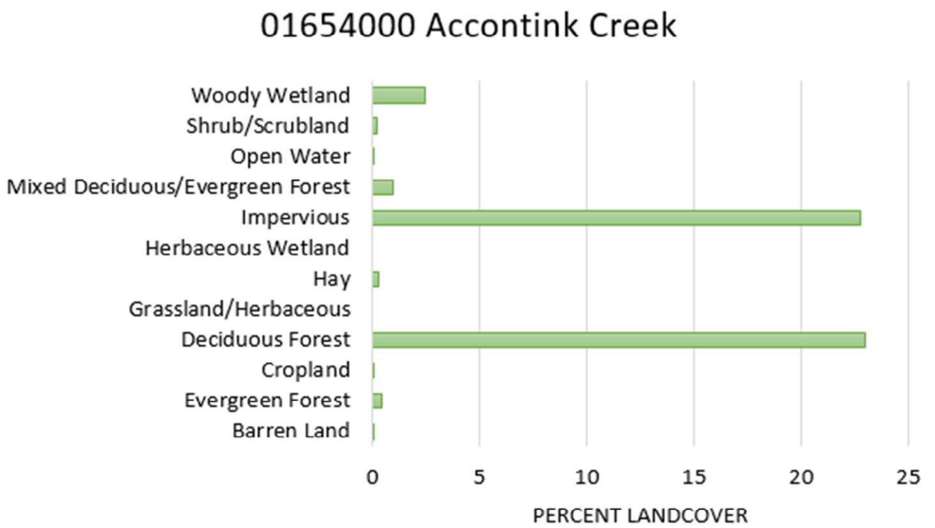

Figure 37. Watershed Landcover Characteristics of Sampling Site USGS-01654000

The site has a total of 37 chlorpyrifos detections out of 99 samples over 7 years between 1994 and 2014 (**Table 33**). Only 4 years of data have 12 or more samples and a detection frequency greater than 25%. **Table 33** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 33. USGS-01654000 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1994	25	12	48%	✓	2	✓
1995	0	—	—	✓		✓
1996	0	—	—	✓		✓
1997	15	9	60%	✓	0	✓
1998	11	5	45%	✓	0	✓
1999	19	6	32%	✓	0	✓
2000	13	5	38%	✓	0	✓
2001	6	0	0%			
2014[2]	10	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).
[2] Years 2002-2013 without monitoring data excluded for brevity.

SEAWAVE-QEX Analysis

Several iterations of SEAWAVE-QEX were attempted to find the best fit to the data, such as including only the years 1997-2000 or 1994-1999. Ultimately, the best fit was determined to be for the period

from 1994 to 2000 without modification of the default SEAWAVE-QEX parameters (e.g., no constant added). The maximum measured concentration at this site is 0.041 µg/L in 1994.
The 80% confidence bounds on the estimated maximum for each year (blue boxes on first diagnostic plot) are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. SEAWAVE-QEX fit a shallow, two-season wave to the data, likely due to sporadic use of chlorpyrifos at various times and locations within the watershed over the period examined. The 2SSD bounds are not large (i.e., less than an order of magnitude) with most data falling within the 2SSD bounds. The first season has a slightly sharper peak than the second, with seasons running mid-April through late June and the end of August through early December. There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and weakly positive correlation with STFA. There is an overall downward trend of concentrations from 1994 to 2000 and residuals are centered on zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 4.7 days.

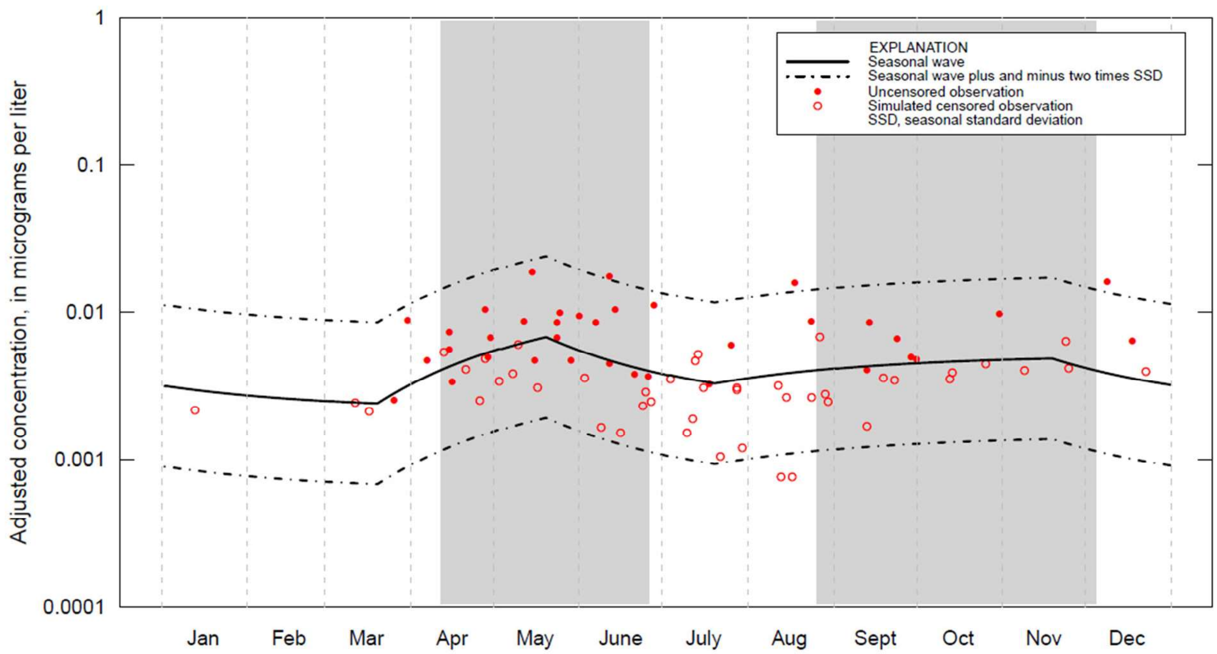

Figure 38. SEAWAVE-QEX Seasonal Wave Fit to Data for USGS-01654000

Based on the resulting estimated chemographs, concentrations of chlorpyrifos at this site are expected to be below well 1 µg/L. **Table 34** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. These do not range substantially higher than the highest measured concentration of 0.041 µg/L.

Table 34. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-01654000

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1994	0.060	0.033
1995	0.045	0.036
1996	0.048	0.033

1997	0.033	0.016
1998	0.042	0.027
1999	0.026	0.011
2000	0.027	0.014

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 39** and **Figure 40**, respectively. Again, these figures show median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

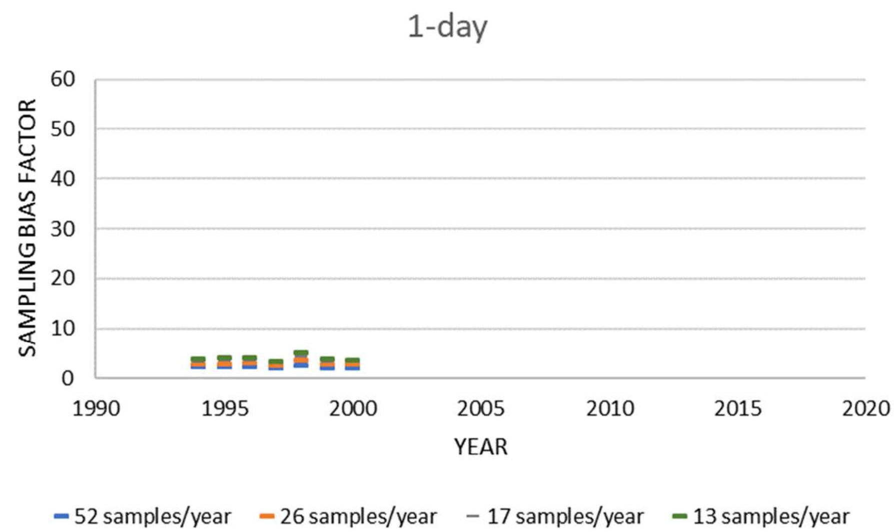

Figure 39. USGS Site 01654000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

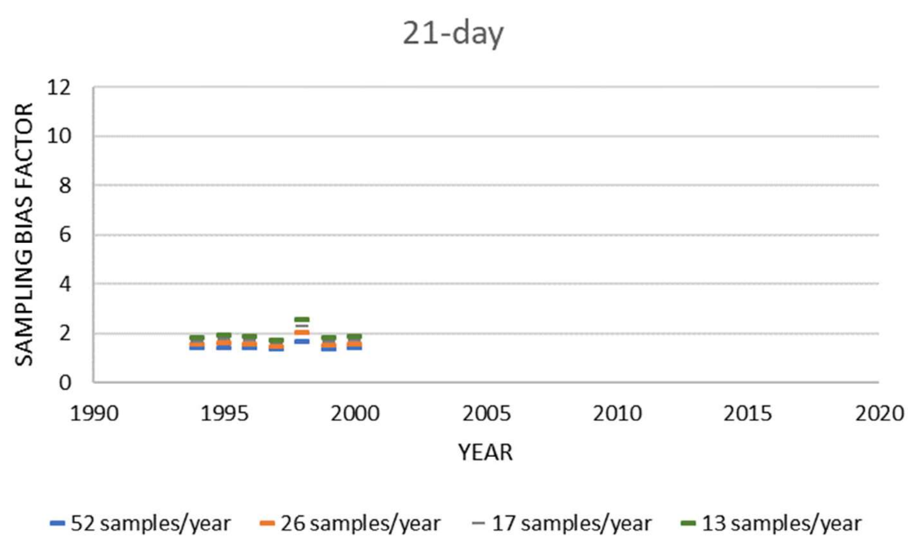

Figure 40. USGS Site 01654000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-0165400 for estimating the upper confidence interval on the 1- and 21-day average concentration. One year, 1998, results in notably higher SBFs; however, all SBFs are roughly 5 or below for all sample number categories for calculating the 1-day average or below 3 for the 21-day average.

4. USGS-02174250

Site and Sampling Characterization

USGS site 02174250 (Cow Castle Creek near Bowman, SC) falls within a 24.9 mi^2 (64.4 km^2) watershed in HUC 03. The sampling location is in a watershed with 26% cropland and a high percentage of other natural areas (e.g., woody wetland, shrub, hay, evergreen forest) as described in **Figure 41.** Watershed Landcover Characteristics of Sampling Site USGS-02174250 . The sampling location is upstream of a drinking water intake with a 2-day time of travel between the sampling site and the intake. This indicates that the site is relevant for source drinking water.

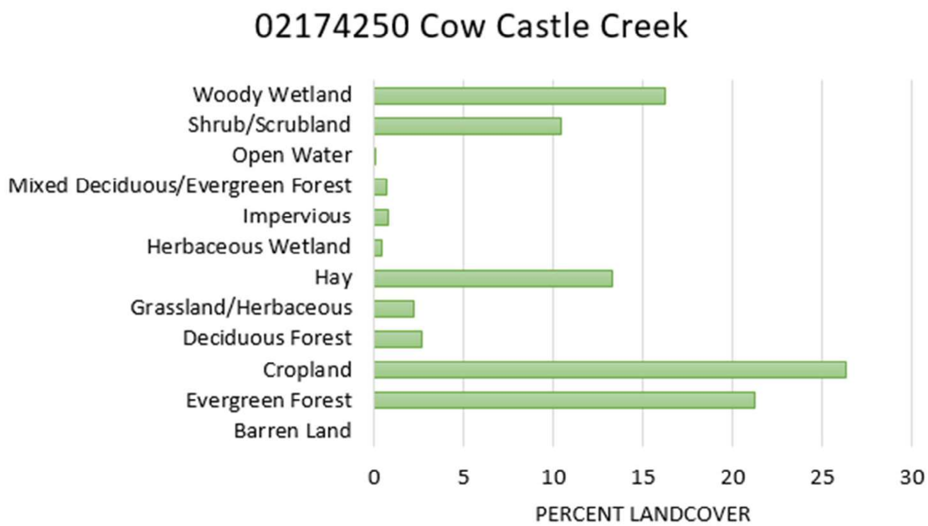

Figure 41. Watershed Landcover Characteristics of Sampling Site USGS-02174250

The site has a total of 83 chlorpyrifos detections out of 162 samples over 14 years of data between 1996 and 2012 (**Table 35**). Five of these years have 12 or more samples and a detection frequency greater than 25%. **Table 35** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 35. USGS-02174250 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	38	31	82%	✓	0	✓
1997	0	—	—	✓	0	✓
1998	1	1	100%	✓	0	✓
1999	15	10	67%	✓	0	✓
2000	17	10	59%	✓	0	✓
2001	10	6	60%	✓	0	✓
2002	9	2	22%	✓	0	✓
2003	7	2	29%	✓	0	✓
2004	8	2	25%	✓	0	✓
2005	8	5	63%	✓	0	✓
2006	14	5	36%	✓	0	✓
2007	3	1	33%	✓	0	✓
2008	14	8	57%	✓	0	✓
2009	0	—	—			
2010	0	—	—			
2011	4	0	0%			
2012	14	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Several cuts of the data were attempted in SEAWAVE-QEX as well as adding a small constant (e.g., a fraction of the LOD of 0.004). This included the following splices of the data based on the diagnostic plots of the full run: 1996-2008 (with and without addition of 0.0012 or 0.0016), 1999-2006, 1996-2000, 2000-2008, 1996-2006. The best fit was determined to be for the period from 1996 to 2008 with the addition of a small constant, 0.0012, which improved the fit of the empirical correlogram.

The 80% confidence bounds on the estimated maximum for each year (blue boxes on first diagnostic plot) span less than an order of magnitude. The highest measured concentration occurs in 2005 (0.338 µg/L); the 80% confidence bounds on the estimated maximum for all other years falls below this value (**Figure 42**). The model shows a single, very shallow seasonal wave from early December to early March, with most data falling within the 2SSD bounds and several outliers of higher concentrations from July to September (i.e., outside of the 2SSD bounds). There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. There is an overall downward trend of concentrations from and residuals are centered on zero. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 20.5 days.

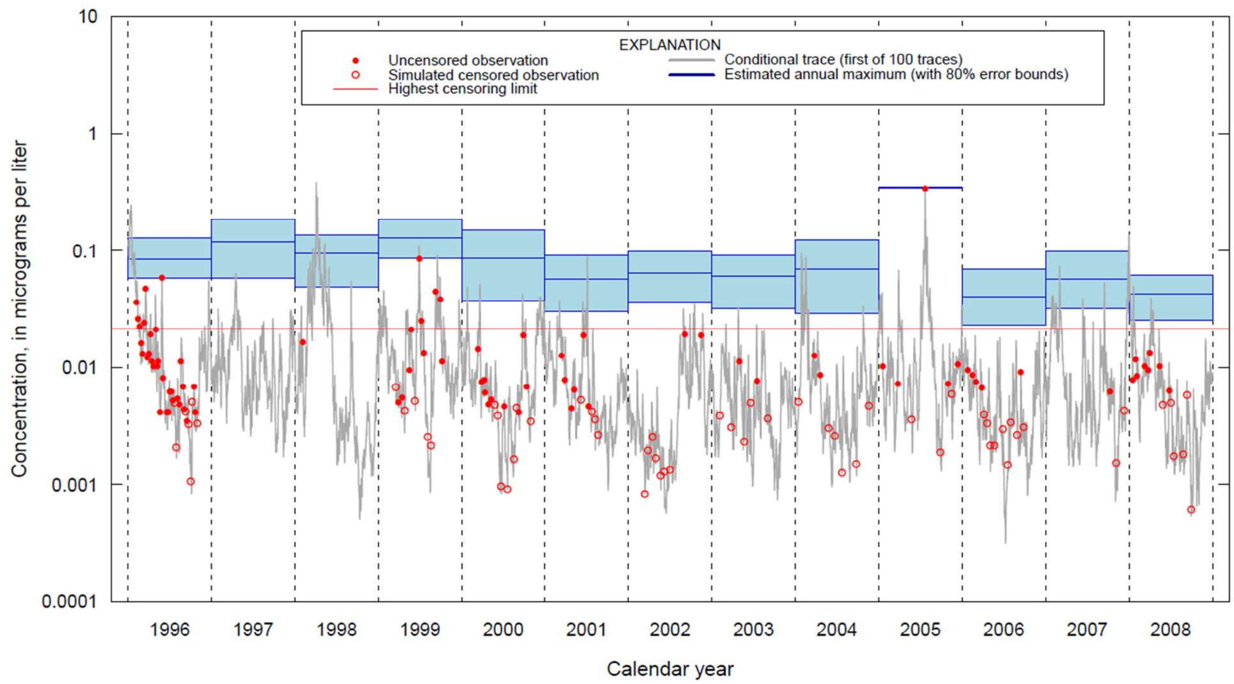

Figure 42. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-02174250

Table 36 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. From this table, choosing the maximum of the 99th percentile 1-day concentration ranges from 0.09-0.5 µg/L, encompassing the highest measured concentration from 2005 (0.338 µg/L) while accounting for uncertainty in infrequent sampling where the peak concentration might be higher than the highest measured.

Table 36. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-02174250

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1996	0.22	0.14
1997	0.50	0.23
1998	0.33	0.15
1999	0.17	0.12
2000	0.18	0.12
2001	0.13	0.06
2002	0.09	0.06
2003	0.12	0.06
2004	0.19	0.15
2005	0.37	0.25
2006	0.09	0.07
2007	0.11	0.08
2008	0.10	0.06

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 43** and **Figure 44**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

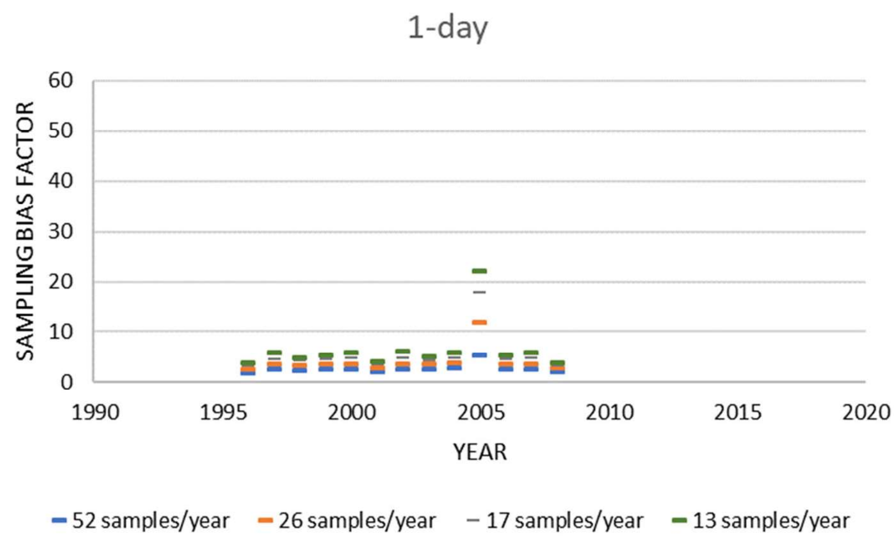

Figure 43. USGS Site 02174250: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

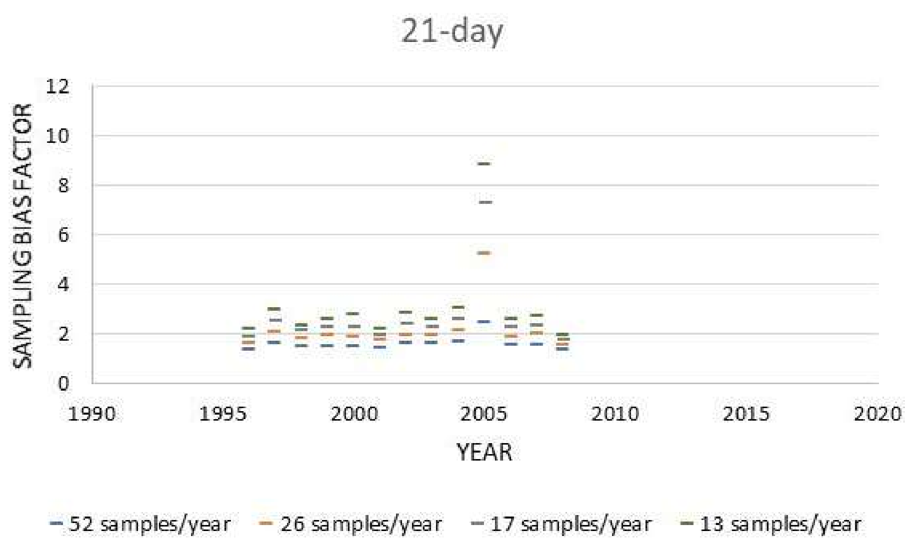

Figure 44. USGS Site 02174250: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

Generally, the SBFs are consistent across all years for USGS-02174250 for estimating the upper confidence interval on the 1- and 21-day average concentration except for one year, 2005, which are much higher than for other years. Investigation of these higher SBFs reveal that the 2005 SBFs are driven by a measured concentration. This introduces uncertainty in the other years of data where peak occurrence concentrations may have gone without being measured. Furthermore, since the other years have SBFs in the range of other sampling sites derived for other sites, it is possible that peak occurrence concentration may have gone undetected for other sites that would have resulted in generation of higher SBFs.

5. USGS-03353637

Site and Sampling Characterization

USGS site 03353637 (Little Buck Creek near Indianapolis, IN) falls within a 19.5 mi^2 (50.6 km^2) urban watershed in HUC 05, comprising of 6% cropland and 25% impervious surfaces (**Figure 45.** Watershed Landcover Characteristics of Sampling Site USGS-03353637). The sampling location is upstream of several community water systems with intakes on the Ohio River. The time of travel between the sampling site on Little Buck Creek and the intakes range from 12-14 days.

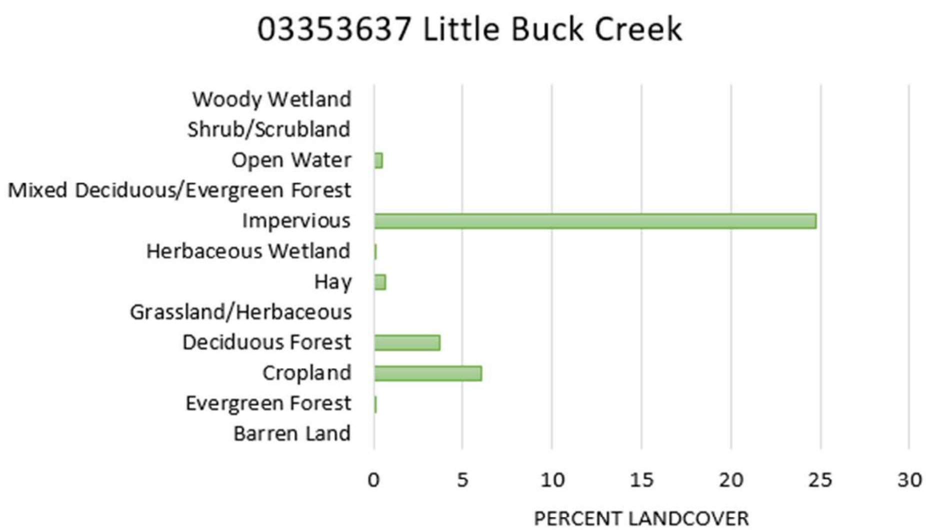

Figure 45. Watershed Landcover Characteristics of Sampling Site USGS-03353637

This site had a total of 96 detections out of 223 samples over 13 years between 1992 and 2004. Only 4 years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 37**. **Table 37** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 37. USGS-03353637 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	49	42	86%	✓	19	✓
1993	32	24	75%	✓	3	✓
1994	14	5	36%	✓	0	✓
1995	11	6	55%	✓	0	✓
1996	13	6	46%	✓	0	✓
1997	9	5	56%			
1998	11	2	18%			
1999	8	0	0%			
2000	13	2	15%			
2001	20	3	15%			
2002	22	1	5%			
2003	14	0	0%			
2004	7	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1992-1996 were input into SEAWAVE-QEX. Other subsets of years were explored (i.e., 1992-1994, 1993-1996) and data for 1992 to 1996 had the best model fit. As seen in **Table 37**, SEAWAVE-QEX excluded a number of samples in 1992 due to the temporal intensity of sampling (see **Figure 46**).

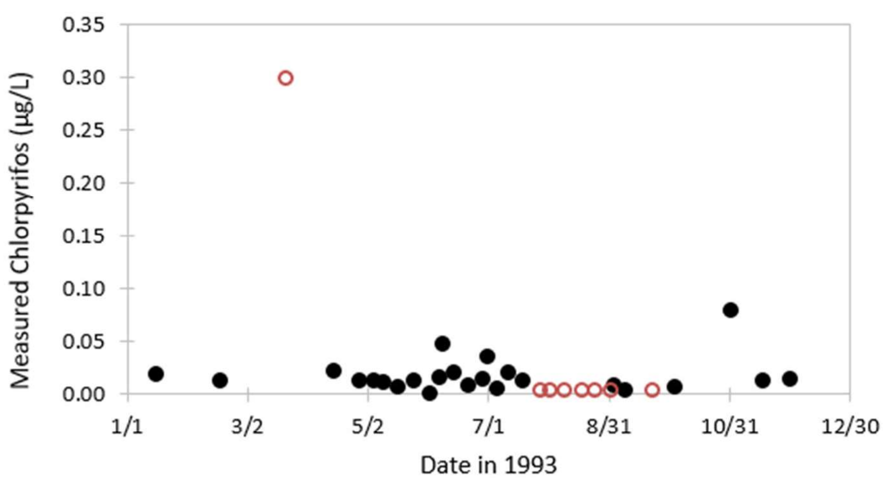

Figure 46. Sampling Intensity in 1993 of Measured Concentrations Above (black) and Below (red) the LOD

The final selected model had 80% confidence bounds on the estimated maximum for each year spanning less than an order of magnitude. The highest measured concentration occurs in 1996 (0.11 µg/L) which is encompassed by the 80% confidence bounds on the estimated maximum for several years, indicating that the model estimated concentrations at and above this concentration. There was a shallow "inverse" seasonal wave with 2SSDs of less than one order of magnitude. This means that SEAWAVE-QEX fit a very long, flat seasonal wave (from mid-October to early July), with a period of lower concentrations in other months (**Figure 47**). While most of the measured observations fall within the 2SSD bounds, it is unclear that concentrations are substantially lower outside of the season. The low seasonality of concentrations combined with the high amount of impervious land cover at this site suggest that the measured concentrations may have resulted from residential applications.

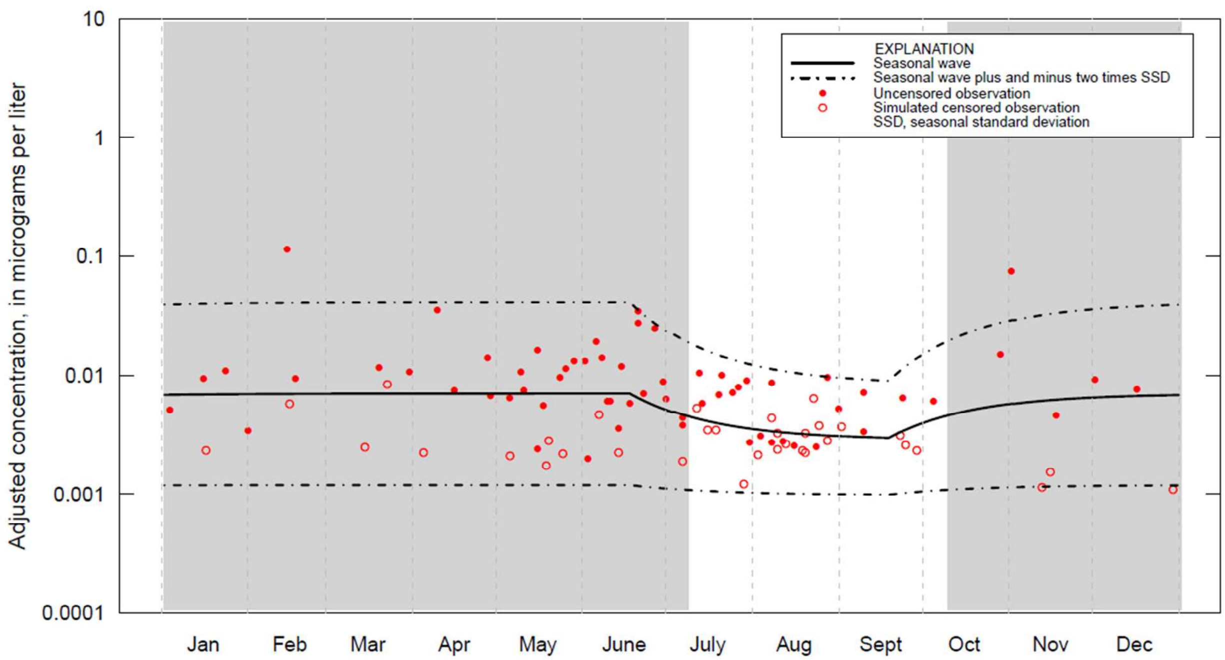

Figure 47. SEAWAVE-QEX Seasonal Wave for USGS-03353637

There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. There is an overall downward trend of concentrations from and residuals are mostly centered on zero with a slightly positive skew. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 3.6 days. **Table 38** summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 38. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-03353637

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	0.152	0.077
1993	0.244	0.107
1994	0.152	0.073
1995	0.134	0.046
1996	0.147	0.075

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 48** and **Figure 49**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

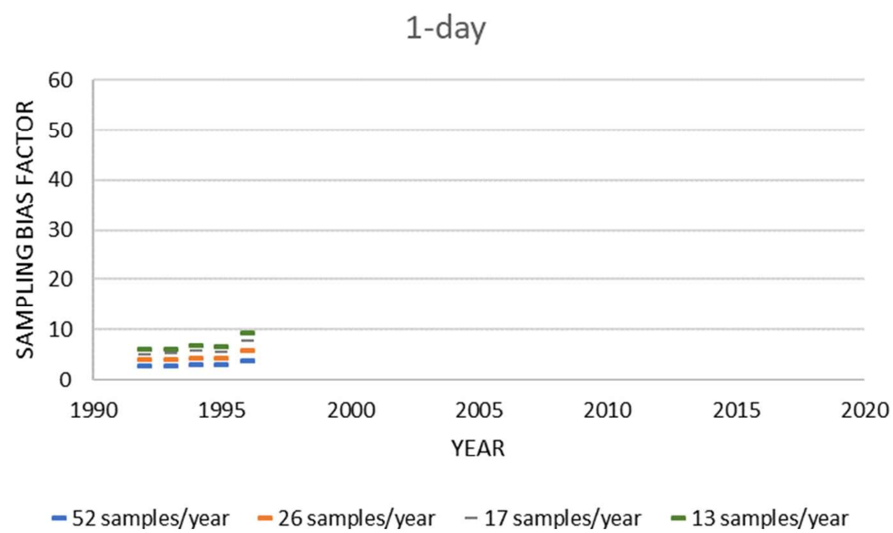

Figure 48. USGS Site 03353637: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

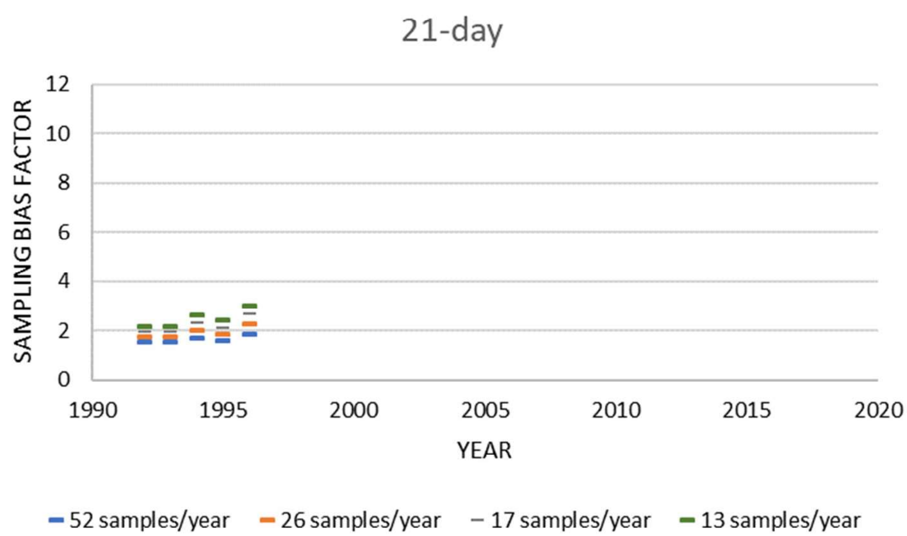

Figure 49. USGS Site 03353637: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

The SBFs are consistent across 4 of the 5 years. The 1996 SBFs are higher than for other years. In general, SBFs for this site are consistently higher for 1-day SBFs when compared to other sites; however, 21-day SBFs calculated for this site are consistent with other sites. SBFs for all sample number categories are below 10 for estimating the upper confidence interval on the 1-day average concentration and below 4 for estimating the upper confidence interval on the 21-day average concentration.

6. USGS-14211720

Site and Sampling Characterization

USGS site 14211720 (Willamette River at Portland, OR) is in a 11,167 mi^2 (28,922 km^2) watershed in HUC 17. The watershed is 8% cropland with a high percentage of evergreen forest (49%). The sampling location is upstream of a drinking water intake. The time of travel between the sampling site and the intake is less than a day, making the site relevant for drinking water.

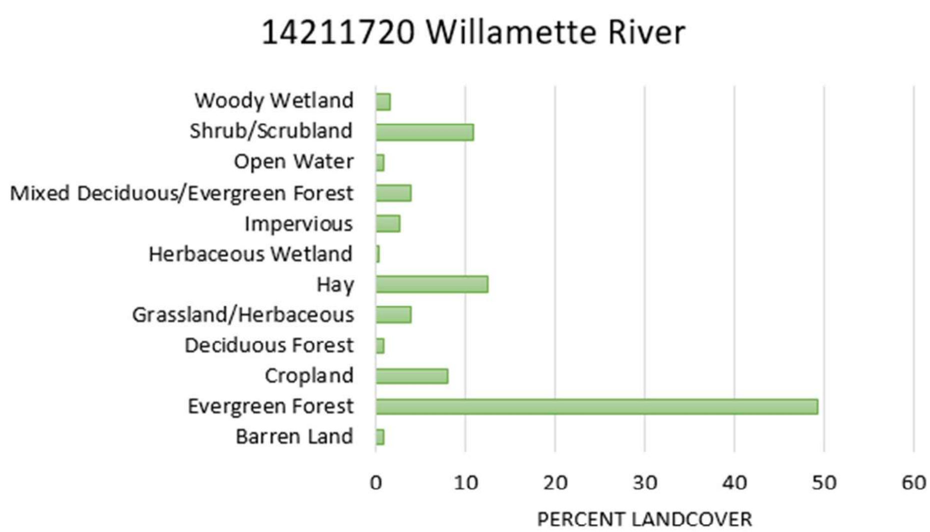

Figure 50. Watershed Landcover Characteristics of Sampling Site USGS-14211720

This site had a total of 69 detections out of 392 samples over 27 years between 1993 and 2019. Only 5 years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 39**. **Table 39** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 39. USGS-14211720 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	3	0	0%			
1994	12	1	8%			
1995	8	1	13%			
1996	9	5	56%			
1997	17	12	71%	✓	1	✓
1998	13	7	54%	✓	0	✓
1999	15	4	27%	✓	0	✓
2000	13	6	46%	✓	0	✓
2001	14	0	0%	✓	0	✓
2002	16	1	6%	✓	0	✓
2003	13	1	8%	✓	0	✓
2004	15	0	0%	✓	0	✓
2005	9	2	22%	✓	0	✓
2006	9	2	22%	✓	0	✓
2007	19	6	32%	✓	0	✓
2008	18	3	17%			
2009	20	0	0%			
2010	19	4	21%			
2011	19	3	16%			
2012	19	4	21%			
2013	18	0	0%			
2014	18	0	0%			
2015	17	1	6%			
2016	18	4	22%			
2017	19	2	11%			
2018	18	0	0%			
2019	4	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data encompassing the 5 years of data meeting the SEAWAVE-QEX criteria were used in modeling (i.e., 1997-2007). Another subset of years was explored (i.e., 1997-2000) but did not have an acceptable model fit. The years 1997-2007 gave an acceptable model fit and included the most years of measured data possible.

The annual estimated maximum concentrations (with 80% confidence bounds) generated are well below 0.1 µg/L and are all less than 0.03 µg/L. The model produces a single flat wave with most data within 2SSD bounds, which suggests that there is similar use throughout the year with a period of no use (off-season) from late June to late September (**Figure 51**). Adjusted concentration has a weakly positive correlation with MTFA and significantly positive correlation with STFA, and concentrations increase slightly between 1997-2007. Normalized residuals are centered on zero both within years and across years. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function at time intervals less than the average with a CTS of 11.7 days.

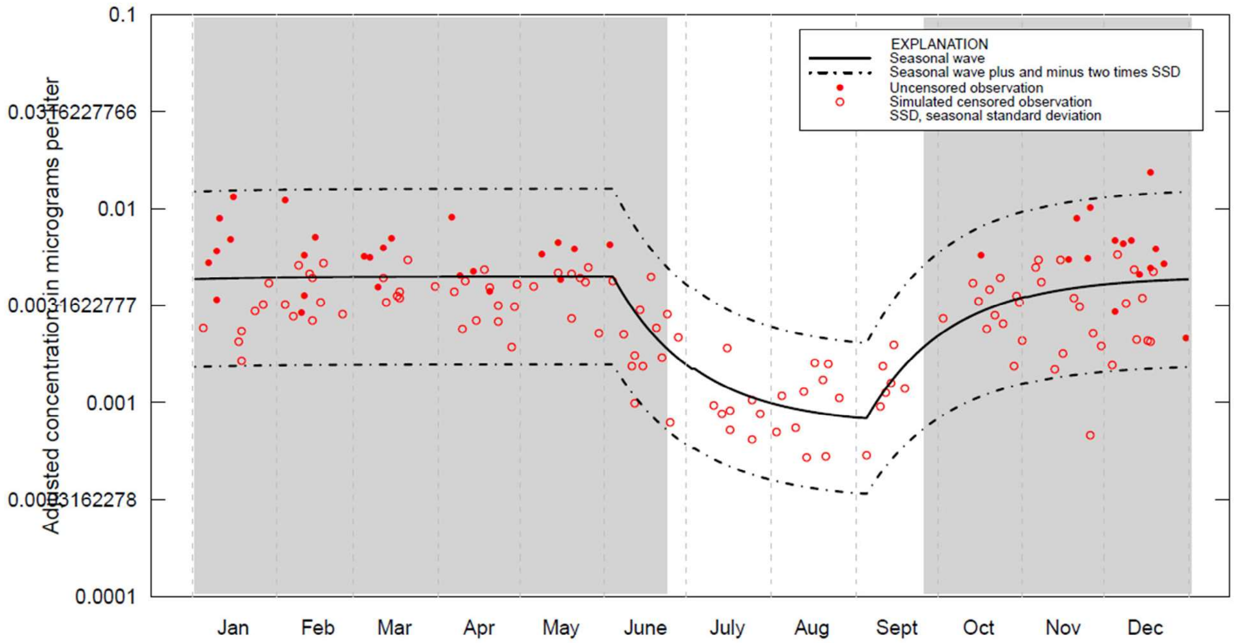

Figure 51. SEAWAVE-QEX Seasonal Wave for USGS-14211720

Table 40 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 40. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-14211720

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1997	0.018	0.012
1998	0.015	0.011
1999	0.020	0.012
2000	0.020	0.015
2001	0.024	0.015
2002	0.019	0.012
2003	0.027	0.019
2004	0.021	0.011
2005	0.029	0.017
2006	0.027	0.019
2007	0.027	0.015

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 52** and **Figure 53**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

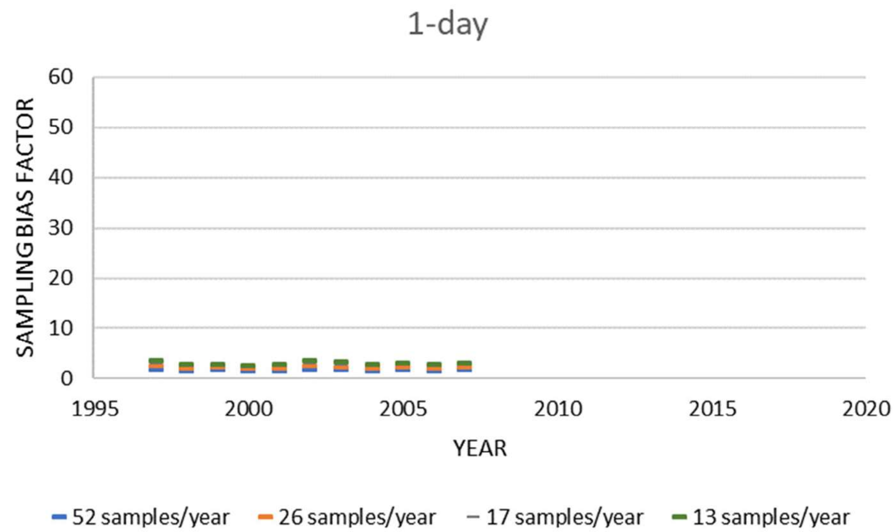

Figure 52. USGS Site 014211720: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

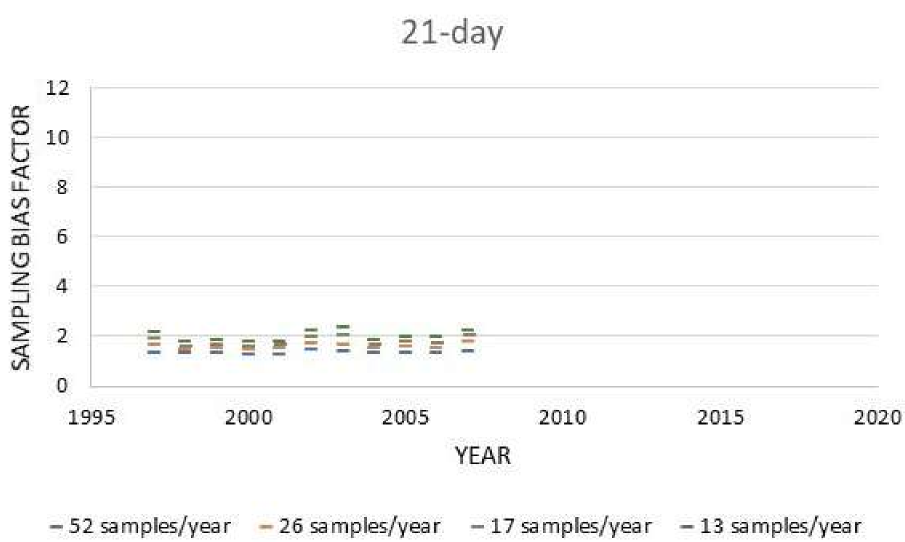

Figure 53. USGS Site 014211720: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

The SBFs are consistent across all years. SBFs for all sample number categories are roughly equal to or below 3.5 for estimating the upper confidence interval on the 1-day average concentration and below 2.5 for estimating the upper confidence interval on the 21-day average concentration.

7. *USGS-04208000*

Site and Sampling Characterization

USGS site 04208000 (Cuyahoga River at Independence, OH) is a 706 mi^2 (1829 km^2) watershed in HUC 04. The watershed is 9% cropland, 11% impervious surfaces, with a high percentage of forestry. This watershed does not supply source drinking water, though it may be representative of other similar sites where chlorpyrifos is used.

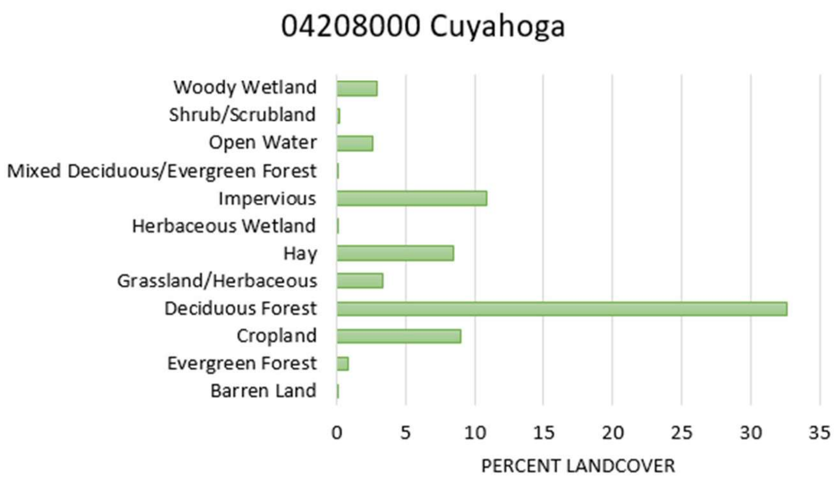

Figure 54. Watershed Landcover Characteristics of Sampling Site USGS-04208000

This site had a total of 40 detections out of 933 samples over 32 years between 1983 and 2015. Only 10 years have any detections, 3 years of which have 12 or more samples and a detection frequency greater than 25% (**Table 41**). **Table 41** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 41. USGS-04208000 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1983	23	0	0%			
1984	19	0	0%			
1985	28	0	0%			
1986	12	0	0%			
1987	12	6	50%	✓	1	✓
1988	20	6	30%	✓	1	✓
1989	25	4	16%	✓	2	✓
1990	17	7	41%	✓	0	✓
1991	11	10	90%	✓	0	✓
1992	12	1	8%			
1993	35	0	0%			
1994	34	1	3%			
1995	32	2	6%			
1996	32	2	6%			
1997	35	1	3%			
1998	41	0	0%			
1999	33	0	0%			
2000	41	0	0%			
2001	34	0	0%			
2002	38	0	0%			
2003	29	0	0%			
2004	31	0	0%			
2005	37	0	0%			
2006	30	0	0%			
2007	31	0	0%			
2008	33	0	0%			
2009	34	0	0%			
2010	32	0	0%			
2011	39	0	0%			
2012	38	0	0%			
2013	36	0	0%			
2014	29	0	0%			
2015	23	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

While only data from 1987 to 1990 met the SEAWAVE-QEX minimum criteria, the model fit was not acceptable using those years. Therefore, data for 1991 was included, which had a 90% detection frequency and 11 samples, and resulted in an acceptable fit.

The 80% confidence bounds on the estimated maximum concentrations for each year span roughly 1 to 10 µg/L for this site. The seasonal wave model selected has two shallow waves of similar amplitudes with most data within the 2SSD lines. The first season is from early March to early May and the second from early September to early January. There is not substantial correlation between adjusted concentrations and either MTFA or STFA and not much change in average concentration over time. Neither MTFA nor STFA are significantly correlated with the adjusted concentrations, and both correlations are generally flat (i.e., have little slope), suggesting that changes in streamflow do not have a strong impact on model outputs. The normalized residuals are centered around zero within years. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function with a CTS of 4.3 days.

Table 42 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. Concentrations were measured up to 0.5 µg/L, occurring in 1988.

Table 42. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-04208000

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1987	4.9	1.9
1988	4.4	2.3
1989	4.6	2.9
1990	2.9	1.3
1991	12.7	4.7

SEAWAVE-QEX estimated concentrations are more than 10x larger than the measured concentrations. While the model assumptions are satisfied based on the diagnostic plots, there are two indicators to evaluate when considering the potential for overestimation. The first can be seen in the first diagnostic plot (**Figure 55**), in which the annual maximum concentration estimates (blue line) are somewhat higher than the midway point in the 80% confidence bounds (blue boxes), particularly for 1988, 1989, and 1991. This gives an indicator that the average concentration for that year is somewhat higher than the mean, suggesting a slightly skewed distribution of concentrations. Generally, unacceptable plots have mean concentrations that are highly skewed to the top of the plot. Additionally, while the 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation, the overlap is toward the top of the confidence limits (gray boxes, **Figure 56**). When the empirical correlogram is entirely below the fitted exponential correlation, concentrations are estimated. In this case, it is not expected that the difference observed would cause substantial overestimation given that the confidence limits are overlapping. Variability in the degree of overlap is commonly observed in SEAWAVE-QEX diagnostic plots and not expected to indicate overestimation.

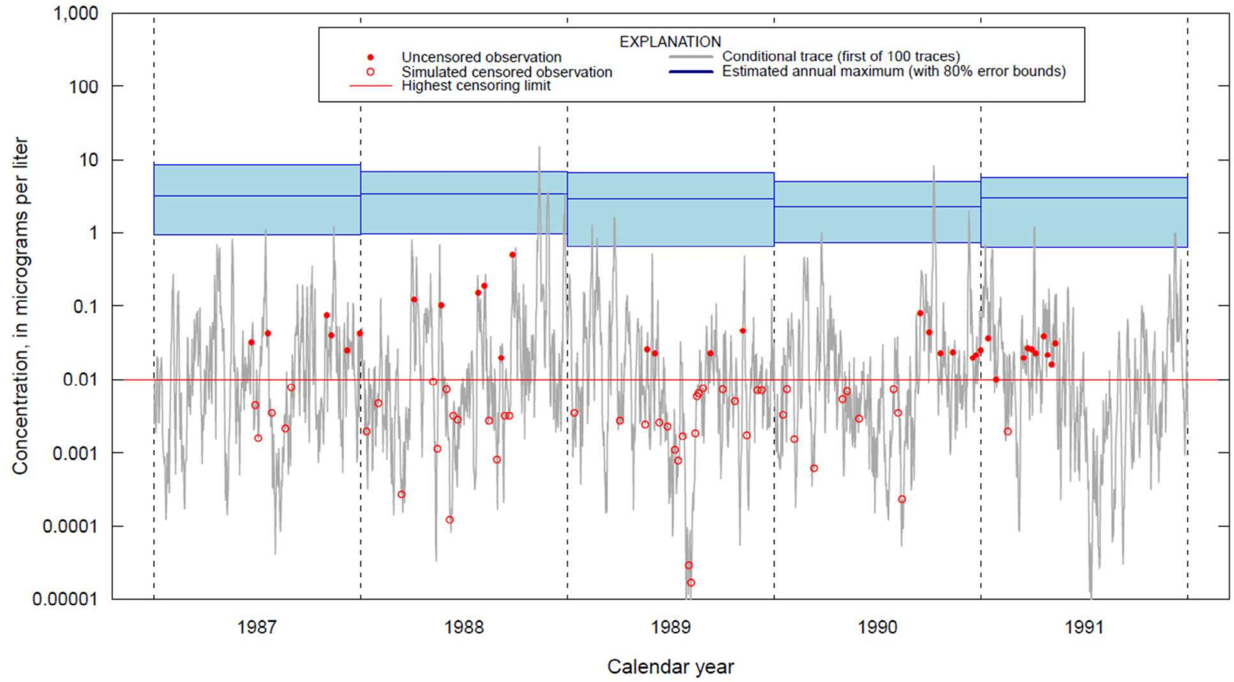

Figure 55. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-04208000

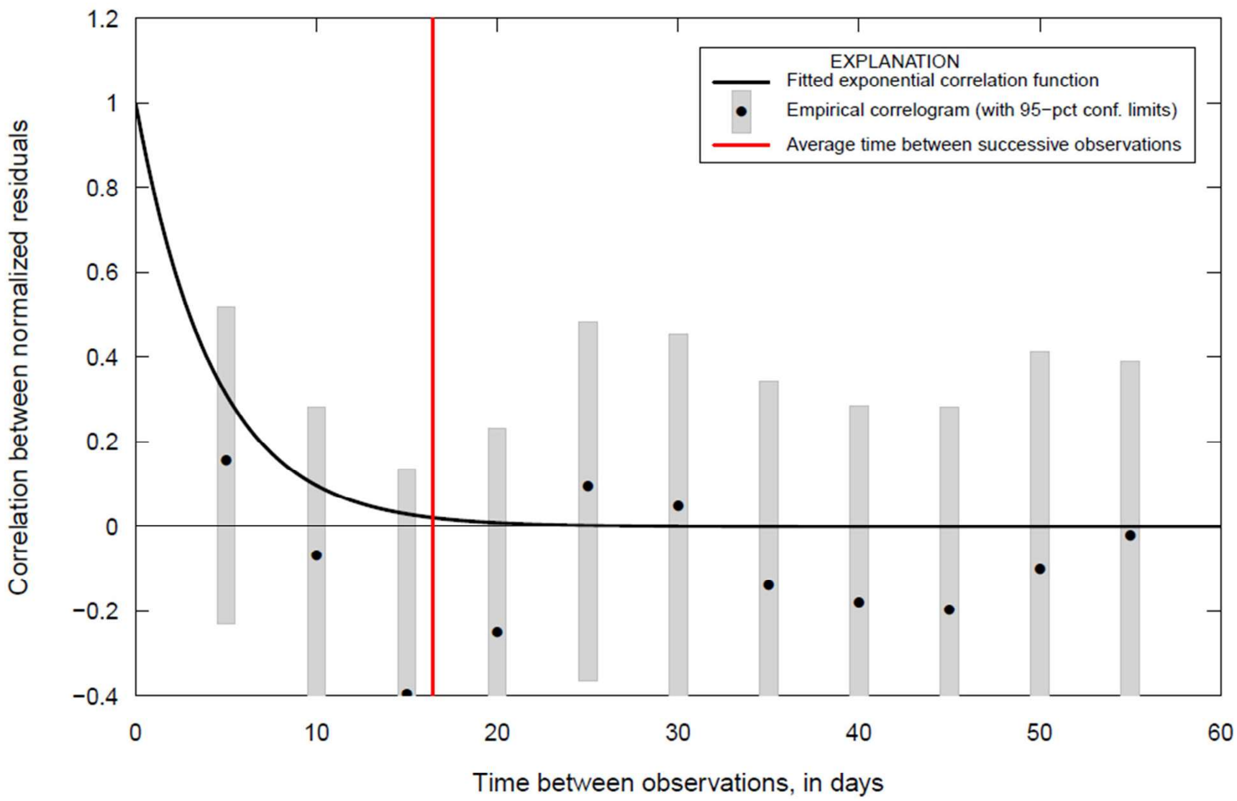

Figure 56. Plot of Correlation Between Normalized Residuals for USGS-04208000

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 57** and **Figure 58**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

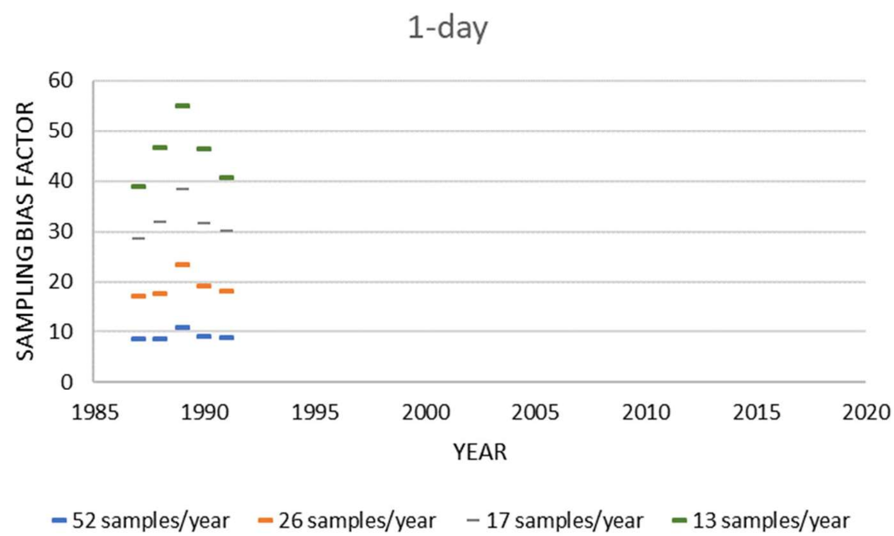

Figure 57. USGS Site 04208000: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

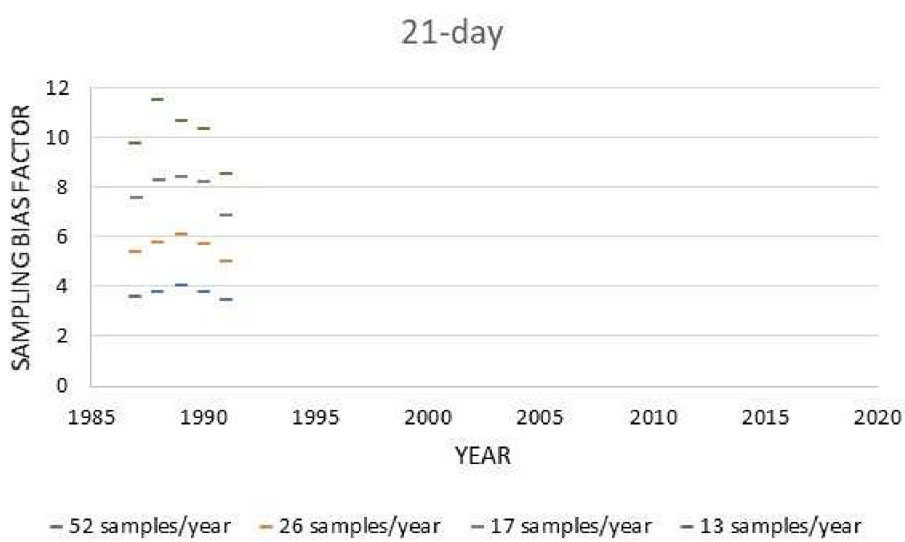

Figure 58. USGS Site 04208000: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

The SBFs are consistently high across all years. SBFs for all sample number categories are much higher for all years than all the other sites. SBFs for estimating the upper confidence interval on the 1-day average concentration ranged from 9 to 11 for 52+ samples per year, 17 to 23 for 26-51 samples/year, 29 to 38 for 17-25 samples/year and 39 to 55 for 13-16 samples/year. SBFs for estimating the upper confidence interval on the 21-day average concentration ranged roughly 4 to almost 12 for 52+ samples per year and 13-16 samples/year, respectively.

8. USGS-02335870

Site and Sampling Characterization

USGS site 02335870 (Sope Creek near Marietta, GA) is in a 33.3 mi^2 (86.3 km^2) urban watershed in HUC 03. The watershed has no cropland but 20% impervious surfaces and 22% forested areas (**Figure 59**). The sampling location is upstream of seven drinking water intakes serving community water systems, with several pulling from the Chattahoochee River. Travel times of the water range from <1 day up to 3 days from the sampling site to each intake.

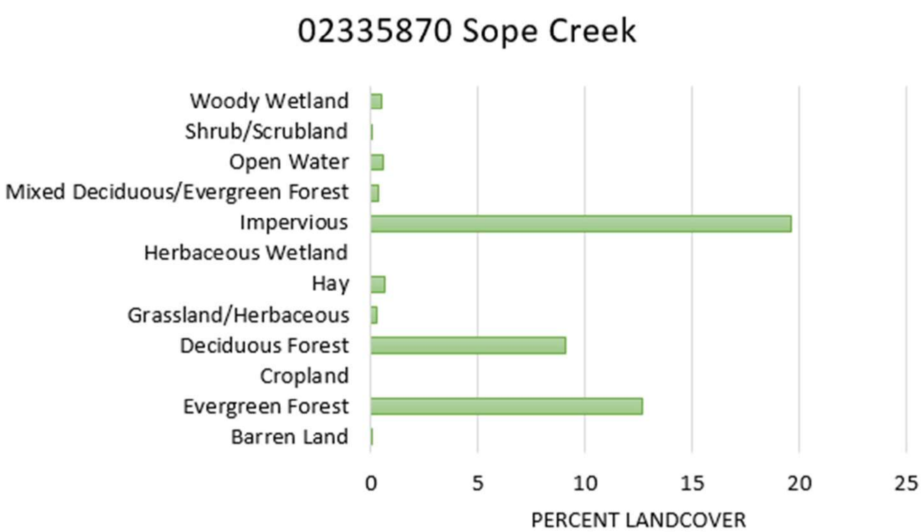

Figure 59. Watershed Landcover Characteristics of Sampling Site USGS-02335870 (2006 data)

This site had a total of 41 detections out of 401 samples over 26 years between 1993 and 2019. Only 3 years have 12 or more samples and a detection frequency greater than 25% (**Table 43**). **Table 43** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 43. USGS-02335870 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	32	17	53%	✓	0	✓
1994	12	7	58%	✓	0	✓
1995	3	1	33%	✓	0	✓
1996	0	—	—	✓	0	✓
1997	9	5	56%	✓	0	✓
1998	6	2	33%	✓	0	✓
1999	10	1	10%	✓	0	✓
2000	12	4	33%	✓	0	✓
2001	12	1	8%			
2002	23	0	0%			
2003	18	0	0%			
2004	7	0	0%			
2005	6	2	33%			
2006	6	0	0%			
2007	18	0	0%			
2008	22	0	0%			
2009	8	0	0%			
2010	18	0	0%			
2011	6	0	0%			
2012	24	0	0%			
2013	24	0	0%			
2014	27	0	0%			
2015	24	0	0%			
2016	23	0	0%			
2017	24	1	4%			
2018	22	0	0%			
2019	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

SEAWAVE-QEX was run only with the years encompassing the 3 years meeting the minimum requirements. The model did not produce an acceptable fit using SEAWAVE-QEX default parameters and the fitting was attempted by adding a small constant (0.0006 or 0.0009). Fitting with the addition of 0.0006 resulted in acceptable results with low confidence.

The 80% confidence bounds on the estimated maximum for each year are below 0.1 µg/L and the confidence bounds span much less than an order of magnitude. There are two shallow seasonal waves of similar amplitude; one season spanning early April to early August and the second from mid-December to early February. Most data are within the 2SSD bounds. There is a significant (α=0.05) positive correlation of adjusted concentration with MTFA and STFA. The adjusted concentrations trend slightly downward over time. The normalized residuals are centered on zero although have more spread (positive and negative) in 1993 compared to other years (**Figure 60**). The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 3.5 days.

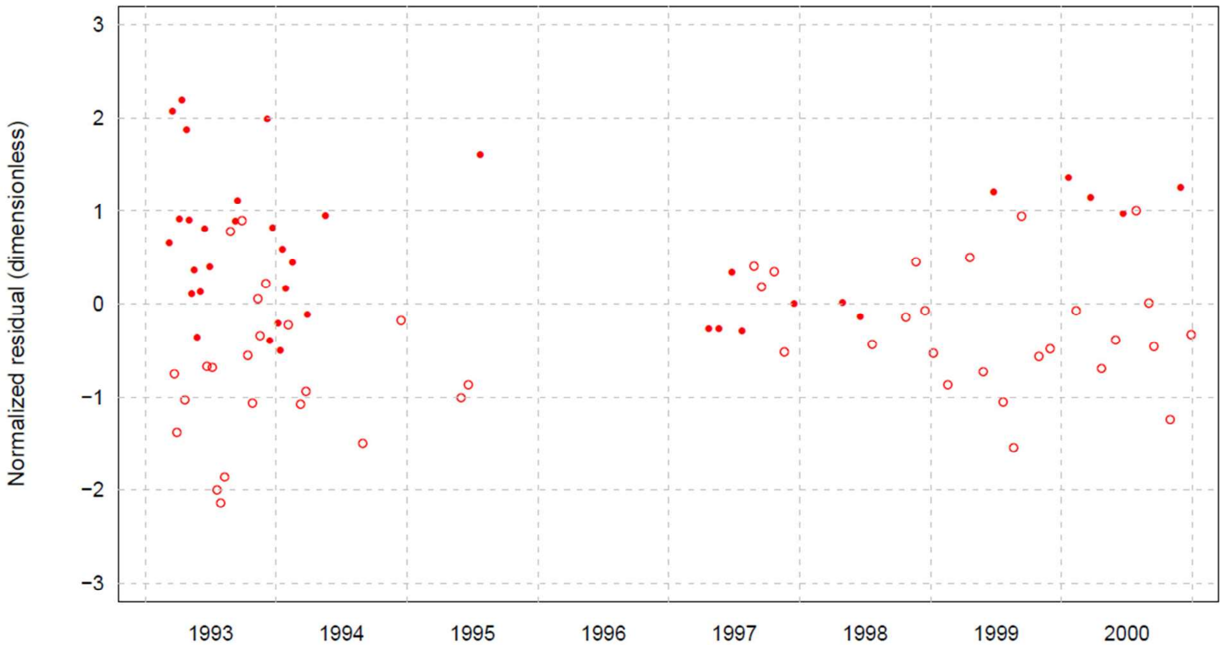

Figure 60. Normalized Residuals Across Years for USGS-02335870

Table 44 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 44. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-02335870

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1993	0.085	0.041
1994	0.065	0.032
1995	0.040	0.020
1996	0.051	0.027
1997	0.052	0.021
1998	0.061	0.031
1999	0.056	0.022
2000	0.022	0.013

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 61** and **Figure 62** respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

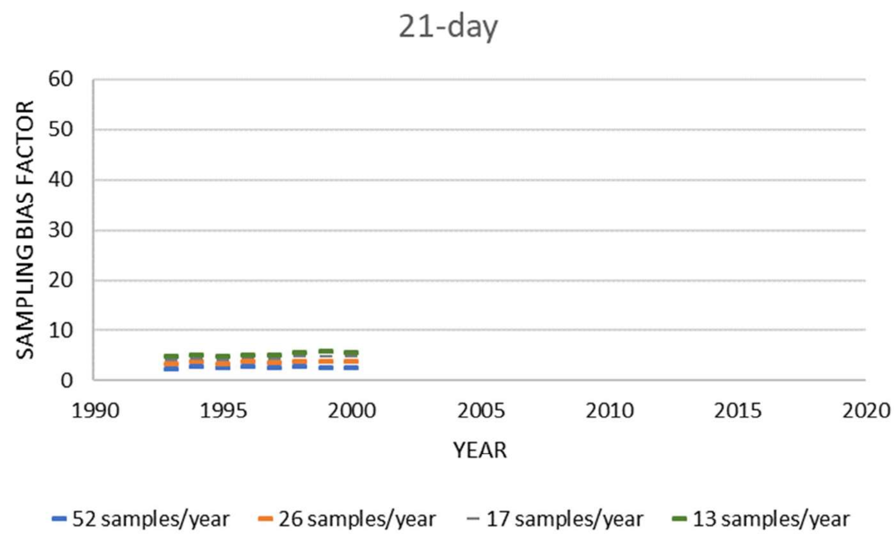

Figure 61. USGS Site 02335870: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

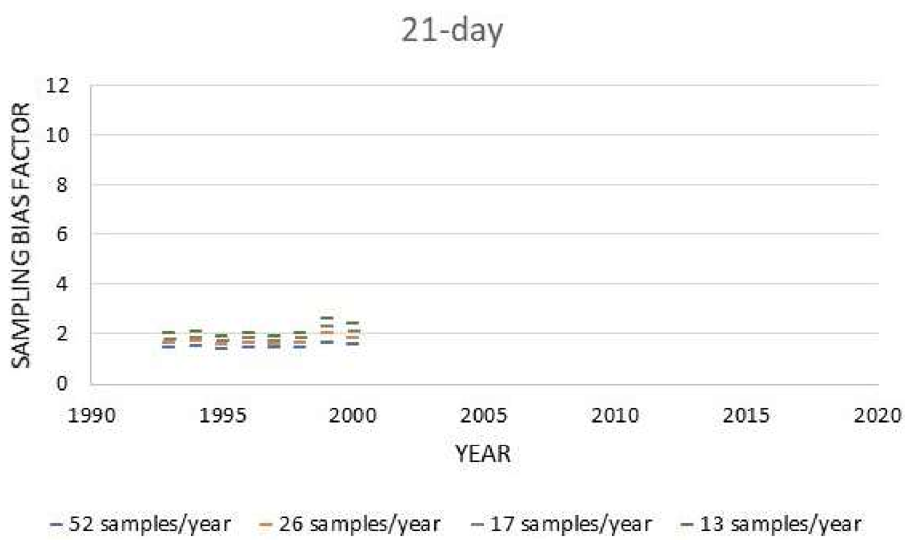

Figure 62. USGS Site 02335870: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

SBFs for estimating the upper confidence interval on the 1-day and 21-day average concentration for all sampling intervals were below 6 and 3, respectively. The values were generally consistent across the years with the last two years (1999 and 2000) having the highest SBFs.

9. USGS-04193500

Site and Sampling Characterization

USGS site 04193500 (Maumee River at Waterville, OH) is in a 6,283 mi^2 (16,274 km^2) agricultural watershed in HUC 04 dominated by cropland (73% of landcover) (**Figure 63.** Watershed Landcover

Characteristics of Sampling Site USGS-04193500). This watershed does not supply source drinking water, though it may be representative of other similar sites where chlorpyrifos is used, particularly given the high percentage of cropland landcover. Additionally, the site is downstream of numerous intakes, several with travel times less than a day and it is unclear whether measured concentrations result from chlorpyrifos use within this watershed or upstream.

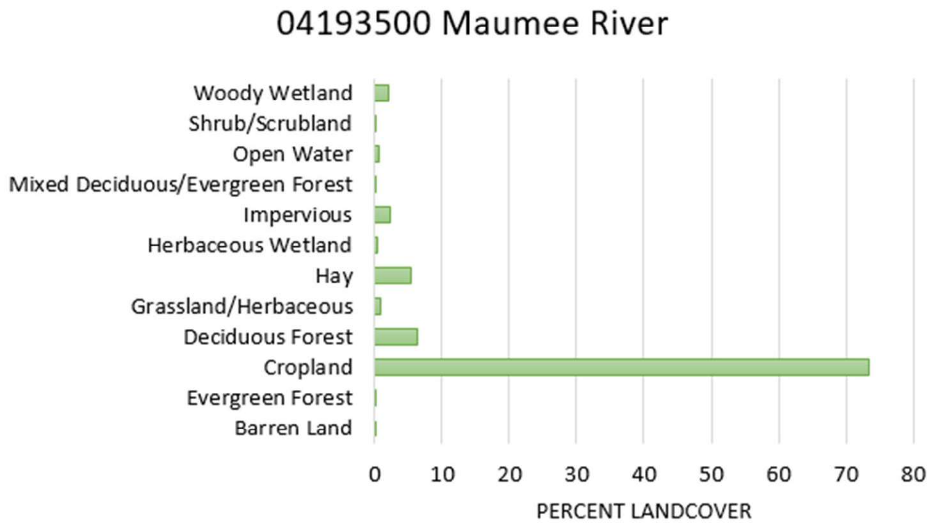

Figure 63. Watershed Landcover Characteristics of Sampling Site USGS-04193500

This site had a total of 29 detections out of 268 samples between 1996 and 2018 (**Table 45**)**. Table 45** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below. Data from NCWQR was not included with the USGS data download as the sampling frequency was much higher (near-daily) and detection frequency was much lower.

Table 45. USGS-04193500 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	13	9	69%	✓	0	✓
1997	17	5	29%	✓	0	✓
1998	14	0	0%	✓	0	✓
1999	13	0	0%	✓	0	✓
2000	14	2	14%	✓	0	✓
2001	11	2	18%	✓	0	✓
2002	8	0	0%	✓	0	✓
2003	8	1	13%	✓	0	✓
2004	8	1	13%	✓	0	✓
2005	7	2	29%	✓	0	✓
2006	16	3	19%	✓	0	✓
2007	16	4	25%	✓	0	✓
2008	0	—	—			
2009	0	—	—			
2010	1	0	0%			
2011	16	0	0%			
2012	3	0	0%			
2013	18	0	0%			
2014	18	0	0%			
2015	19	0	0%			
2016	18	0	0%			
2017	18	0	0%			
2018	12	0	0%			

[redacted]

SEAWAVE-QEX Analysis

While only 3 years of the USGS data have 12 or more samples and a detection frequency greater than 25% (Table 45), these were able to be modeled. Data from the NCWQR was not included as no years of data met the minimum SEAWAVE-QEX criteria. The data for 1996-2007 were input into SEAWAVE-QEX as they encompassed the 3 years meeting the minimum requirements. Since the empirical correlogram did not overlap with the fitted exponential correlation function using SEAWAVE-QEX default parameters, several small constants were added to improve fit (i.e., 0.0004, 0.0008, 0.0012). Fitting with the addition of 0.0012 resulted in the best model fit with low confidence.

For many years in the simulation, the 80% confidence bounds on the estimated maximum for each year span roughly an order of magnitude. There is a broad, shallow wave with a season from early May to early January and all measured concentrations fitting within the 2SSD bounds. Adjusted concentration is significantly (α=0.05) positively correlated with both MTFA and STFA. There is not much trend in the concentration data over the years. The normalized residuals are somewhat negatively skewed by season; viewing normalized residuals by year shows that residuals in 1996 are skewed positive while 1998-2001 are skewed negative. However, these negatively skewed residuals include many censored values, meaning that the exact location of the residuals will change in each conditional simulation. The empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 19.9 days.

Table 46 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations. In the year 2007, the mean estimated annual maximum (blue line) is high in the error bounds (blue box), indicating that the mean for that year is much higher than the median and the concentration data for 2007 may be skewed (**Figure 64**) and therefore may be overestimates.

Table 46. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-04193500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1996	0.36	0.17
1997	0.31	0.14
1998	0.18	0.08
1999	0.11	0.05
2000	0.08	0.05
2001	0.18	0.12
2002	0.13	0.07
2003	0.70	0.27
2004	0.20	0.12
2005	0.47	0.19
2006	0.20	0.13
2007	2.08	1.44

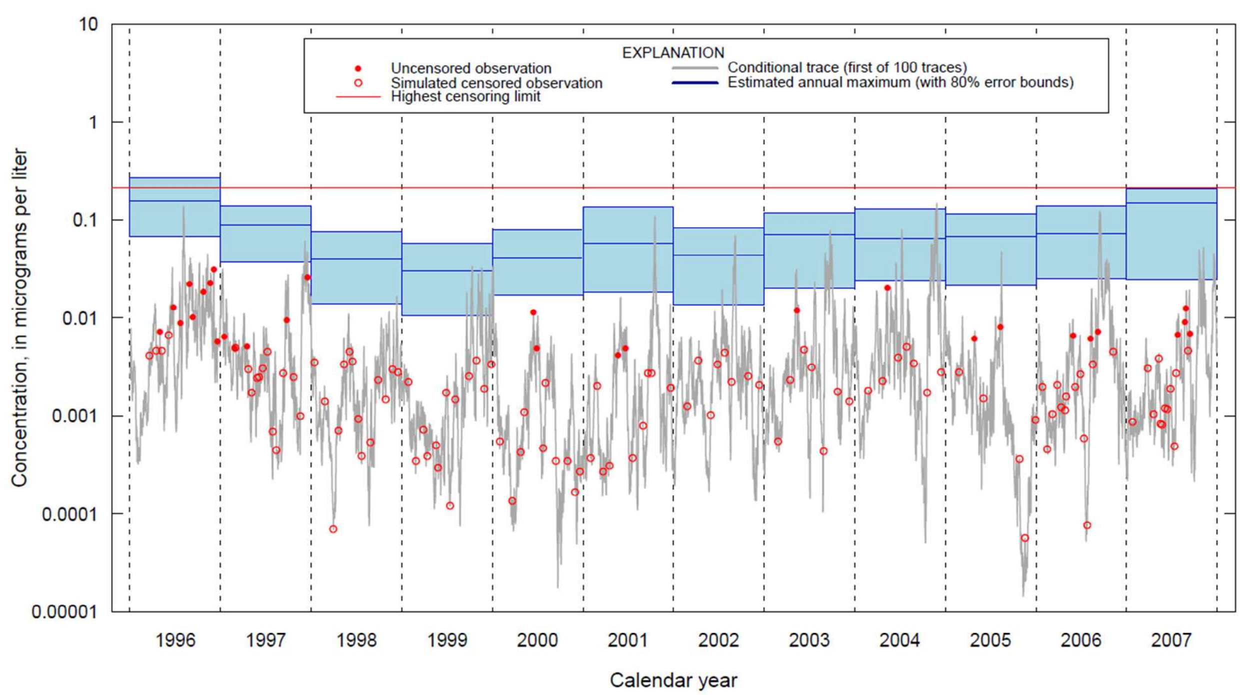

Figure 64. SEAWAVE-QEX Run Summary Diagnostic Plot for USGS-04193500 with High Mean in 2007

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown **Figure 61** and **Figure 62** respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

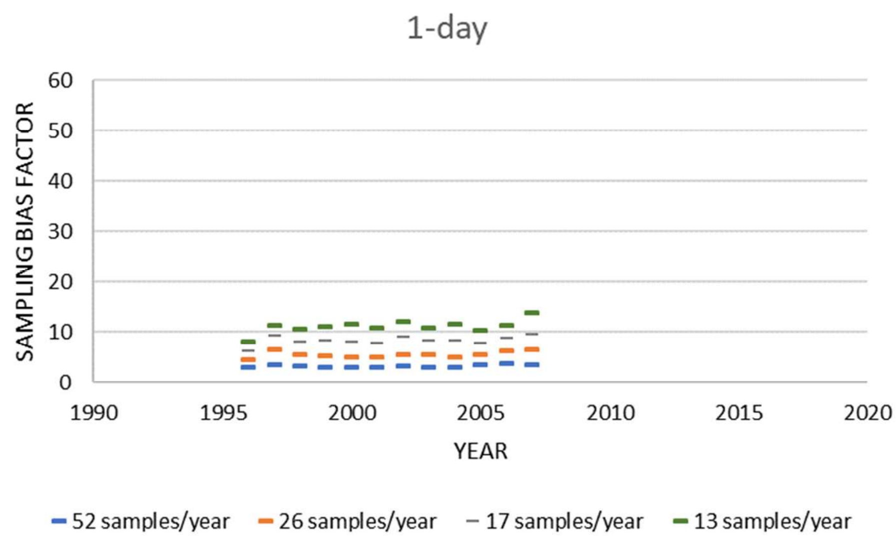

Figure 65. USGS Site 04193500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

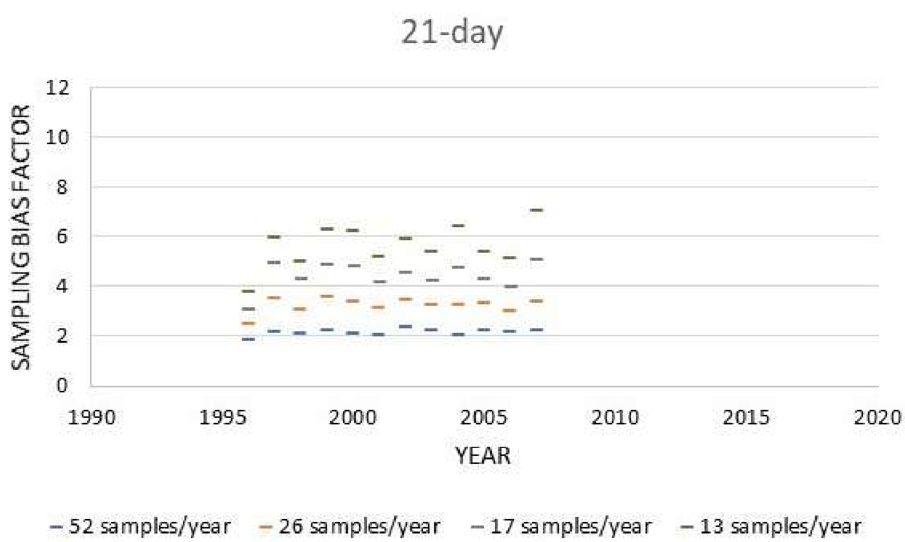

Figure 66. USGS Site 04193500: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

SBFs for estimating the upper confidence interval on the 1-day and 21-day average concentration for all sampling intervals were below 11.5 and 8, respectively. The values were generally consistent across the years with the last year (2007) having the highest SBFs.

10. USGS-11274538

Site and Sampling Characterization

USGS site 11274538 (Orestimba Creek near Crows Landing, California) falls within a 180 mi^2 (465.2 km^2) watershed. The percent agriculture in 2006 in the sample site watershed was only 5% cropland and included a combined 74% of grassland and shrubs (**Figure 67.** Watershed Landcover Characteristics of Sampling Site USGS-11274538). This site is upstream of three community water system intakes, with two either on or receiving water through diversion of the San Joaquin River. These are the same three CWSs that the USGS site 11303500 is also upstream meaning water flow or pesticide loading from these sites would both likely occur at the downstream intake. The time of travel between the sample site on Orestimba Creek and each community water system intake is 1 day.

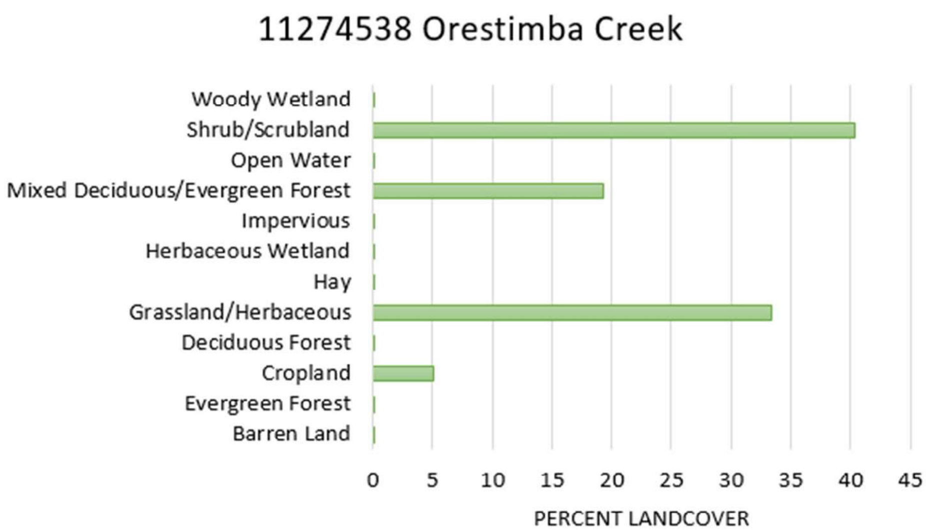

Figure 67. Watershed Landcover Characteristics of Sampling Site USGS-11274538

Based on available USGS data this site had a total of 163 detections out of 284 samples over 22 years between 1992 and 2017 (**Table 47**). Dow Agrosciences, currently known as Corteva Agriscience, also conducted a surface monitoring program in California on Orestimba Creek with daily and weekly sample collection (MRID 44711601). This program is described in more detail in the 2016 DWA (USEPA, 2016). USGS site 11274538 is "immediately above sampling location L1" where weekly samples were collected in 1996 and 1997 by Dow (Corteva Agriscience) for analysis of chlorpyrifos. **Table 47** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 47. USGS-11274538 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	44	40	91%	✓	21	✓
1993	40	22	55%	✓	4	✓
1994	1	1	100%	✓	0	✓
1995	1	1	100%	✓	0	✓
1996[2]	35	7	20%	✓	0	✓
1997[2]	26	15	58%	✓	0-3	✓
1998	14	9	64%	✓	0	✓
1999	16	5	31%	✓	0	✓
2000	20	15	75%	✓	2	✓
2001	43	24	56%	✓	8	✓
2002	18	8	44%	✓	0	✓
2003	16	8	50%	✓	0	✓
2004	8	5	63%	✓	0	✓
2005	6	4	67%	✓	0	✓
2006	4	3	75%	✓	0	✓
2007	0	—	—	✓	0	✓
2008	0	—	—	✓	0	✓
2009	1	1	100%	✓	0	✓
2010	15	5	33%	✓	0	✓
2011	0	—	—			
2012	2	0	0%			
2013	12	1	8%			
2014	3	0	0%			
2015	1	0	0%			
2016	4	2	50%			
2017	5	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).
[2] 1996-1997 include additional data. Without additional data, 1996 has no samples and 1997 has 10 with 90% detection rate. No samples excluded without addition of data in 1997 and 3 samples excluded with extra data.

SEAWAVE-QEX Analysis

Initial SEAWAVE-QEX trials used chlorpyrifos concentration data from USGS. Nine years of data have 12 or more samples and a detection frequency greater than 25%, as shown in **Table 47**. The maximum measured concentration at this site is 0.3 µg/L (April 24, 1992). Several iterations of inputs to SEAWAVE-QEX were attempted to find the best fit to the data, such as including only the years 1998-2003 or 1998-2010. Ultimately, using data from the years 1998-2010 had the best model fit for USGS data although 1992-2010 also had an acceptable, low confidence fit and encompassed more years of data.

Given that additional data, from Dow Agrosciences (referred to Dow in this section, and is now Corteva Agriscience), was available with high frequency sampling directly downstream of the site, SEAWAVE-QEX output from the USGS data model run was compared to unadjusted measured chlorpyrifos data for

1996 and 1997 from Dow at site L1. These data added 51 samples with 13 detections (**Table 47**). The maximum measured concentration at L1 in 1996 and 1997 was 1.126 µg/L and 1.066 µg/L, respectively. Since the model fit by SEAWAVE-QEX is dependent on the input data, and the USGS data from 1992-2010 produced a poorer model fit than the data from 1998-2010, the latter was used for comparison to the more robust data set of USGS and supplemental Dow data from 1992-2010. Both the USGS (1998-2010) and USGS with Dow (1992-2010) data produced SEAWAVE-QEX results with medium confidence based on the diagnostic plots.

The data from USGS alone encompassed the highest measured concentration in the Dow data from the site (1.126 µg/L), however, the summary statistics used as point estimates of concentration (i.e., the maximum of the 99th 1- and 21-day average concentrations) did not reflect the maximum measured in the other data set. This can be seen in **Figure 68**, which shows the upper centiles (> 95 percentile) of all conditional simulations overlaid in blue, the maximum measured concentration as a red line, and each of the annual point estimates encircled along the top. Conversely, the USGS with Dow data in green has enough estimates beyond the measured maximum that the concentration is captured by the point estimates and better reflect the expected concentrations at that site. The full distributions of estimated concentrations from both runs, shown in **Figure 69**, shows that the addition of the Dow data increased the percentage of concentrations at the lower tail of the distribution. Overall, this comparison suggests that SEAWAVE-QEX may underestimate chlorpyrifos concentrations at the upper tail if run for datasets with high censorship and infrequent sampling (≥7-day sampling). Therefore, the USGS data along with the more frequent (i.e., weekly) sampling collected by Dow were combined and analyzed using SEAWAVE-QEX for the years 1992-2010 and used in the development of SBFs.

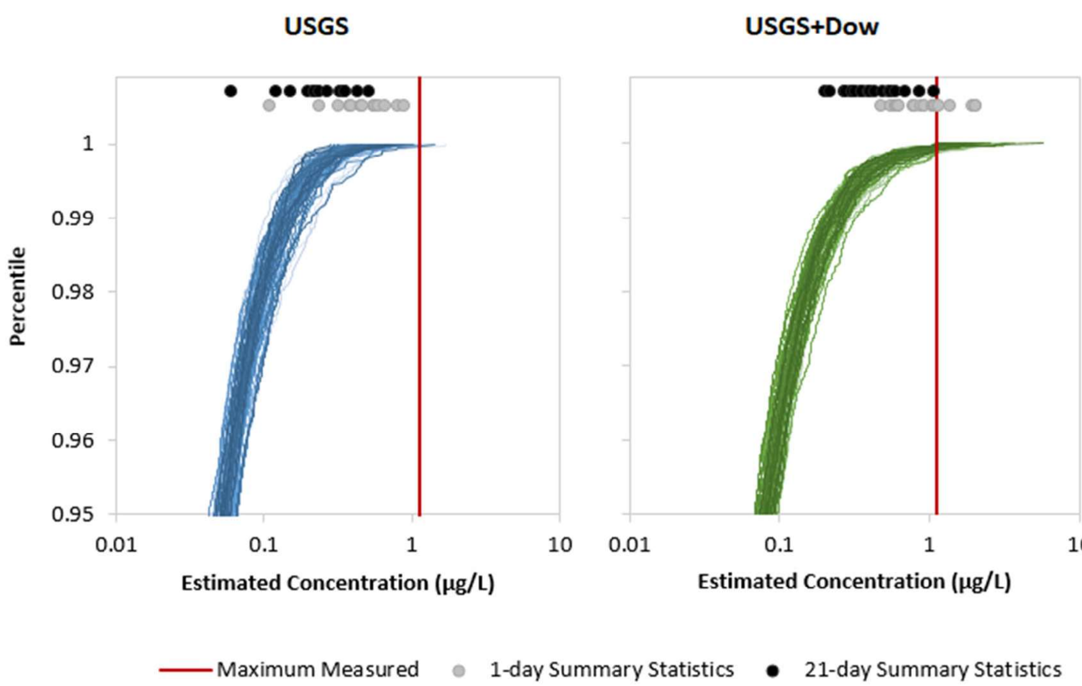

Figure 68. Upper Tail of Distribution of Estimated Concentrations from SEAWAVE-QEX and Associated Summary Statistics for USGS-11274538 With and Without Dow Monitoring Data

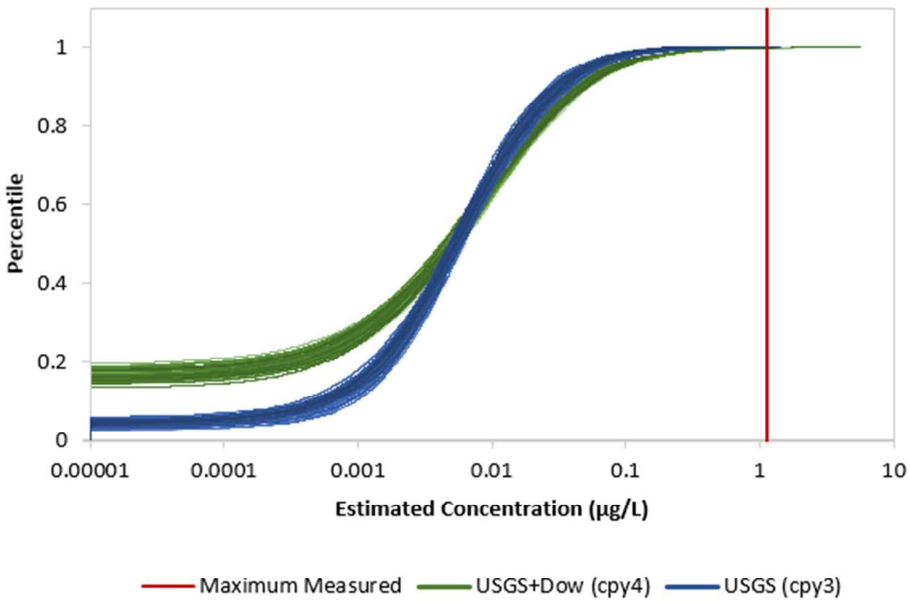

Figure 69. Distribution of Estimated Concentrations from SEAWAVE-QEX for USGS-11274538 With and Without Dow Monitoring Data Compared to Maximum Measured Concentration in 1996

SEAWAVE-QEX fit a shallow, long seasonal wave to the data and the 2xSSD on the model are approximately one order of magnitude. The season extends first of February to mid-October. The shape and season of the wave are very similar to that produced for the USGS data alone. The measured data are mostly within the 2xSSD lines and other model assumptions are satisfied (all diagnostic plots are provided in **ATTACHMENT 4**).

For just the USGS data from 1998-2010 (file name cpy3), the 80% confidence bounds on the estimated maximum for each year span up to an order of magnitude and all are below 1 µg/L. SEAWAVE-QEX fit a broad, shallow wave with a season from early April to early October and most measured concentrations fitting within the 2SSD bounds. Adjusted concentration is generally not correlated with MTFA but has a slight negative weak correlation with STFA. Concentration data trends somewhat upward over the years. The normalized residuals are somewhat positively skewed viewed across season and seem to be particularly skewed positive in 2000, 2006, and 2010. The empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 9.3 days.

When including the daily sampling data taken from another sample location on Orestimba Creek from 1996-1997 (file name cpy4), the 80% confidence bounds on the estimated maximum for each year similarly span up to an order of magnitude but include concentrations above 1 µg/L. The 80% error bounds for the two years with weekly samples added (i.e., 1996-1997) are much tighter (i.e., low uncertainty) than for the years of USGS data only, though the upper bound (i.e., top of the blue box) is not substantially higher than those of other years. SEAWAVE-QEX fits a single broad wave for these data as well, with an extended season from late January to mid-October and several measured data points falling outside the 2SSD bounds. Adjusted concentration is weakly negatively correlated with both MTFA and STFA; the negative correlation with STFA is present in both SEAWAVE-QEX runs but does not significantly impact the model. Measured concentrations trend somewhat downward from 1992-2010 and normalized residuals are still positively skewed in this run. There are several data points in season that have the maximum residual value (+3); these are all from the extra measured data in 1996-1997 that are at higher concentrations. Additionally, 2006 and 2010 remain skewed positive relative to other years. The empirical correlogram 95% confidence limits overlaps well with the estimated correlation function at short sampling intervals (i.e., to the left of the red line) with a CTS of 7.7 days.

Table 48 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 48. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-11274538

Year	USGS		USGS+Dow	
	1-day Conc. (µg/L)	21-day Conc. (µg/L)	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	—	—	1.11	0.54
1993	—	—	0.48	0.20
1994	—	—	1.95	1.09
1995	—	—	1.04	0.56
1996	—	—	1.39	0.59
1997	—	—	2.05	0.69
1998	0.38	0.20	0.63	0.27
1999	0.32	0.15	0.88	0.43
2000	0.47	0.22	0.61	0.31
2001	0.11	0.06	0.61	0.22
2002	0.24	0.12	0.59	0.31
2003	0.45	0.27	0.94	0.40
2004	0.39	0.22	0.79	0.36
2005	0.60	0.24	1.07	0.39
2006	0.57	0.33	1.17	0.49
2007	0.80	0.51	2.06	0.87
2008	0.66	0.35	0.61	0.32
2009	0.55	0.35	0.55	0.36
2010	0.90	0.43	0.81	0.28

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 70** and **Figure 71**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

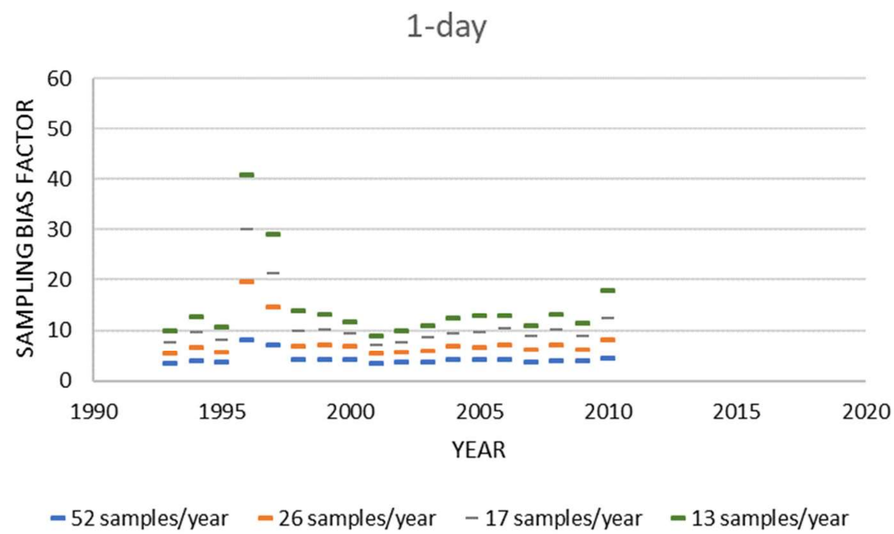

Figure 70. USGS Site 11274538: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

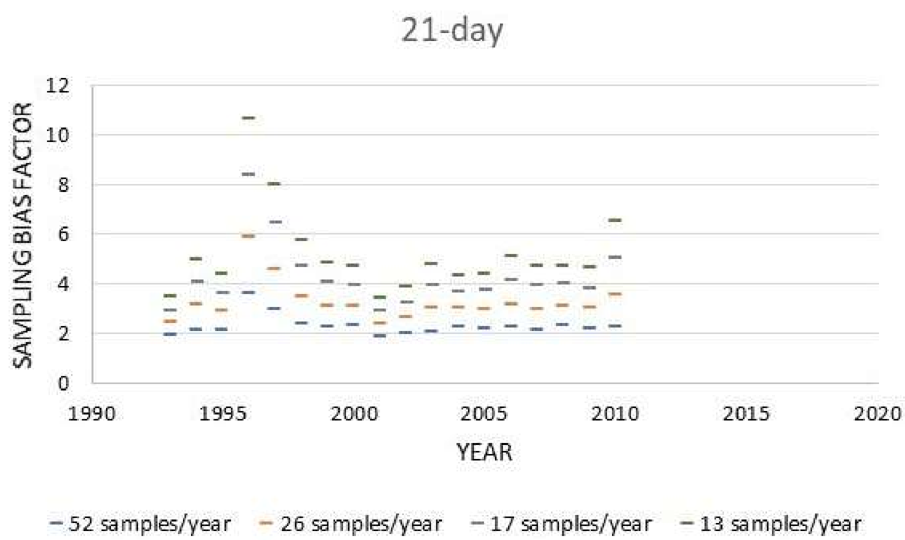

Figure 71. USGS Site 04193500: **Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration**

SBFs varied across years. The highest SBFs were estimated for the years (1996 and 1997) with the most monitoring data (i.e., daily). Like USGS-02174250, the highest SBFs are driven by measured concentrations. Again, this calls into question the ability to estimate accurate SBFs when infrequent sampling (i.e., non-daily) is conducted or misses peak occurrence concentrations.

11. USGS-03612500

Site and Sampling Characterization

USGS site 03612500 (Ohio River at Dam 53 near Grand Chain, IL) is in HUC-06 in a 203,100 mi^2 (526,000 km^2) drainage area. The watershed has roughly 20% cropland, 15% hay, and 46% deciduous forests (**Fig**).

The sampling location is upstream of several drinking water intakes serving community water systems, pulling from the Ohio River. Travel times from the sampling site to each intake is less than a day, making the site very relevant for source drinking water.

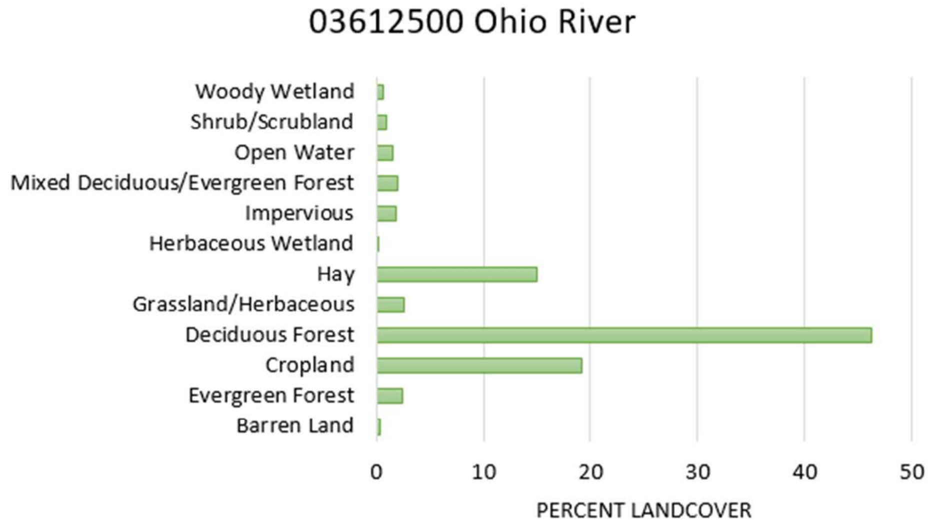

Figure 72. Watershed Landcover Characteristics of Sampling Site USGS-11274538

The site has 42 chlorpyrifos detections out of 262 samples from 1992-2014 (**Table 49**). **Table 49** also includes information on the years simulated in SEAWAVE-QEX as well as the years SBFs were developed. SEAWAVE-QEX analysis and the developed SBFs are described in the subsections below.

Table 49. USGS-03612500 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1992	10	10	100%	✓	0	✓
1993	1	1	100%	✓	0	✓
1994	0	—	—	✓		✓
1995	0	—	—	✓		✓
1996	12	10	83%	✓	0	✓
1997	15	6	40%	✓	0	✓
1998	13	3	23%	✓	0	✓
1999	11	3	27%	✓	0	✓
2000	13	7	54%	✓	0	✓
2001	15	1	7%			
2002	15	0	0%			
2003	13	0	0%			
2004	15	0	0%			
2005	14	0	0%			
2006	12	0	0%			
2007	13	0	0%			
2008	12	0	0%			
2009	12	0	0%			
2010	12	0	0%			
2011	15	1	7%			
2012	12	0	0%			
2013	14	0	0%			
2014	13	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The site has 42 chlorpyrifos detections out of 262 samples from 1992-2014, with only 3 years meeting the minimum criteria for SEAWAVE-QEX as outlined earlier (**Table 49**). The site does not have daily streamflow measurements to use as a covariate in SEAWAVE-QEX. However, in a USGS study (Aulenbach et al., 2007), streamflow from a nearby site is used in conjunction with water quality data from this site. Therefore, streamflow from USGS-03611500 (Ohio River at Metropolis, IL) is also used in this analysis as a surrogate for USGS-03612500. The site was run in SEAWAVE-QEX unsuccessfully using years 1996-2000 with and without adding a constant (0.004 and 0.012). The analysis was repeated with a start date of 1992, since 1992 has 10 samples with 100% detection frequency. Including 1992 improved the fit and was considered acceptable after subtracting a constant of 0.012 within the model.

The 80% confidence bounds on the estimated maximum for each year span less than an order of magnitude. The estimated concentrations have a clear downward trend from 1992 to 2000 of nearly an order of magnitude. Similarly, the adjusted concentrations trend significantly downward over the timeframe analyzed. However, it is notable that several measured concentrations from 1996-1998 are in the mid-range of the measured concentrations from 1992, implying that the estimated concentrations for 1992 continue to be relevant for peak values throughout the time period. There are two shallow seasonal waves of similar amplitude; one season spanning early February to late June and the second from late October to late December. All but one measured concentration is within the 2SSD bounds. There is a significant (α=0.05) negative correlation of adjusted concentration with MTFA and weakly negative correlation with STFA. The normalized residuals are mostly centered on zero with slightly positive skew seeming to result from data in 2000. The empirical correlogram 95% confidence limits overlap with the fitted exponential correlation function at time intervals shorter than the average (to the left of the red line) with a CTS of 20.5 days.

Table 50 summarizes the 1- and 21-day estimated concentrations from SEAWAVE-QEX for each year based on the maximum of the 99th percentile concentrations.

Table 50. Maximum of the 99th Percentile 1- and 21-day Concentrations of Chlorpyrifos at USGS-03612500

Year	1-day Conc. (µg/L)	21-day Conc. (µg/L)
1992	0.35	0.23
1993	0.20	0.14
1994	0.32	0.21
1995	0.10	0.068
1996	0.059	0.042
1997	0.036	0.023
1998	0.046	0.033
1999	0.031	0.023
2000	0.040	0.021

Sampling Bias Factor Development

SBFs developed for estimating the 1-day and 21-day average concentrations are shown in **Figure 73** and **Figure 74**, respectively. These figures show the median SBFs across SEAWAVE-QEX chemographs for each site year and sample number category.

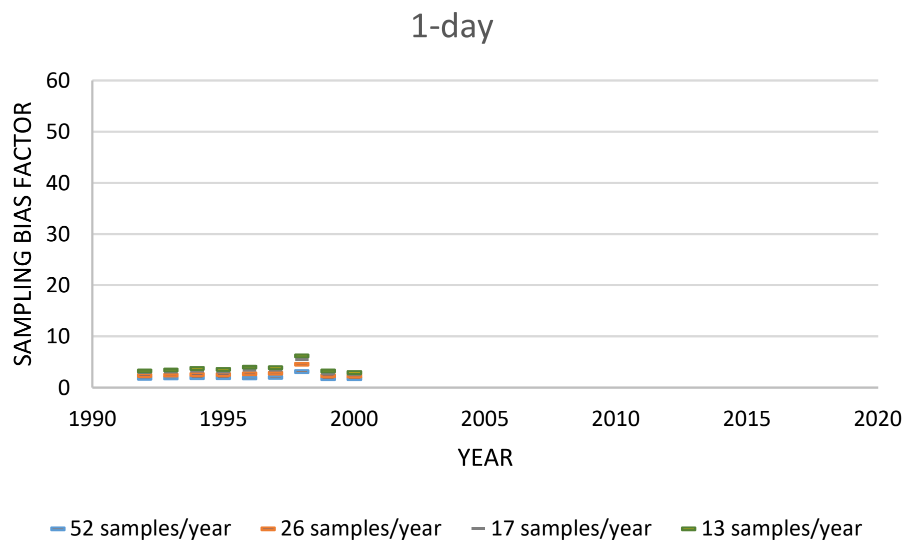

Figure 73. USGS Site 03612500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 1-day Average Concentration

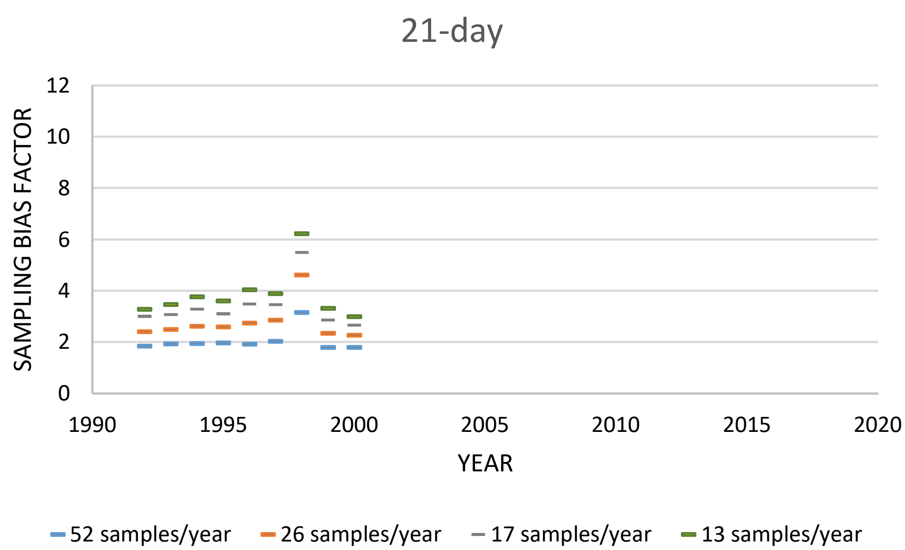

Figure 74. USGS Site 03612500: Sampling Bias Factors for Estimating the Upper Confidence Interval on the 21-day Average Concentration

SBFs are consistent across years except 1998. There is nothing notable about the diagnostic plots that would suggest that the estimated concentrations from SEAWAVE-QEX would be out of line for 1998. Like USGS site 03612500, the highest bias factors are driven by measured concentrations. The confidence bounds on the 1998 simulation are tight around the measured concentration. Giving confidence in the estimated SBFs. Again, this calls into question the ability to estimate accurate SBFs using SEAWAVE-QEX when infrequent (i.e., non-daily) sampling is conducted or misses peak occurrence concentrations.

12. USGS-11447360

Site and Sampling Characterization

USGS site 11447360 (Arcade Creek near Del Paso Heights, CA) falls has a 38 mi^2 (98.5 km^2) urban watershed in HUC 18, with 42% impervious surfaces and no cropland (**Figure 75.** Watershed Landcover Characteristics of Sampling Site USGS-11447360). The water travel time is noted to be less than a day to a community water system intake.

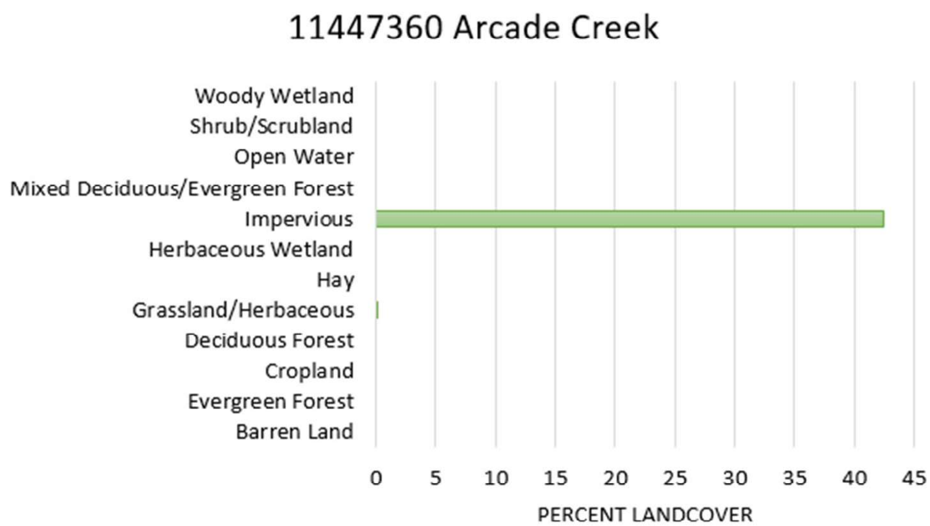

Figure 75. Watershed Landcover Characteristics of Sampling Site USGS-11447360

This site had a total of 57 detections out of 128 samples between 1996 and 2012. Four years of data have 12 or more samples and a detection frequency greater than 25% as shown in **Table 51**. SEAWAVE-QEX analysis is described in the subsection below.

Table 51. USGS-11447360 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1996	2	2	100%			
1997	24	18	75%	✓	0	✓
1998	4	2	50%	✓	0	✓
1999	0	—	—	✓	0	✓
2000	0	—	—	✓	0	✓
2001	10	6	60%	✓	0	✓
2002	9	2	22%	✓	0	✓
2003	9	4	44%	✓	0	✓
2004	13	6	46%	✓	0	✓
2005	20	8	40%	✓	0	✓
2006	4	3	75%	✓	0	✓
2007	4	0	0%	✓	0	✓
2008	13	6	46%	✓	0	✓
2011	5	0	0%			
2012	11	0	0%			

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

Data for 1997-2008 were input into SEAWAVE-QEX. Other subsets of years were explored; however, the best fit was determined to be for the period from 1997 to 2008 with the addition of a small constant (0.0012), which resulted in an acceptable model fit of low confidence. The maximum measured concentration at this site is 0.04 μg/L (January 13, 1997).

The 80% error bounds on the estimated maximum are <1 μg/L for each year and span much less than 1 order of magnitude. The seasonal wave is very shallow in an extended season from September to early May, which is the wetter time of year in California, with few measured concentrations outside of the 2SSD bounds. Adjusted concentration has a significant positive correlation with MTFA and weakly positive correlation with STFA. The adjusted concentrations decrease over time (1997 to 2008) and the residuals are centered on zero. The 95% confidence limits on the empirical correlogram overlaps with the fitted exponential correlation function at time intervals less than the average. However, there is more uncertainty at the shortest time intervals (large 95% confidence limits without much overlap). The CTS is 22.6 days and all other model assumptions are satisfied (diagnostic plots are provided in **ATTACHMENT 4**).

Further analysis of the streamflow data indicates that results from SEAWAVE-QEX for this site may not be appropriate to use quantitatively, based on feedback from the SAP. This is because 6.5% of the streamflow values are zero for this site (see **Figure 76**). Therefore, SEAWAVE-QEX chemographs from this site were not used for the development of SBFs.

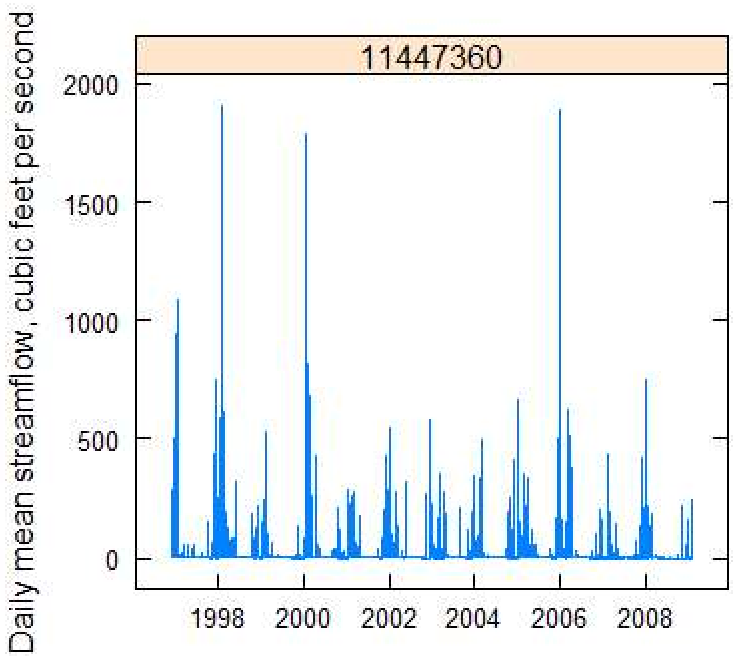

Figure 76. USGS-04193500 Streamflow Data

13. USGS-14201300

Site and Sampling Characterization

USGS site 14201300 (Zollner Creek near Mount Angel, OR) is in a 15.7 mi^2 (40.6 km^2) watershed in HUC 17 with 53% cropland and 35% hay landcover (**Figure 77.** Watershed Landcover Characteristics of Sampling Site USGS-14201300). The time of travel of water from the sampling site to a community water system intake is one day.

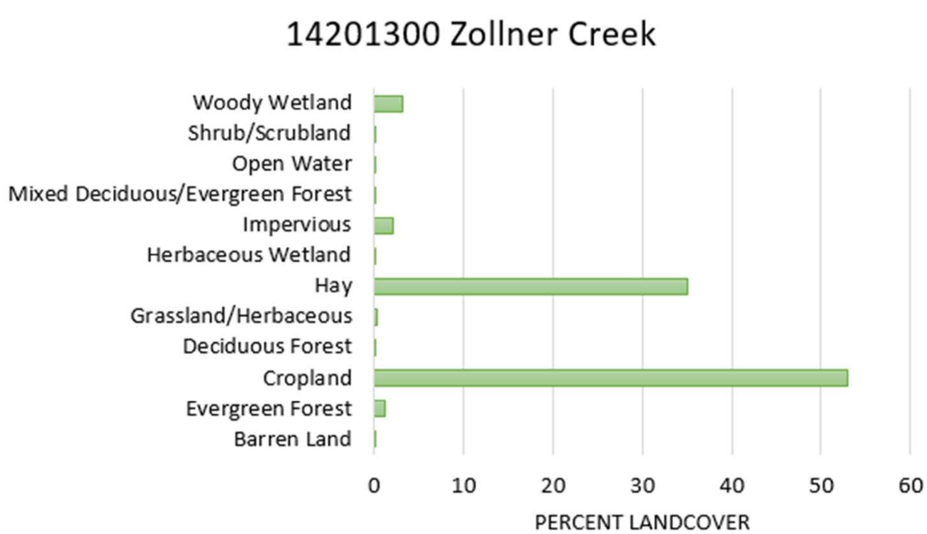

Figure 77. Watershed Landcover Characteristics of Sampling Site USGS-14201300

This site had a total of 205 detections out of 354 samples over 25 years between 1993 and 2019. Twelve years of data have 12 or more samples and a detection frequency greater than 25% (**Table 52**) spanning from 1993-2018.

Table 52. USGS-14201300 Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency	Years Simulated in SEAWAVE-QEX	Number of Samples Excluded by SEAWAVE-QEX[1]	Years Sampling Bias Factors Developed
1993	14	9	64%	✓	8	
1994	11	8	73%	✓	0	
1995	5	3	60%	✓	0	
1996	3	2	67%	✓	0	
1997	9	7	78%	✓	0	
1998	11	5	45%	✓	0	
1999	12	5	42%	✓	0	
2000	11	9	82%	✓	0	
2001	19	14	74%	✓	0	
2002	24	20	83%	✓	0	
2003	13	4	31%	✓	0	
2004	9	8	89%	✓	0	
2005	6	6	100%	✓	0	
2006	4	4	100%	✓	0	
2007	5	5	100%	✓	0	
2008	17	14	82%	✓	0	
2009	0	—	—	✓	n/a	
2010	0	—	—	✓	n/a	
2011	5	5	100%	✓	0	
2012	23	19	83%	✓	0	
2013	24	6	25%	✓	0	
2014	24	9	38%	✓	0	
2015	31	7	23%	✓	0	
2016	24	11	46%	✓	0	
2017	24	13	54%	✓	0	
2018	23	11	48%	✓	0	
2019	3	1	33%		n/a	

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Samples may be excluded by SEAWAVE-QEX when samples are spaced <3 days apart (see SEAWAVE-QEX SOP).

SEAWAVE-QEX Analysis

The years 1993-2018 were included in the SEAWAVE-QEX modeling with default parameters, resulting in a low confidence fit. Due to the limitations of site relevance due to intermittent flow, additional fits were not pursued further.

The 80% error bounds on the estimated maximum vary in size by year, but all are <1 µg/L and appear to span less than 1 order of magnitude. The seasonal wave is very shallow in an extended season from late September to late June, with few measured concentrations outside of the 2SSD bounds. Adjusted concentration has a weakly positive correlation with MTFA and significantly positive correlation with STFA; however, both diagnostic plots indicate that there are a number of flow days where the flow anomaly does not correlate with concentration at all, typically observed for sites with zeros in the flow data (see **Figure 78**).

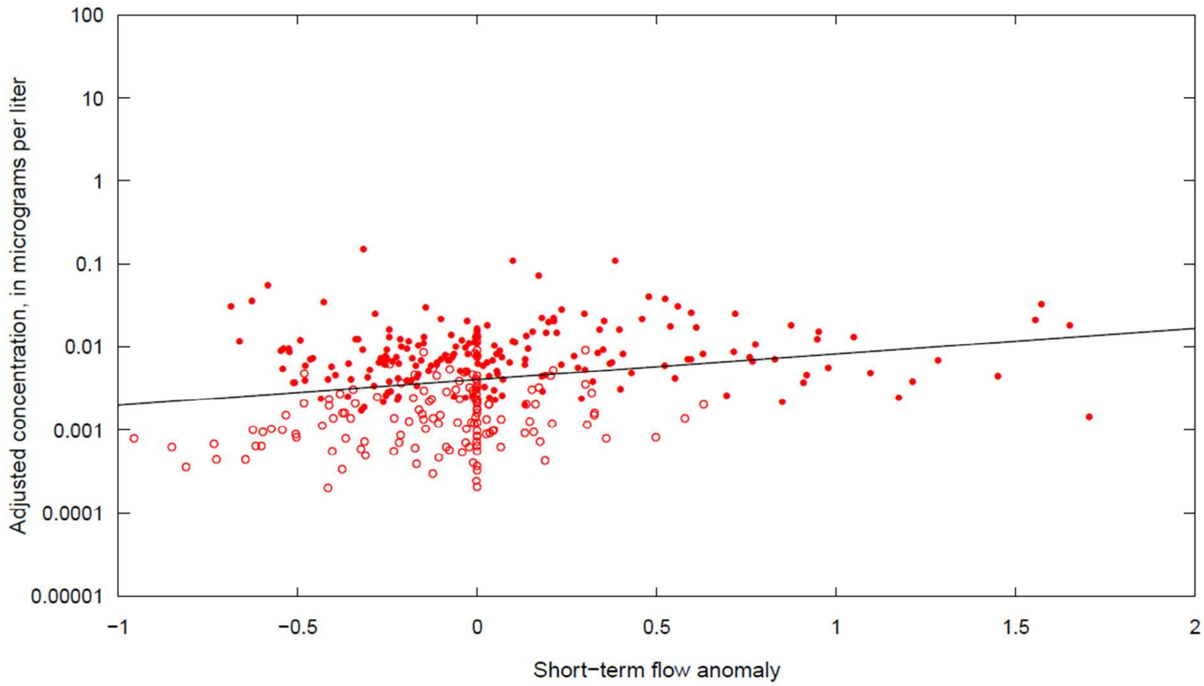

Figure 78. Correlation Between Adjusted Concentration and Short-term Flow Anomaly for USGS-14201300

The adjusted concentrations decrease over time (1993 to 2018) and the residuals are centered on zero with a few individual residuals skewing positive. By year, the residuals skew positive from roughly 2001 to 2008, suggesting that further subsets of the data (e.g., 2012 to 2018) may produce improved results. The 95% confidence limits on the empirical correlogram does not always overlap with the fitted exponential correlation function at time intervals less than the average; when there is not overlap, the empirical correlogram is lower, indicating the potential to overestimate concentrations. The CTS is 43.9 days.

While the flow data for the site does not have measurements of zero, the seasonality of flow (**Figure 79**) and unusual diagnostic plots have decreased confidence in quantitative use of the SEAWAVE-QEX output to an unacceptable level. Therefore, SEAWAVE-QEX chemographs from this site were not used for the development of SBFs.

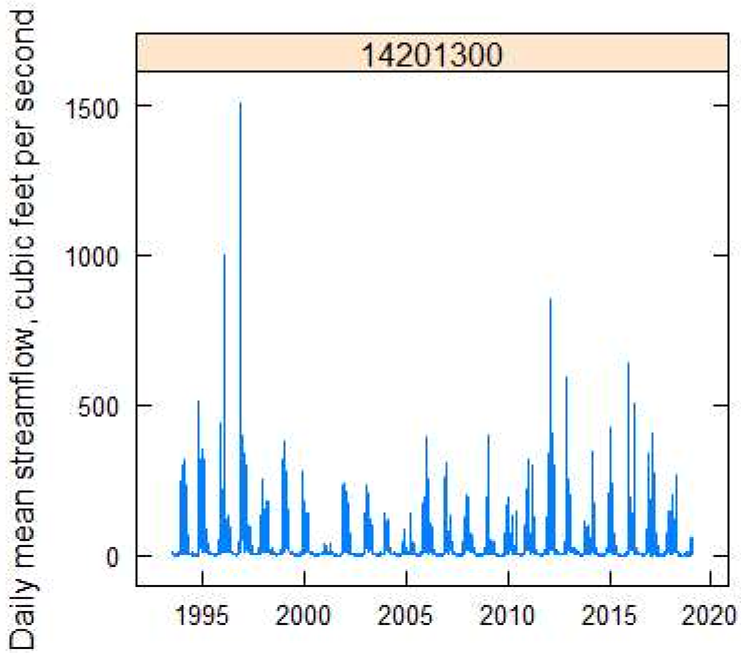

Figure 79. USGS-14201300 Streamflow Data

14. OREGONDEQ-32010-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32010-ORDEQ sampling site (West Prong Little Walla Walla River south of Stateline Road, OR) is in a 24.1 mi^2 (62.3 km^2) watershed in HUC 17 with 55% evergreen forest, 14.5% grassland, 12% cropland and <1% hay landcover (**Figure 80.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32010-ORDEQ). This sample site is located upstream of two community water system intakes. Based on flow data, this site is within a 2-day travel time of one community water system intake and within in a 3-day travel time of a second community water system intake.

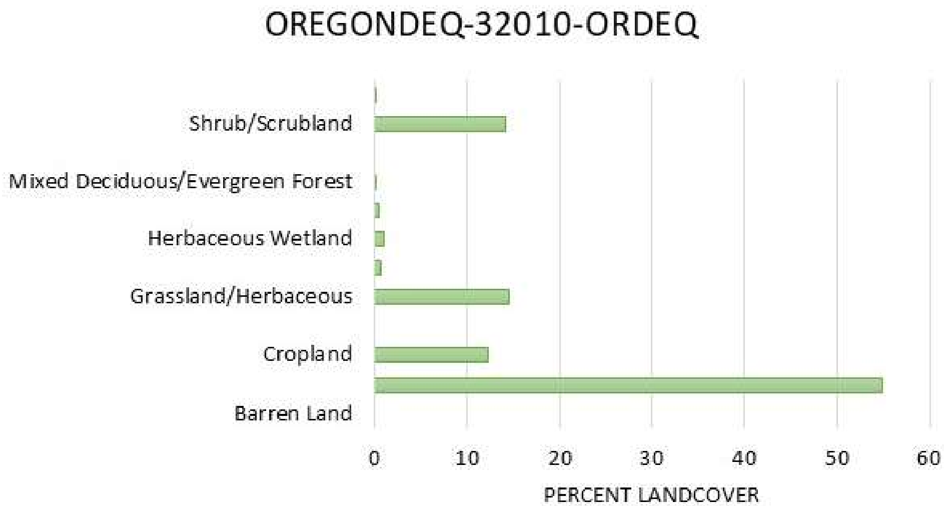

Figure 80. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32010-ORDEQ

A summary of the data collected for OREGONDEQ-32010-ORDEQ is provided in **Table 53**. Sample collection began in 2005 and continues today. Between 9 and 15 samples have been collected each year. Detection frequencies at this site are high in most years. All quantifiable detections at this site occurred in the months of March or April (**Figure 81**).

Table 53. OREGONDEQ-32010-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	15	6	40%
2006	14	5	36%
2007	10	3	30%
2008	12	6	50%
2009	14	3	21%
2010	10	2	20%
2011	10	1	10%
2012	10	3	30%
2013	11	1	9%
2014	11	2	18%
2015	13	1	8%
2016	12	2	17%
2017	12	2	17%
2018	10	4	40%
2019	9	0	0%
Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25% [1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.			

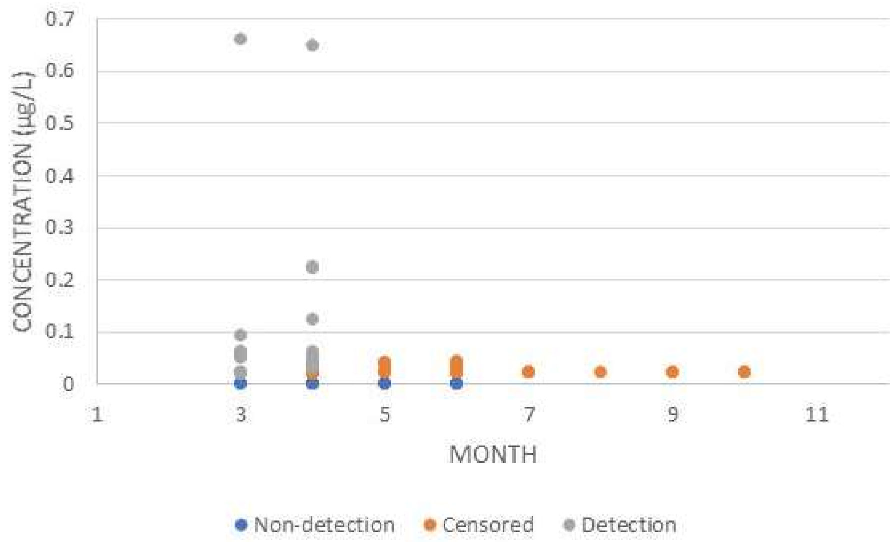

Figure 81. OREGONDEQ-32069-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linear interpolated) 21-day average concentration. The results are shown in **Table 57**.

Table 54. Sampling Bias Factor Analysis Summary for OREGONDEQ-32010-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2009	14	0.65	0.14	54.8 (22.2)	11.5 (8.9)	35.6 (14.41)	1.6 (1.2)
Bracketed values are for sub-set of SBFs for years 2005-2015							

15. OREGONDEQ-32068-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32068-ORDEQ sampling site (Noyer Creek at Hwy 212, St. Paul Lutheran Church (North Fork, Deep Creek, Clackamas, OR) is in a 33.3 mi^2 (86.3 km^2) watershed in HUC 17 with 7.1% evergreen forest, 8.4% cropland, 39.3% hay landcover and 9.7% impervious (**Figure 82.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32068-ORDEQ). This sample site is located upstream of 5 community water system intakes. Based on flow data, all 5 of these community water system intakes are located within a day's travel time from the monitoring site.

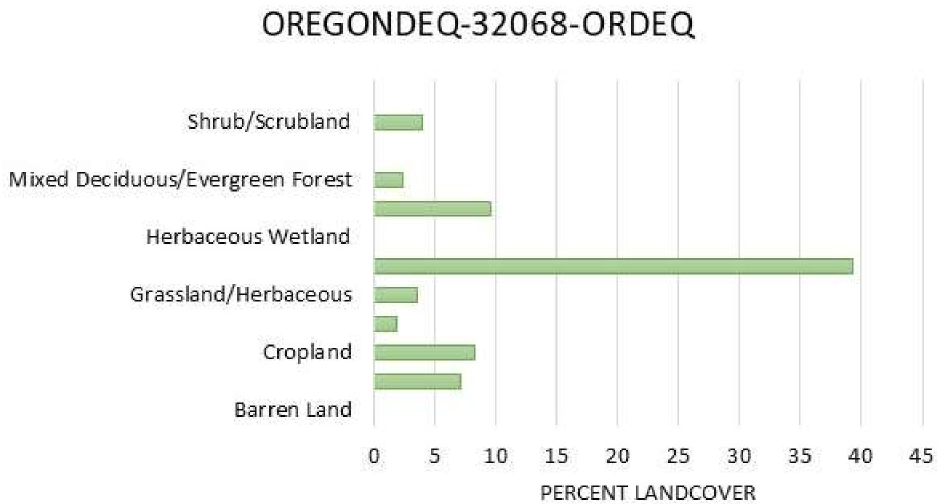

Figure 82. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32068-ORDEQ

A summary of the data collected for OREGONDEQ-32068-ORDEQ is provided in **Table 55**. Sample collection at this site began in 2005 and is ongoing. Detection frequencies are high with between 6 and 16 samples collected per year. With the highest detection frequency occurring in 2016. Quantifiable detections at this site occur throughout the year, mainly March through December with peak measured concentrations occurring in May and October.

Table 55. OREGONDEQ-32068-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	12	5	42%
2006	16	6	38%
2007	14	5	36%
2008	10	1	10%
2009	9	4	44%
2010	6	2	33%
2011	8	2	25%
2012	11	2	18%
2013	15	4	27%
2014	13	0	0%
2015	15	2	13%
2016	13	9	69%
2017	14	4	26%
2018	13	4	31%
2019	8	1	13%
Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25% [1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.			

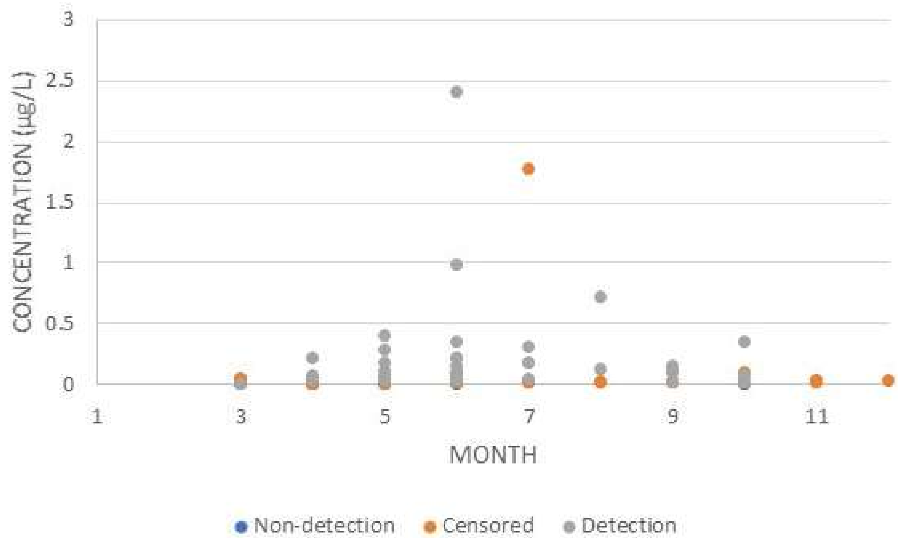

Figure 83. OREGONDEQ-32068-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linear interpolated) 21-day average concentration. The results are shown in **Table 56**.

Table 56. Sampling Bias Factor Analysis Summary for OREGONDEQ-32068-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2007	14	2.4	1.7	54.8 (22.2)	11.5 (8.9)	131.5 (53.3)	19.3 (14.9)
2015	15	1.8	0.7	54.8 (22.2)	11.5 (8.9)	97.0 (39.3)	7.6 (5.6)
2016	13	0.7	0.6	54.8 (22.2)	11.5 (8.9)	39.6 (16.0)	6.5 (5.0)
Bracketed values are for sub-set of SBFs for years 2005-2015							

16. OREGONDEQ-32069-ORDEQ

Site and Sampling Characterization

OREGONDEQ-32069-ORDEQ sampling site (NF Deep Creek at Springwater trail, Boring, between 2nd and 3rd towers from trailhead (Clackamas, OR)) is in a 19.5 mi^2 (50.6 km^2) watershed in HUC 17 with 7.1% evergreen forest, 27.3% cropland and 30.3% hay landcover (**Figure 84.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32069-ORDEQ). This sample site is located upstream of 5 community water system intakes. All community water system intakes are located within a day's travel time of the monitoring site. These are the same community water system intakes downstream of OREGONDEQ-32068-ORDEQ.

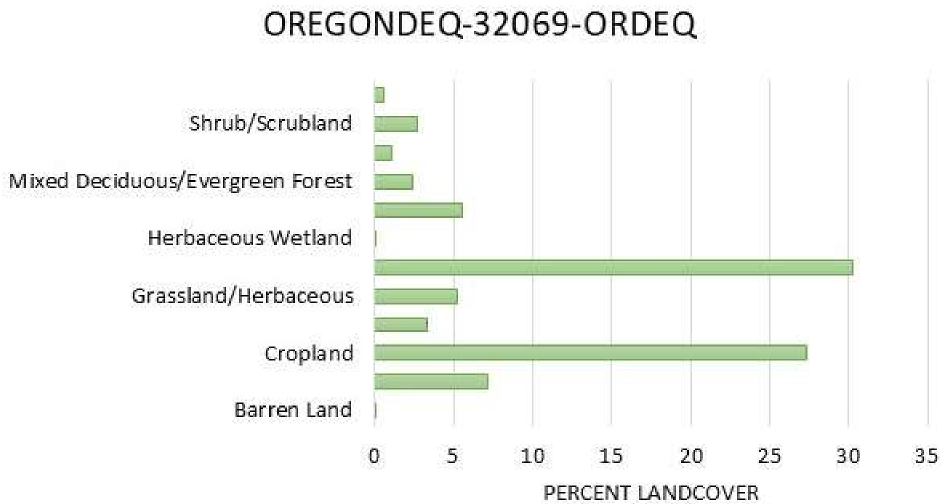

Figure 84. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-32069-ORDEQ

A summary of the data collected for OREGONDEQ-32069-ORDEQ is provided in **Table 57**. Sample collection began in 2005; however, the last year of sampling collection at this site ended in 2011. Sample frequency ranged from 5 to 16 per year. Detection frequency was high in those years with the most samples collected. Quantifiable detections at this site occur throughout the year except for January and February. The maximum measured concentrations occurred in May and October (**Figure 85**).

Table 57. OREGONDEQ-32069-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2005	12	8	67%
2006	16	1	6%
2007	13	7	54%
2008	9	1	11%
2009	9	0	0%
2010	5	1	20%
2011	8	0	0%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

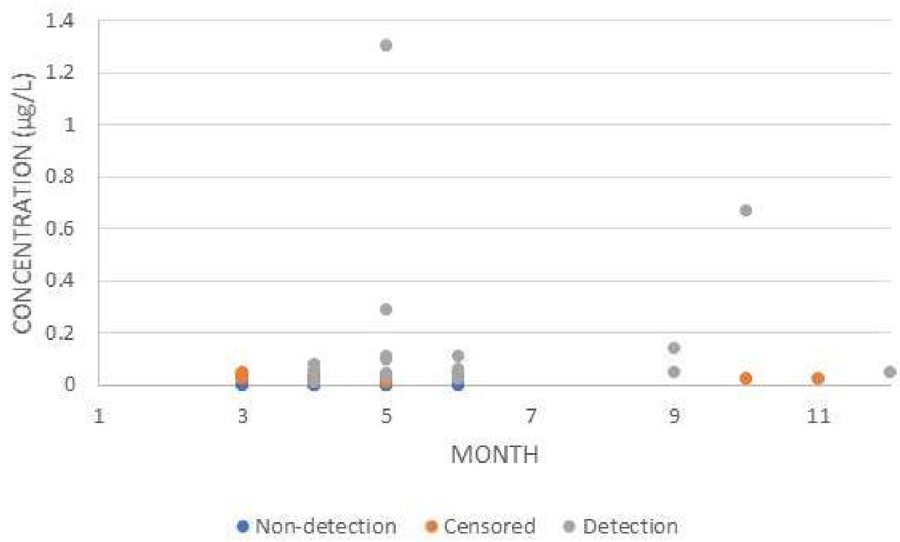

Figure 85. OREGONDEQ-32069-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. The results are shown in **Table 58**.

Table 58. Sampling Bias Factor Analysis Summary for OREGONDEQ-32069-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2007	13	1.3	0.4	54.8 (22.2)	11.5 (8.9)	71.2 (28.9)	4.8 (3.7)
Bracketed values are for sub-set of SBFs for years 2005-2015							

17. OREGONDEQ-34235-ORDEQ

Site and Sampling Characterization

OREGONDEQ-34235-ORDEQ sampling site (Middle Cozine at Old Sheridan Road (McMinnville, OR)) is in a 73.5 mi^2 (190.3 km^2) watershed in HUC 17 with 2.8% evergreen forest, 35.7% cropland, 9.4% hay landcover and 11.1% impervious (**Figure 86.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-34235-ORDEQ). This sample site is located upstream of 2 community water system intakes. Both community water system intakes have a 1-day travel time between the sampling site and the intake.

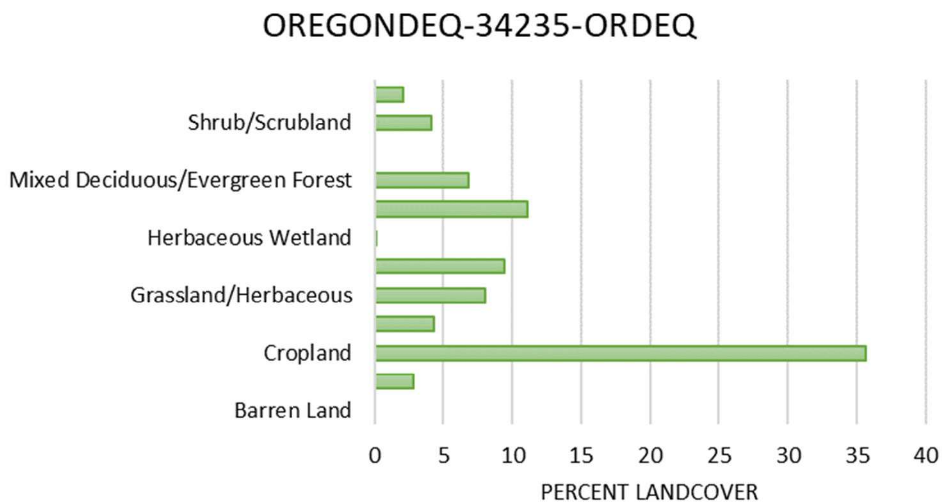

Figure 86. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-34235-ORDEQ

A summary of the data collected for OREGONDEQ-34235-ORDEQ is provided in **Table 59**. Sample collection at this site began in 2007 and is ongoing. Detection frequencies are much lower at this site compared to other Oregon sites. Sample collection ranged between 7 and 15 samples per year. With the highest detection frequency occurring in 2017. Quantifiable detections at this site occur throughout the growing season (**Figure 87)**. The highest sample value for this site is for a censored sample collected on August 10, 2018. Additional information on these reported values was solicited but not additional information became available as of the writing of this assessment.

Table 59. OREGONDEQ-34235-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2007	14	0	0%
2008	10	0	0%
2009	7	0	0%
2010	6	0	0%
2011	8	0	0%
2012	12	2	17%
2013	15	0	0%
2014	14	0	0%
2015	15	0	0%
2016	14	0	0%
2017	13	3	23%
2018	13	1	8%
2019	8	0	0%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

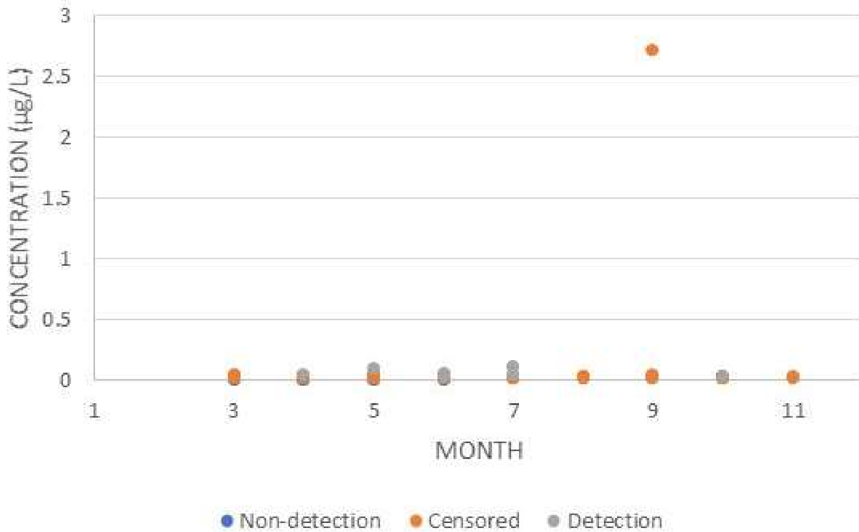

Figure 87. OREGONDEQ-34235-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFS for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. The results are shown in **Table 60**.

Table 60. Sampling Bias Factor Analysis Summary for OREGONDEQ-34235-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2018	13	2.72[1]	1.4	54.8 (22.2)	11.5 (8.9)	74.5 (30.2)	16.4 (12.7)
Bracketed values are for sub-set of SBFs for years 2005-2015 [1] value is a censored concentration.							

18. OREGONDEQ-37639-ORDEQ

Site and Sampling Characterization

OREGONDEQ-37639-ORDEQ sampling site (West Fork Palmer Creek at SE Palmer Creek Road) is in a 73.5 mi^2 (465.2 km^2) watershed in HUC 17 with 56.8% cropland, and 26.3% hay landcover (**Figure 88.** Watershed Landcover Characteristics of Sampling Site OREGONDEQ-37639-ORDEQ). This sample site is located upstream of 2 community water system intakes. Based on flow data, both community water system intakes are within a 1-day travel time from the monitoring site. These community water systems are the same systems in line with OREGONDEQ-34235-ORDEQ.

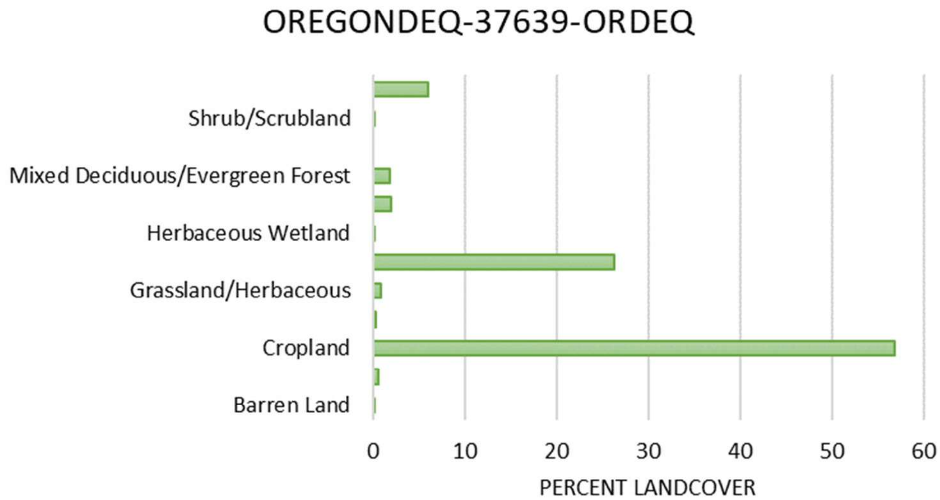

Figure 88. Watershed Landcover Characteristics of Sampling Site OREGONDEQ-37639-ORDEQ

A summary of the data collected for OREGONDEQ-34235-ORDEQ is provided in **Table 61**. Sample collection occurred between 2014 and 2018. Samples number ranged between 13 and 15 while detection frequencies ranged between 7 and 46 percent. With the highest detection frequency occurring in 2017.The highest quantifiable detections at this site occur in April (**Figure 89**).

Table 61. OREGONDEQ-37639-ORDEQ Data Summary

Year	Number of Samples Collected	Number of Detections	Detection Frequency
2014	14	4	29%
2015	15	1	7%
2016	14	2	14%
2017	13	6	46%
2018	13	1	8%

Gray shading highlights sites with at least 12 samples per year and a detection frequency of 25%
[1] Flow data or alternatively suitable covariate data are not available for SEAWAVE-QEX analysis.

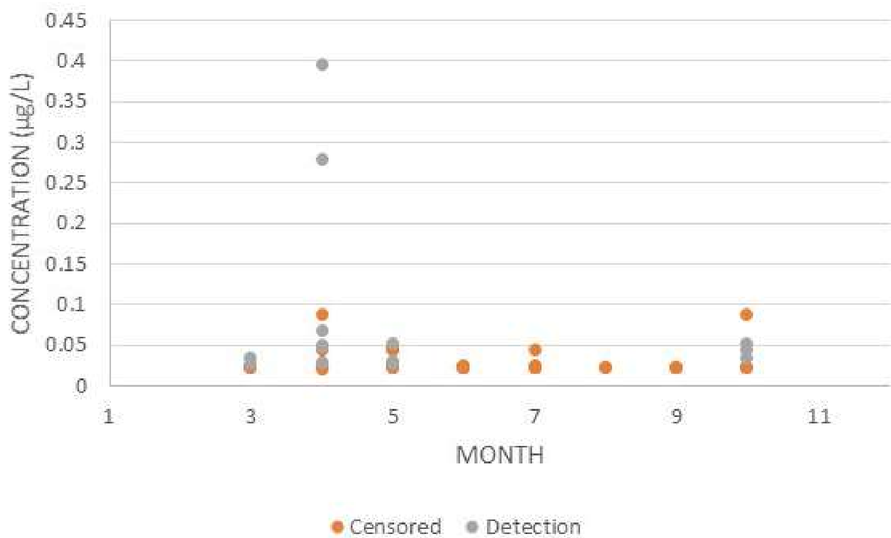

Figure 89. OREGONDEQ-37639-ORDEQ Monthly Summary

Sampling Bias Factor Application

The maximum 1- or 21-day sampling bias factor SBFs for the respective time periods (i.e., 1987-2012 or 2005-2012) were multiplied by the by the maximum measured concentration (1-day) or the maximum estimated (log-linearly interpolated) 21-day average concentration. This site was identified for additional analysis using the 1-day maximum measured concentration when estimating upper confidence bound for the 21-day average. Estimation on the 21-day average concentration for estimation of the upper bound are shown in **Table 62**.

Table 62. Sampling Bias Factor Analysis Summary for OREGONDEQ-34235-ORDEQ

Year	Number of samples	Maximum Measured Concentration µg/L	Maximum Imputed 21-day Average Concentration	Maximum Sampling Bias Factor		Sampling Bias Factor Adjusted Upper Bound Concentration µg/L	
				1-day	21-day	1-day	21-day
2014	14	0.09	0.22 (0.20)	-	2.5 (2.3)	-	23. (1.8)
Bracketed values are for sub-set of SBFs for years 2005-2015							

EXHIBIT 20

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; 5993–05–OCSPP]

Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In response to EPA's August 2021 final rule revoking all tolerances for the insecticide chlorpyrifos under the Federal Food, Drug, and Cosmetic Act (FFDCA), several objections, hearing requests, and requests for stay were filed by numerous parties representing a wide variety of growers and pesticide users. In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the final rule.

DATES: The Order is effective February 28, 2022.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

In this document, EPA denies all objections to, requests for hearing on those objections, and requests for stay of EPA's August 2021 final rule (Ref. 1) revoking all tolerances for the insecticide chlorpyrifos under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346(d). This action may be of interest to all parties filing objections, requests for hearing on those objections, and requests for stay. This action may also be of interest to agricultural producers, food manufacturers or pesticide manufacturers, and others interested in food safety issues generally. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT.**

B. What action is the Agency taking?

In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the August 2021 final rule (Ref. 1). This Order is issued under FFDCA section 408(g)(2)(C), 21 U.S.C. 346a(g)(2)(C)).

Based on information available as of August 20, 2021—the date by which the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) ordered EPA to issue a final rule concerning chlorpyrifos tolerances—EPA was unable to conclude that the tolerances for chlorpyrifos residues were safe in accordance with the FFDCA safety standard. In other words, EPA could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency's analysis indicated that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), resulting from currently registered uses, exceeded safe levels. This decision relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment and included the default Food Quality Protection Act (FQPA) tenfold (10X) margin of safety to account for uncertainties related to the potential for neurodevelopmental effects to infants, children, and fetuses. Accordingly, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. (*See* 86 FR 48315, Aug. 30, 2021) The prepublication of the final rule was issued on August 18, 2021, the final rule was published in the **Federal Register** on August 30, 2021, and the final rule became effective on October 29, 2021.

Pursuant to the procedures set forth in FFDCA section 408(g)(2), objections to, requests for evidentiary hearings on those objections, and/or requests for stays of, the final rule were filed by the persons listed in Unit V. (each, an Objector, and collectively, the Objectors) on or before the close of the objections period on October 29, 2021. (Ref. 1) The Objectors raised challenges to the final rule, including, for example, objections relating to the scope of the revocations in the final rule, retention of the additional FQPA Safety Factor, and use of the 2016 drinking water assessment, as well as raising procedural or other irrelevant concerns that do not change the basis for the final rule itself.

Four Objectors requested a hearing on their objections. The American Soybean Association, American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, ''Sugarbeet Associations''), and Cherry Marketing Institute each submitted requests for evidentiary hearings to dispute EPA's revocation of tolerances for the 11 ''high-benefit'' uses identified in the ''Proposed Interim Decision for the Registration Review of Chlorpyrifos'' (2020 PID) (Ref. 31)—including soybean uses, sugarbeet uses, and the Michigan tart cherry industry's use. Gharda also submitted a request for an evidentiary hearing on an issue related to the assessment of chlorpyrifos oxon in EPA's aggregate assessment.

Finally, EPA received several written requests for EPA to stay the effective date of the final rule due to impacts on the agricultural industry and in order to provide more time for EPA to fully consider the objections filed.

This Order denies all of the objections, requests for evidentiary hearings on those objections, and requests for stays of the final rule. EPA has undertaken a comprehensive analysis of the merits of each of the Objectors' objections, hearing requests, and requests for stay. That analysis shows, as set out in Units VI., VII., and VIII. of this document, respectively, that none of the Objectors' objections support the claims raised, none of the Objectors' requests for hearing meet the regulatory standard for granting a hearing, and none of the Objectors' requests for stay warrant staying the effective date of the final rule. There are numerous reasons for EPA's conclusions, for which additional detail is provided in Units VI., VII., and VIII. of this document.

C. What is the Agency's authority for taking this action?

The procedure for filing objections and requests for hearings thereon to EPA's final rule and EPA's authority for acting on such objections is contained in FFDCA section 408(g)(2) (21 U.S.C. 346a(g)(2)) and EPA's regulations at 40 CFR part 178.

II. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing pesticides and tolerances, objections, requests for hearing, and requests for a stay, as well as on pertinent Agency policies and practices.

Unit II.A. summarizes the requirements and procedures in FFDCA section 408 and applicable regulations pertaining to pesticide tolerances, including the procedures for objecting to EPA tolerance actions and the substantive standards for evaluating the safety of pesticide tolerances. This unit also discusses the closely-related statute under which EPA regulates the sale, distribution, and use of pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

Unit II.B. provides an overview of EPA's Office of Pesticide Programs (OPP) risk assessment process. It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern (level of concern), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on the Agency's policy on the FQPA safety factor and acetylcholinesterase (AChE) inhibition.

A. FFDCA/FIFRA and Applicable Regulations

1. General

EPA establishes, modifies, or revokes tolerances for pesticide residues in food under FFDCA section 408. (21 U.S.C. 346a) A ''tolerance'' represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, pesticide residues in or on food are considered unsafe (21 U.S.C. 346a(a)(1)), and such food, which is then rendered ''adulterated'' under FFDCA section 402(a) (21 U.S.C. 342(a)), may not be distributed in interstate commerce. (21 U.S.C. 331(a)) Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FFDCA section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions establishing a detailed safety standard for pesticides and additional protections for infants and children, among other things. (Pub. L. 104–170, 110 Stat. 1489 (1996))

EPA also regulates pesticides under FIFRA. (7 U.S.C. 136 *et seq.*) While FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution (*Id.* at section 136a(a)), and establishes a registration regime for regulating the use of pesticides. In order for a pesticide to be registered, EPA must determine that a pesticide ''will not generally cause unreasonable adverse effects on the environment'', among other things. (*Id.* at section 136a(c)(5)) The term ''unreasonable adverse effects on the environment'' is defined to include ''a human dietary risk from residues that results from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.'' (*Id.* at section 136(bb)) The FFDCA safety standard was integrated into the FIFRA registration standard in the FQPA, which also directed that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1))

Also under FIFRA, EPA is required to re-evaluate existing registered pesticides every 15 years in a process called ''registration review.'' (7 U.S.C. 136(a)(g)) The purpose of registration review is ''to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration,'' (40 CFR 155.40(a)(1)) taking into account changes that have occurred since the last registration decision, including any new relevant scientific information and any changes to risk-assessment procedures, methods, and data requirements. (40 CFR 155.53(a)) To ensure that a pesticide continues to meet the standard for registration, EPA must determine, based on the available data, including any additional information that has become available since the pesticide was originally registered or re-evaluated, that the pesticide does not cause ''unreasonable adverse effects on the environment.'' (7 U.S.C. 136a(c)(1), (5); *see also* 40 CFR 152.50)

2. Safety Standard for Pesticide Tolerances

FFDCA section 408(b)(2) directs that EPA may establish or leave in effect a tolerance for a pesticide only if it finds that the tolerance is safe and that EPA must revoke or modify tolerances determined to be unsafe. (21 U.S.C. 346a(b)(2)(A)(i)) FFDCA section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' (*Id.* At section 346a(b)(2)(A)(ii)) FFDCA section 408(b)(2)(D) directs EPA, in making a safety determination, to consider, among other relevant factors ''available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.'' (*Id.* at section 346a(b)(2)(D)(vi)) As the language indicates, this includes exposure through food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but does not include occupational exposures to workers (*i.e.,* occupational).

Risks to infants and children are given special consideration. Specifically, pursuant to FFDCA section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on ''available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals''; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III))

This provision also creates a presumption that EPA will use an additional safety factor for the protection of infants and children. Specifically, it directs that ''in the case of threshold effects, ... an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)) EPA is permitted to ''use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' (*Id.*) Due to Congress's focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to prenatal exposure as well as to exposure during childhood years. This section providing for the special consideration of infants and children in section 408(b)(2)(C) was added to the FFDCA by the FQPA in 1996; therefore, this additional margin of safety is referred to throughout this Order as the ''FQPA safety factor (SF)''.

3. Procedures for Establishing, Amending, or Revoking Tolerances

Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (*See* 21 U.S.C. 346a(d)(1)) EPA publishes in the **Federal Register** a notice announcing the filing of a petition filing and requesting public comment. (*Id.* at section 346a(d)(3)) After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance; issue a proposed rule subject to public comments and then finalize a rule to do the same; or deny the petition. (*Id.* at section 346a(d)(4))

Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)) Objections and hearing requests must be filed within 60 days after EPA takes that action. (*Id.*) The statute provides that EPA shall ''hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.'' (*Id.* at section 346a(g)(2)(B)) EPA regulations make clear that hearings will only be granted where it is shown that there is ''a genuine and substantial issue of fact,'' the requestor has identified evidence ''which, if established, resolve one or more of such issues in favor of the requestor,'' and the issue is ''determinative'' with regard to the relief requested. (40 CFR 178.32(b)) EPA's final Order on the objections and requests for hearing is subject to judicial review. (21 U.S.C. 346a(h)(1)) The statute directs that tolerance regulations shall take effect upon publication unless EPA specifies otherwise. (*Id.* at section 346a(g)(1)) EPA is authorized to stay the effectiveness of the tolerance if objections are filed. (*Id.*) Because EPA does not have its own regulations governing stay requests, EPA typically evaluates requests for stay under the criteria set out in FDA's regulations at 21 CFR 10.35(e) due to the fact that the FFDCA provisions governing EPA's objections and hearings process were adapted from the similar parallel statutory process governing FDA objections and hearings.

B. EPA Risk Assessment—Policy and Practice

1. The Safety Determination—Risk Assessment

To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps, which are discussed in further detail in this section: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the ''level of concern'' with respect to human exposure to the pesticide, which includes choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide and uncertainty factors; (3) estimation of human exposure to the pesticide through all applicable routes; and (4) characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern. For tolerances, characterization of risk involves determining whether the tolerances are safe; if aggregate exposure to humans is greater than the Agency's determined level of concern, the Agency's determination is that the tolerances are not safe.

a. Hazard Identification

Any risk assessment begins with an evaluation of a chemical's potential to cause adverse effects, and whether those properties have the potential to cause adverse effects (*i.e.,* a hazard identification). In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. For most pesticides, the animal toxicity database usually consists of studies investigating a broad range of endpoints including potential for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and neurotoxicity. These studies include gross and microscopic effects on organs and tissues; functional effects on bodily organs and systems; effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential); effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransferase, and cholinesterases); and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). For chlorpyrifos, the Agency examined acute and steady-state durations because of the potential to cause adverse effects based on acute (single day, 24 hours) and steady-state (21-day) exposures. The latter duration is based on the observation in the available studies for organophosphates (OPs) indicating a consistent pattern of AChE inhibition that reaches a steady-state (or comes to an equilibrium) around 2–3 weeks and does not change in studies of longer duration. (Ref. 2 at pg. 7) Further, EPA evaluates potential adverse effects in different age groups (adults as well as fetuses and juveniles). (Ref. 3 at pgs. 8 through 10)

EPA also considers whether the adverse effect has a threshold—a level below which exposure has no appreciable chance of causing the adverse effect. For effects that have no threshold, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur.

b. Level of Concern/Dose-Response Analysis

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). EPA follows differing approaches to identifying a level of concern for threshold and non-threshold hazards.

i. Threshold effects. In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL), which by definition is the next lower tested dose level below the LOAEL. Generally, EPA will use a NOAEL from the available studies as a starting point (called ''the Point of Departure'' or ''PoD'') in estimating the level of concern for humans. At times, however, EPA will use a LOAEL from a study as the Point of Departure when no NOAEL is identified in that study and the LOAEL is close to, or lower than, other relevant NOAELs. PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario and are chosen from toxicity studies that show clearly defined NOAELs or LOAELs and dose-response relationships. The Point of Departure is, in turn, used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and corresponding levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation).

EPA has also used other approaches for choosing the Point of Departure. One approach, called a benchmark dose, or BMD, estimates a point along a dose-response curve that corresponds to a specific response level. (Ref. 4) For example, a BMD_{10} represents a 10% change from the background or typical value for the response of concern. In contrast to the NOAEL/LOAEL approach, a BMD is calculated using a range of dose-response data and thus better accounts for the variability and uncertainty in the experimental results due to characteristics of the study design, such as dose selection, dose spacing, and sample size. In addition to a BMD, EPA generally also calculates a ''confidence limit'' in the BMD. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency often uses as the PoD. Use of the BMDL for deriving the PoD rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. It also provides a health protective conservative estimate of the safe dose. Numerous scientific peer review panels have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving PoDs in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. (Refs. 5 and 6)

Another approach for deriving Points of Departure uses a sophisticated model called a physiologically based pharmacokinetic-pharmacodynamic (PBPK–PD) model. PBPK models are mathematical descriptions of how a chemical enters the body (*e.g.,* breathing, drinking, eating); the amount of chemical that gets into the blood; how the chemical moves between body tissues (*e.g.,* fat, brain) and the blood; and how the body alters (*i.e.,* metabolizes) and eliminates the chemical (*e.g.,* via urine, feces). PBPK models incorporate information about the body's anatomical and physiological structure as well as biochemical processes into the model structure. EPA uses PBPK models to better translate animal toxicity data to potential human risks (*i.e.,* extrapolation). A PBPK model that describes a chemical in a laboratory animal species can be used for humans by changing the physiological parameters. In the case of chlorpyrifos assessment, the PBPK–PD model is used to derive age-, duration-, and route-specific PoDs that would have resulted in a maximum RBC AChE inhibition level at 10% in humans. Rather than converting an animal BMDL to derive a human POD, the PBPK–PD modeling approach accounts for human physiology, biochemistry, life-stage, and exposure scenarios to derive human PODs based on predicted AChE inhibition in humans. (Ref. 7) Numerous Federal Advisory Committees and external review panels have encouraged the use of such a modeling approach to reduce inherent uncertainty in the risk assessment and facilitate more scientifically sound extrapolations across studies, species, routes, and dose levels. The PBPK–PD model for chlorpyrifos has undergone extensive peer review by various individual and groups, including the FIFRA Scientific Advisory Panel (SAP) (discussed in Unit III.A.3.) Significant improvements have been made to the model over the years in response to recommendations from the 2008, 2011, and 2012 FIFRA SAPs and comments from both internal and external peer reviewers. (Ref. 2 at pg. 20)

In estimating and describing the level of concern, the Point of Departure is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the PoD to calculate an acceptable level of exposure or reference dose (RfD). The RfD is calculated by dividing the PoD by all applicable safety or uncertainty factors. Typically, EPA uses a baseline safety/uncertainty factor of 100X in assessing pesticide risk. That value includes a factor of 10 (10X) where EPA is using data from laboratory animals to account for the possibility that humans potentially have greater sensitivity to the pesticide than animals (also known as the ''inter-species factor'' or ''inter-species extrapolation factor'') and another factor of 10X to account for potential variations in sensitivity among members of the human population (also known as the ''intra-species factor'' or ''intra-species extrapolation factor''). These factors may vary if data is available to indicate that another extrapolation factor would be appropriate and protective. For example, where a PBPK–PD model using human parameters is used for deriving Points of Departure, there is no need for an interspecies factor since the model directly predicts human Points of Departure based on human physiology and biochemistry, rather than animal studies. Moreover, because the PBPK–PD model used for assessing chlorpyrifos accounts for differences in metabolism and toxicity response across the human population for some age groups and some subpopulations, the intraspecies extrapolation factor can be refined in accordance with EPA's 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.* (Ref. 8)

Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA additional safety factor largely replaces EPA's pre-FQPA practice regarding additional safety factors (*e.g.,* LOAEL to NOAEL factor or database uncertainty factor), but it might also account for residual concerns related to pre- and postnatal toxicity or exposure. (Ref. 9 at pgs. 4 through 11)

In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). A PAD is the RfD divided by the FQPA safety factor. (*Id.* at pgs. 13 through 16) RfDs and PADs are generally calculated for both acute and chronic dietary risks. Throughout this document, general references to OPP's calculated safe dose are denoted as an RfD/PAD.

For non-dietary, and combined dietary and non-dietary, risk assessments of threshold effects, the toxicological level of concern is not expressed as an RfD/PAD but rather in terms of an acceptable (or target) margin of exposure (MOE) between human exposure and the Point of Departure. The ''margin'' of interest is the ratio between human exposure and the Point of Departure, which is calculated by dividing human exposure into the Point of Departure. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, if a pesticide needs a 10X factor to account for potential inter-species differences, 10X factor for potential intra-species differences, and 10X factor for the FQPA children's safety provision, the safe or target MOE would be an MOE of at least 1,000. What that means is that for the pesticide in the example to meet the safety standard, human exposure to the pesticide would generally have to be at least 1,000 times smaller than the Point of Departure. Like RfD/PADs, specific target MOEs are selected for exposures of different durations. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral.

ii. Non-threshold effects. For risk assessments for non-threshold effects, EPA does not use the RfD/PAD or MOE approach to choose a level of concern if quantification of the risk is deemed appropriate. Rather, EPA calculates the slope of the dose-response curve for the non-threshold effects from relevant studies frequently using a linear, low-dose extrapolation model that assumes that any amount of exposure will lead to some degree of risk. This dose-response analysis will be used in the risk characterization stage to estimate the risk to humans of the non-threshold effect.

c. Estimating Human Exposure

Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA must evaluate the aggregate exposure to a pesticide chemical residue. This means that EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)) This statutory requirement specifically clarifies that the assessment of dietary exposures includes exposure under the tolerances at issue, as well as ''all other tolerances in effect for the pesticide chemical residue''. (Id.) Additionally, EPA must take into account exposure from ''other related substances.'' (Id.)

i. Exposure from food. There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed and (2) the residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the USDA. (Ref. 3 at pg. 12) Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction (or concentration) due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (Ref. 3 at pg. 17)

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance, assesses exposure using the worst-case assumptions that 100% of the crop or commodity in question is treated with, or exposed to, the pesticide and 100% of the food from that crop or commodity contains pesticide residues at the tolerance level. (Ref. 3 at pg. 11) When such an assessment shows no risks of concern, a more refined risk assessment is unnecessary. By using worst-case assumptions as a starting point for risk assessment, EPA's resources are conserved, and regulated parties are spared the cost of any additional studies that may be needed. The risk assessments produced using the worst-case assumptions yield conservative and health-protective outcomes; however, if a first-tier assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop or commodity actually treated with, or exposed to, the pesticide and data on the level of residues that may be present on the treated crop or commodity. These latter data are used to estimate what has been traditionally referred to by EPA as ''anticipated residues''.

Use of percent crop/commodity treated data and anticipated residue information is appropriate because EPA's worst-case assumptions of 100% treatment and residues at tolerance value significantly overstate residue values. There are several reasons why this is true. First, all growers of a particular crop would rarely choose to apply the same pesticide to that crop (some may apply no pesticide; some may apply an alternative pesticide); generally, the proportion of the crop treated with a particular pesticide is significantly below 100%. (70 FR 46706, 46731, August 10, 2005) (FRL–7727–4) Second, the tolerance value represents a high-end or worst-case value. Tolerance values are chosen only after EPA has evaluated data from experimental trials in which the pesticide has been used in a manner, consistent with the draft FIFRA label, that is likely to produce the highest residue in the crop or food in question (*e.g.,* maximum application rate, maximum number of applications, minimum pre-harvest interval between last pesticide application and harvest). (Refs. 3 and 10) These experimental trials are generally conducted in several locations and involve multiple samples. (Ref. 10 at pgs. 5 and 7 and Tables 1 and 5) The results from such experimental trials invariably show that the residue levels for a given pesticide use will vary from as low as non-detectable to measurable values in the parts per million (ppm) range with the majority of the values falling at the lower part of the range. (70 FR 46706 at 46731) EPA uses a statistical procedure to analyze the experimental trial results and identify the upper bound of expected residue values. This upper bound value is typically used as the tolerance value. There may be some commodities for which pesticide residues come close to the tolerance value where the maximum label rates are followed, but most generally fall significantly below the tolerance value. If less than the maximum legal rate is applied, residues will be even lower. Third, residue values measured at the time of treatment do not take into account the lowering of residue values that frequently occurs as a result of degradation over time and through food processing and cooking.

EPA uses several techniques to refine residue value estimates. (Ref. 3 at pgs. 17 through 28) First, where appropriate, EPA will take into account all the residue values reported in the experimental trials, either through an average of all the field trials or consideration of individual field trials. Second, EPA will consider data showing what portion of the crop or commodity is not treated with, or exposed to, the pesticide. Third, data can be produced showing pesticide degradation and decline over time, and the effect of commercial and consumer food handling and processing practices. Finally, EPA can consult monitoring data gathered by the FDA, the USDA, or pesticide registrants, on pesticide levels in food at points in the food distribution chain distant from the farm, including retail food establishments. Monitoring data, including data gathered by USDA's Pesticide Data Program (PDP), generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real-world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide immediately after harvest.

Another critical component of the exposure assessment is how data on consumption patterns are combined with data on pesticide residue levels in food. Traditionally, EPA has calculated exposure by simply multiplying average consumption by average residue values for estimating chronic risks and high-end consumption by maximum residue values for estimating acute risks. Using average residues is a realistic approach for chronic risk assessment due to the fact that variations in residue levels and consumption amounts average out over time, especially given the nationwide market for food in the United States. Using average values is inappropriate for acute risk assessments, however, because in assessing acute exposure situations it matters how much of each treated food a given consumer eats in the short-term and what the residue levels are in the particular foods consumed. Yet, using maximum residue values for acute risk assessment tends to greatly overstate exposure because it is unlikely that a person would consume at a single meal multiple food components bearing high-end residues. To take into account the variations in short-term consumption patterns and food residue values for acute risk assessments, EPA uses probabilistic modeling techniques for estimating exposure when more simplistic models appear to show risks of concerns.

In practice, EPA uses a computer program known as the Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate dietary exposure from pesticide residues in food by combining data on human consumption amounts with residue values in food commodities. The model used for assessment of chlorpyrifos in the 2020 human health risk assessment (HHRA) incorporated 2003–2008 consumption data from USDA's National Health and Nutrition Examination Survey/What We Eat in America database (NHANES/WWEIA). The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods ''as consumed'' (*e.g.,* apple pie) are linked to EPA-defined food commodities (*e.g.,* apples, peeled fruit—cooked; fresh or N/S (Not Specified); baked; or wheat flour—cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA Agricultural Research Service (ARS) and EPA. For chronic exposure assessment (or in the case of chlorpyrifos, for steady-state exposure assessment), consumption data are averaged for the entire U.S. population and within population subgroups; however, for acute exposure assessment, consumption data are retained as individual consumption events. Using this consumption information and residue data, the exposure estimates are calculated for the general U.S. population and specific subgroups based on age, sex, ethnicity, and region.

All of these refinements to the exposure assessment process, from use of food monitoring data through probabilistic modeling, can have dramatic effects on the level of exposure predicted, typically reducing worst-case estimates by at least 1 or 2 orders of magnitude. (Ref. 11 at pgs. 16 through 17; 70 FR 46706 at 46732)

For chlorpyrifos, EPA has calculated potential risk by using probabilistic techniques to combine distributions of potential exposures in sentinel populations. The resulting probabilistic assessments present a range of dietary exposure/risk estimates. Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the acute PAD (aPAD), the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. (The same assumptions apply to estimates for steady-state dietary exposure and the steady-state PAD (ssPAD).) To the extent that one or a few values seem to ''drive'' the exposure estimates at the high-end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making. (Ref. 11)

ii. Exposure from water. (a) Modeling and monitoring data. EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used. When monitoring data meet certain data quantity criteria, EPA has tools available to quantify the uncertainty in available monitoring data such that it can be used quantitively to estimate pesticide concentrations in drinking water. (Ref. 12) Furthermore, monitoring data can be used in a weight of evidence (WOE) approach with model estimated concentrations to increase confidence in the conclusions of a drinking water assessment.

Due often to the limitations in many monitoring studies, EPA uses mathematical water exposure models to estimate pesticide exposure levels in drinking water. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label. (Ref. 13 at pgs. 27 and 28) (*See also* 69 FR 30042, 30058 through 30065, May 26, 2004) (FRL–7355–7) These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. The modeling provides an estimate of pesticide concentrations in ground water and surface water. Depending on the modeling algorithm (*e.g.,* surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites and can be used to estimate peak concentrations from infrequent, large rain events.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and groundwater. The most common model used to conduct drinking water assessments is the Pesticide in Water Calculator (PWC). PWC couples the Pesticide Root Zone Model (PRZM) and Variable Volume Water Model (VVWM) together to simulate pesticide fate and transport from the field of application to an adjacent reservoir. (Ref. 13 at pgs. 27 and 28) The PWC estimates pesticide concentrations for an index reservoir that is modeled for site-specific scenarios (*i.e.,* weather and soil data) in different areas of the country. A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Aquatic Models website: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model ''typical'' concentrations occurring across the nation. EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

(b) Drinking Water Level of Comparison (DWLOC). The drinking water level of comparison (DWLOC) is an estimate of the maximum concentration of the pesticide (and other residues of concern) that may be in drinking water without triggering a risk concern for human health. (Ref. 13 at pg. 10) The DWLOC is a benchmark that can be used to guide refinements of the drinking water assessment (DWA). This value relates to the concept of the ''risk cup,'' which EPA developed to facilitate risk refinement when considering aggregate human health risk to a pesticide. (Ref. 14) The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration and population being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (*e.g.,* acute, short-term, chronic). The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for AChE reversible inhibition from exposure to *N*-methyl carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to OP insecticides is usually 21-days based on steady-state kinetics. (Ref. 5)

When using the DWLOC approach, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect, and this allowable remaining exposure becomes the remaining space in the ''risk cup'' for pesticide exposures in drinking water. Knowing this allowable remaining exposure and the water consumption for each population subgroup (*e.g.,* infants), the Agency can calculate the DWLOC, which is the estimate of safe concentrations of pesticides in drinking water. Using this process of DWLOC calculation allows EPA to determine a target maximum safe drinking water concentration, which makes it easier to identify instances where drinking water estimates require refinement. (Ref. 13 at pgs. 19 and 20)

(c) Scale of drinking water assessment. Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly because of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location, characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure, which influences the application timing, rate used, and number of treatments in a crop production cycle.

EPA may conduct a drinking water assessment (DWA) for a national scale depending on the pesticide use under evaluation. A national-scale DWA may use a single upper-end pesticide concentration as a starting point for assessing whether additional refinements are needed or estimated pesticide concentrations for certain site-specific scenarios that are associated with locations in the United States vulnerable to pesticide contamination based on pesticide use patterns. (Ref. 13 at pg. 22)

EPA may also conduct a regional-scale DWA to focus on areas where pesticide concentrations may be higher than the DWLOC. Under this type of assessment, EPA estimates pesticide concentrations across different regions in the United States that correspond with specific hydrologic units identified by a unique hydrologic unit code (HUC). For purposes of assessing chlorpyrifos, EPA evaluated concentrations in the 21 major geographic areas (or regions) used that comprise the United States. These areas contain either the drainage area of a major river or a combined drainage of a series of rivers. This information can be found at: *https://water.usgs.gov/GIS/huc.html.* Estimated pesticide concentrations under this approach would be associated with a vulnerable pesticide use area somewhere within the evaluated region. (Ref. 13 at pg. 23)

(d) Refinements to drinking water assessments. Much like the tiered approach used for assessing exposures of pesticides in food, EPA has defined four tiers for drinking water assessments. Lower-tiered assessments are more conservative based on the defaults or upper bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the certainty in the estimated pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. Tier 1 requires the least amount of effort and the least amount of data, whereas Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit. The order in which refinements are considered (*i.e.,* the order in which the assessment is refined) is pesticide-specific and depends on the nature and quality of the available data used to support the refinement. Additional information on the conduct of drinking water assessments can be found in EPA's ''Framework for Conducting Pesticide Drinking Water Assessment for Surface Water'' (Drinking Water Framework) (Ref. 13).

As discussed in the Drinking Water Framework, EPA can incorporate several refinements in higher tiered modeling. Two such refinements are the percent cropped area (PCA) and the percent crop treated (PCT). The PCA refers to the amount of area in a particular community water system that is planted with the crop of interest (*e.g.,* the default assumption is that the entire watershed is planted with a crop of interest). The PCT refers to the amount of the cropped area that is treated with the pesticide of interest (*e.g.,* the default is that the entire cropped area is treated with the pesticide of interest). With additional use and usage data, EPA can refine assumptions about the application rate and PCT for use in modeling to generate estimated drinking water concentrations (EDWCs) that are appropriate for human health risk assessment and more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations. The goal of the PCA and PCT refinements are to generate EDWCs that are appropriate for human health risk assessment that reduce the magnitude of overestimation due to variability in crops and actual pesticide usage. (Ref. 15)

iii. Non-occupational (Residential) exposures. Residential assessments examine exposure to pesticides in non-occupational or residential settings (*e.g.,* homes, parks, schools, athletic fields, or any other areas frequented by the general public), based on registered uses of the pesticide. Exposures to pesticides may occur to persons who apply pesticides (which is referred to as residential handler exposure) or to persons who enter areas previously treated with pesticides (which is referred to as post-application exposure). Such exposures may occur through oral, inhalation, or dermal routes and may occur over different exposure durations (*e.g.,* short-term, intermediate-term, long-term), depending on the type of pesticide and particular use pattern.

Residential assessments are conducted through examination of significant exposure scenarios (*e.g.,* children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To standardize this process, EPA has prepared Standard Operating Procedures (SOPs) for conducting residential assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment. (Ref. 16) SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack-and-crevice treatments.

The SOPs identify relevant generic data and construct algorithms for calculating application and post-application exposures in a residential or non-occupational setting using these generic data in combination with pesticide-specific information. The generic data typically involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities) and transfer coefficient data (*i.e.,* data measuring the amount of pesticide that transfers from the environment to humans during some activity). Specific information on pesticides can include information on residue levels as well as information on environmental fate such as degradation data.

Once EPA assesses all the potential exposures from all applicable residential exposure scenarios, EPA selects the highest exposure scenario for each exposed population to calculate representative risk estimates for use in the aggregate exposure assessment. Those specific exposure values are then combined with the life-stage appropriate exposure values provided for food and drinking water to determine whether a safety finding can be made.

iv. Aggregate exposures. The aggregate exposure assessment process considers exposure through multiple pathways or routes of exposure (*e.g.,* food, water, and residential) for different sub-populations (*e.g.,* infants, children ages 1 through 6) and exposure duration or types of effects (*e.g.,* acute noncancer effects (single dose), chronic noncancer effects, and cancer). The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and are dependent on the level of refinement or assessment tier.

EPA evaluates aggregate exposure by comparing combined exposure from all relevant sources to the safe level. Where exposures exceed the safe level, those levels exceed the risk cup and are of potential concern. There are risk cups for each pertinent duration of exposure for a pesticide because the amount of exposure that can be incurred without adverse health effects will vary by duration (*e.g.,* acute, short-term, chronic, steady-state). The size of the risk cup is dependent on the maximum safe exposure for the different relevant durations (*e.g.,* acute, short-term, intermediate-term, long-term, steady-state).

d. Risk Characterization

The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

Whether exposures will exceed the available space in the risk cup (*i.e.,* whether exposures are expected to exceed safe levels) is expressed differently, depending on the type of level of concern (*i.e.,* RfD/PAD or MOE) the Agency has identified. For dietary assessments for which EPA calculates an RfD/PAD, the risk is expressed as a percentage of the acceptable dose (*i.e.,* the dose which EPA has concluded will be ''safe''). Dietary exposures greater than 100% of the percentage of the acceptable dose are generally cause for concern and would be considered ''unsafe'' within the meaning of FFDCA section 408(b)(2)(B). For non-dietary (and combined dietary and non-dietary) risk assessments of threshold effects, the toxicological level of concern is typically not expressed as an RfD/PAD, but rather in terms of an acceptable (or target) Margin of Exposure (MOE) between human exposure and the PoD. Non-dietary (and combined) exposures that result in an MOE equal to or exceeding the product of all applicable safety factors would not generally be of concern.

As a conceptual matter, the RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if exposure to a pesticide were found to be acceptable under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa. However, for any specific pesticide, risk assessments for different exposure durations or routes may yield different results. This is a function not of the choice of the RfD/PAD or MOE approach but of the fact that the levels of concern and the levels of exposure may differ depending on the duration and route of exposure.

Where EPA has calculated a DWLOC, the Agency can assess risk by comparing estimated pesticide concentrations in drinking water to the DWLOC. As noted previously, an aggregate DWLOC represents the amount of maximum safe residues of pesticide in drinking water because it represents the room remaining in the risk cup for drinking water exposures, after accounting for the food and residential exposures. When the EDWC is less than the DWLOC, there are no risk concerns for aggregate exposures because the Agency can conclude that the contribution from drinking water, when aggregated with food and non-occupational exposures, will not exceed safe levels of exposure. Conversely, an EDWC at or exceeding the DWLOC would indicate a risk of concern, as pesticide exposures in drinking water, when aggregated with exposures from food and residential exposures, would exceed safe levels of exposure. (Ref. 14)

For non-threshold risks (generally, cancer risks), EPA uses the slope of the dose-response curve for a pesticide in conjunction with an estimation of human exposure to that pesticide to estimate the probability of occurrence of additional adverse effects. Under FFDCA section 408, for non-threshold cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million. EPA describes this quantitative standard as a ''range'' because it does not want to impart a false precision to numerical cancer risk estimates. EPA seeks to identify risks differing significantly from a 1 in 1 million risk, and that involves both a quantitative as well as qualitative assessment of what a risk estimate represents.

2. EPA Policy on the FQPA Children's Safety Factor

As the summary of EPA's risk assessment practice indicates, the use of safety factors plays a critical role in the process. This is true for traditional safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species factor) and potential differences among humans (intra-species factor), as well as the FQPA's additional 10X children's safety factor.

In implementing the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying a 10X safety factor, in addition to the traditional safety factors for inter- and intra-species extrapolation. (Ref. 9 at pgs. 4 and 11) Thus, EPA generally refers to the FQPA 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the FQPA 10X safety factor is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (*Id.*) In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) of the FFDCA—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and postnatal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a WOE evaluation, does not understate the risk to children. (*Id.* at pgs. 24 through 25 and 35)

3. Acetylcholinesterase Inhibition

Acetylcholinesterase (AChE) inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (*i.e.,* another nerve cell, a muscle fiber, or a gland) is facilitated by the chemical, acetylcholine. When a nerve cell is stimulated, it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to receptors in the target cell, stimulating the target cell in turn. As EPA has explained, ''the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (*e.g.,* in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (*e.g.,* sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system.'' (Ref. 17 at pg. 10)

AChE is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When AChE is inhibited, acetylcholine builds up prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition, these effects can be serious or even fatal.

EPA's cholinesterase inhibition policy statement explains EPA's approach to evaluating the risks posed by AChE-inhibiting pesticides such as chlorpyrifos. (*Id.*) The policy focuses on three types of effects associated with AChE-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) Physiological and behavioral/functional effects; (2) AChE inhibition in the central and peripheral nervous system; and (3) AChE inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving an acceptable dose (*e.g.,* RfD/PAD) for an AChE-inhibiting pesticide.

After clinical signs or symptoms, AChE inhibition in the nervous system provides the next most important endpoint for evaluating AChE-inhibiting pesticides. Although AChE inhibition in the nervous system is not itself regarded as a direct adverse effect, it is ''generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects.'' (*Id.* at pg. 25) As such, the policy states that it should be treated as ''direct evidence of potential adverse effects'' and ''data showing this response provide valuable information in assessing potential hazards posed by anticholinesterase pesticides.'' (*Id.*) Unfortunately, useful data measuring AChE inhibition in the peripheral nervous system tissues has only been relatively rarely captured by standard toxicology testing. For central nervous system effects, however, more recent neurotoxicity studies ''have sought to characterize the time course of inhibition in * * * [the] brain, including brain regions, after acute and 90-day exposures.'' (*Id.* at pg. 27)

AChE inhibition in the blood is one step further removed from the direct harmful consequences of AChE-inhibiting pesticides. According to the policy, inhibition of blood AChEs ''is not an adverse effect, but may indicate a potential for adverse effects on the nervous system.'' (*Id.* at pg. 28) The policy states that ''[a]s a matter of science policy, blood cholinesterase data are considered appropriate surrogate measures of potential effects on peripheral nervous system acetylcholinesterase activity in animals, for CNS [central nervous system] acetylcholinesterase activity in animals when CNS data are lacking and for both peripheral and central nervous system acetylcholinesterase in humans.'' (*Id.* at pg. 29) The policy notes that ''there is often a direct relationship between a greater magnitude of exposure [to an AChE-inhibiting pesticide] and an increase in incidence and severity of clinical signs and symptoms as well as blood cholinesterase inhibition.'' (*Id.* at pg. 30) Thus, the policy regards blood AChE data as ''appropriate endpoints for derivation of reference doses or concentrations when considered in a weight-of-the-evidence analysis of the entire database * * *.'' (*Id.* at pg. 29) Between AChE inhibition measured in red blood cell (''RBC'') or blood plasma, the policy states a preference for reliance on RBC AChE measurements because plasma cholinesterase is composed of a mixture of acetylcholinesterase and butyrylcholinesterase, and inhibition of the latter is less clearly tied to inhibition of acetylcholinesterase in the nervous system. (*Id.* at pgs. 29 and 32)

In the Agency's analysis for chlorpyrifos, EPA used a response level of 10% RBC AChE inhibition; this value represents the estimated dose where AChE is inhibited by 10%, compared to untreated animals. For the last several years EPA has used the 10% value to regulate AChE-inhibiting pesticides, including other organophosphorous pesticides. For a variety of toxicological and statistical reasons, EPA chose 10% RBC AChE inhibition as the response level for use in its PBPK–PD modeling. (Ref. 2 at pg. 7) EPA analyses have demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies; is generally at or near the limit of sensitivity for discerning a statistically significant decrease in AChE activity across the brain compartment; and is a response level close to the background.

III. Chlorpyrifos Background

A. Regulatory Background

1. General

a. Chlorpyrifos Uses

Chlorpyrifos (0,0-diethyl-0–3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. (The OPs are a group of closely related pesticides that affect functioning of the nervous system.) Pesticide products containing chlorpyrifos are registered for use on many agricultural crops, including, but not limited to, corn, soybeans, alfalfa, oranges, wheat, and walnuts. Additionally, chlorpyrifos products are registered for use on nonfood sites such as ornamental plants in nurseries, golf course turf, and as wood treatment. There are also public health uses including aerial and ground-based mosquito adulticide fogger treatments, use as fire ant control in nursery stock grown in USDA-designated quarantine areas, and for some tick species that may transmit diseases such as Lyme disease. The majority of uses in residential settings were voluntarily canceled over two decades ago (*e.g.,* 65 FR 76233, December 6, 2000 (FRL–6758–2); 66 FR 47481, September 12, 2001 (FRL–6799–7)).

b. Chlorpyrifos Risks

i. Acetylcholinesterase (AChE) inhibition. Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting AChE, an enzyme necessary for the proper functioning of the nervous system, and ultimately leading to signs of neurotoxicity. This mode of action, in which AChE inhibition leads to neurotoxicity, is well-established, and thus has been used as basis for the PoD for OP human health risk assessments, including chlorpyrifos. This science policy is based on decades of work, which shows that AChE inhibition is the initial event in the pathway to acute cholinergic neurotoxicity. (Ref. 17 at pg. 14)

The Agency has conducted a comprehensive review of the available data and public literature regarding this adverse effect from chlorpyrifos. (Ref. 18 at pgs. 25 through 27) There are many chlorpyrifos studies evaluating RBC AChE inhibition or the brain in multiple lifestages (gestational, fetal, postnatal, and non-pregnant adult); multiple species (rat, mouse, rabbit, dog, human); methods of oral administration (oral gavage with corn oil, dietary, gavage via milk); and routes of exposure (oral, dermal, inhalation via vapor and via aerosol). In addition, chlorpyrifos is unique in the availability of AChE data from peripheral tissues in some studies (*e.g.,* heart, lung, liver). There are also literature studies comparing the *in vitro* AChE response to a variety of tissues that show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral AChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues. Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

Female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.,* developmental neurotoxicity (DNT), reproductive, and subchronic data).

In addition, studies are available in juvenile pups that show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon metabolite. This sensitivity is not derived from differences in the AChE enzyme itself but instead are derived largely from the immature metabolic clearance capacity in the juveniles.

ii. Neurodevelopmental toxicity. In addition to information on the effects of chlorpyrifos on AChE, there is an extensive body of information (in the form of laboratory animal studies, epidemiological studies, and mechanistic studies) studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos.

There are numerous laboratory animal studies on chlorpyrifos in the literature that have evaluated the impact of chlorpyrifos exposure in pre- and postnatal dosing on the developing brain. These studies vary substantially in their study design, but all involve gestational and/or early postnatal dosing with behavioral evaluation from adolescence to adulthood. The data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain with adverse outcomes in several neurological domains including cognitive, anxiety and emotion, social interactions, and neuromotor function. It is, however, important to note that there is little consistency in patterns of effects across studies. In addition, most of these studies use doses that far exceed EPA's 10% benchmark response level for RBC AChE inhibition. There are only a few studies with doses at or near the 10% brain or RBC AChE inhibition levels; among these only studies from Carr laboratory at Mississippi State University are considered by EPA to be high quality. EPA has concluded that the laboratory animal studies on neurodevelopmental outcomes are not sufficient for quantitatively establishing a PoD. (Ref. 2 at pgs. 88 and 89)

EPA evaluated numerous epidemiological studies on chlorpyrifos and other OP pesticides in accordance with the Agency's ''Framework for

Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment'' (''Epidemiologic Framework''). (Ref. 19) The most robust epidemiologic research comes from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University (''CCCEH study''); (2) the Mount Sinai Inner-City Toxicants, Child Growth and Development Study (''Mt. Sinai study''); and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley (''CHAMACOS study''). (Ref. 20 at pgs. 32 through 43)

In the case of the CCCEH study, which specifically evaluated the possible connections between chlorpyrifos levels in cord blood and neurodevelopmental outcomes on a specific cohort, there are a number of notable associations. (*Id.* at pgs. 35 through 38) Regarding infant and toddler neurodevelopment, the CCCEH study authors reported statistically significant deficits of 6.5 points on the Psychomotor Development Index at three years of age when comparing high to low exposure groups. Notably, these decrements persist even after adjustment for group and individual level socioeconomic variables. These investigators also observed increased odds of mental delay and psychomotor delay at age three when comparing high to low exposure groups. The CCCEH study authors also report strong, consistent evidence of a positive association for attention disorders, attention deficit hyperactivity disorder (ADHD), and pervasive development disorder (PDD) when comparing high to low chlorpyrifos exposure groups. Moreover, it was reported that for children in the CCCEH study cohort at age seven for each standard deviation increase in chlorpyrifos cord blood exposure, there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In addition, the CCCEH study authors evaluated the relationship between prenatal chlorpyrifos exposure and motor development/movement and reported elevated risks of arm tremor in children around 11 years of age in the CCCEH cohort.

Notwithstanding the observed associations, EPA and the 2012 and 2016 FIFRA SAPs identified multiple uncertainties in the CCCEH epidemiology studies. (Refs. 21 and 22) Some of these include the relatively modest sample sizes, which limited the statistical power; exposure at one point in prenatal time with no additional information regarding postnatal exposures; representativeness of a single-point exposure where time-varying exposures or the ability to define cumulative exposures would be preferable; lack of specificity of a critical window of effect and the potential for misclassification of individual exposure measures; and lack of availability of the raw data from the studies that would allow verification of study conclusions.

One of the notable uncertainties in the CCCEH epidemiology studies identified by EPA and the 2016 FIFRA SAP is the lack of specific exposure information on the timing, frequency, and magnitude of chlorpyrifos application(s) in the apartments of the women in the study. Despite extensive effort by EPA to obtain or infer this exposure information from various sources, the lack of specific exposure data remains a critical uncertainty. EPA made efforts in 2014 and 2016 to develop dose reconstruction of the exposures to these women. These dose reconstruction activities represent the best available information and tools but are highly uncertain. In addition, the pregnant women and children in the CCCEH studies were exposed to multiple chemicals, including multiple potent AChE inhibiting OPs and *N*-methyl carbamates. Moreover, using EPA's dose reconstruction methods from 2014 suggest that the pregnant women likely did not exhibit RBC AChE inhibition above 10%. The 2012 and 2016 FIFRA SAP reports expressed concern that it is likely that the CCCEH findings occurred at exposure levels below those that result in 10% RBC AChE inhibition. (Refs. 21 and 22) However, given the available CCCEH exposure information and the exposures to multiple potent AChE inhibiting pesticides, EPA cannot definitively attribute all AChE inhibition to chlorpyrifos. EPA remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by CCCEH investigators. (Ref. 20 at pg. 43) Moreover, given the uncertainties, particularly in the exposure information available from CCCEH (single timepoints, lack of time varying exposure, lack of knowledge about application timing), uncertainties remain about the dose-response relationships from the epidemiology studies.

Finally, there are several lines of evidence for actions of chlorpyrifos distinct from the classical mode of action of AChE inhibition. This information has been generated from model systems representing different levels of biological organization and provide support for molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling), and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Among the many *in vitro* studies on endpoints relevant to the developing brain available for chlorpyrifos, only three have identified outcomes in picomole concentrations, including concentrations lower than those that elicit AChE inhibition *in vitro.* However, as is the case for many other developmental neurotoxicants, most of these studies have not been designed with the specific goal of construction or testing an adverse outcome pathway. Thus, there are not sufficient data available to test rigorously the causal relationship between effects of chlorpyrifos at the different levels of biological organization in the nervous system. (*Id.* at pgs. 27 through 31)

Due to the complexity of nervous system development involving the interplay of many different cell types and developmental timelines, it is generally accepted that no single *in vitro* screening assay can recapitulate all the critical processes of neurodevelopment. As a result, there has been an international effort to develop a battery of new approach methodologies (NAMs) to inform the DNT potential for individual chemicals. This DNT NAM battery is comprised of *in vitro* assays that assess critical processes of neurodevelopment, including neural network formation and function, cell proliferation, apoptosis, neurite outgrowth, synaptogenesis, migration, and differentiation. In combination the assays in this battery provide a mechanistic understanding of the underlying biological processes that may be vulnerable to chemically-induced disruption. It is noteworthy, however, that the quantitative relationship between alterations in these neurodevelopmental processes and adverse health outcomes has, to date, not been fully elucidated. Moreover, additional assays evaluating other critical neurodevelopmental processes such as myelination are still being developed. (Ref. 23)

In September 2020, EPA convened a FIFRA SAP on developing and implementing NAMs using methods such as *in vitro* techniques and computational approaches. Included in that consideration was use of the DNT NAM battery to evaluate OP compounds as a case study. These methods presented to the 2020 FIFRA SAP provide a more systematic approach to evaluating pharmacodynamic effects on the developing brain compared to the existing literature studies. Initial data from the NAM battery were presented to the SAP for 27 OP compounds, including chlorpyrifos and its metabolite, chlorpyrifos-oxon, and, when possible, compared to *in vivo* results (by using *in vitro* to *in vivo* extrapolation). On December 21, 2020, the SAP released its final report and recommendations on EPA's proposed use of the NAMs data. (Ref. 24) The advice of the SAP is currently being taken into consideration as EPA develops a path forward on NAMs. The Agency is continuing to explore the use of NAMs for the OPs, including chlorpyrifos, and intends to make its findings available as soon as it completes this work.

2. Reregistration and Registration Review

In 2006, EPA completed FIFRA section 4 (7 U.S.C. 136a–1) reregistration (a program under which EPA reregisters older pesticides that continue to meet the standard for registration) and FFDCA tolerance reassessment (21 U.S.C. 346a(q)) for chlorpyrifos and the OP class of pesticides. EPA concluded that process by determining that those tolerances were safe and should be left in effect. That decision relied on an endpoint based on 10% RBC AChE inhibition. (Ref. 25)

Given ongoing scientific developments in the study of the OPs generally, in March 2009 EPA announced its decision to prioritize the FIFRA section 3(g) (7 U.S.C. 136a(g)) registration review of chlorpyrifos by opening a public docket and releasing a preliminary work plan to complete the chlorpyrifos registration review by 2015. Despite the ambitions of that original work plan, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated, and thus, chlorpyrifos is currently still undergoing registration review, which must be completed by October 1, 2022. (7 U.S.C. 136a(g)(1)(A)(iv)) For information about the ongoing registration review process for chlorpyrifos, see *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0850.*

Reflecting that complexity, the Agency has engaged in extensive and ongoing analyses of the available science since initiating registration review in 2009, including multiple human health risk assessments and drinking water assessments, development of a new model for deriving points of departure to assess risks of chlorpyrifos, development of a framework for incorporating human epidemiology information into risk assessments as well as conducting an in-depth epidemiology and literature review, and in the process convening the FIFRA SAP at least six times. The following lays out the major milestones of the chlorpyrifos registration review process.

In 2011, EPA released its preliminary human health risk assessment (2011 HHRA) for the registration review of chlorpyrifos. (Ref. 18) The 2011 HHRA used 10% RBC AChE inhibition from laboratory rats as the critical effect (or PoD) for extrapolating risk. It also used the default 10X uncertainty factors for inter- and intra-species extrapolation. The 10X FQPA safety factor was reduced to 1X with a note to the public that a WOE analysis evaluating available epidemiological studies would be forthcoming. Also, in 2011, EPA released its Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment. (Ref. 26) This assessment provided estimated drinking water concentrations (EDWCs) based on Tier I groundwater and Tier II surface water model simulations for registered uses of chlorpyrifos and considered monitoring data from several different programs. Based on data demonstrating the impacts of drinking water treatment on chlorpyrifos, EPA concluded that chlorpyrifos in drinking water would convert to chlorpyrifos-oxon, a metabolite, when going through chlorinated drinking water treatment systems. Based on modeling results, EDWCs for chlorpyrifos and chlorpyrifos-oxon generated from surface water sources provided higher estimates of the potential exposure to either of these chemicals in drinking water than those from groundwater.

In 2014, following the development of the PBPK–PD model and 2012 SAP's review of EPA's epidemiology review, EPA released a revised human health risk assessment (2014 HHRA). (Ref. 20) Using the chlorpyrifos PBPK–PD model for deriving human PoDs for RBC AChE inhibition, which obviated the need for the inter-species extrapolation factor and allowed for data-derived intra-species extrapolation factors (as described in Unit II.B.1.b.i.), the revised risk assessment identified highly refined PoDs that accounted for gender, age, duration and route-specific exposure considerations. In addition, the revised risk assessment retained the 10X FQPA SF, based on EPA's WOE analysis concerning the potential for neurodevelopmental outcomes that followed a draft of EPA's Epidemiologic Framework (Ref. 19), and incorporated recommendations from the 2012 SAP. Also in 2014, EPA released its Updated Drinking Water Assessment for Registration Review (''2014 DWA''). (Ref. 27) As an update to the 2011 DWA, the 2014 DWA included several additional analyses focusing on: (1) Clarifying labeled uses, (2) evaluating volatility and spray drift, (3) revising aquatic modeling input values, (4) comparing aquatic modeling and monitoring data, (5) summarizing the effects of drinking water treatment, and (6) updating model simulations using current exposure tools. The additional analyses did not change the exposure assessment conclusions reported in the preliminary DWA. The 2014 HHRA, taken together with the Agency's drinking water assessment, identified estimated aggregate risks exceeding the level of concern for chlorpyrifos.

In 2016 EPA issued a revised human health risk assessment using a dose-reconstruction approach to derive the PoD based on the neurodevelopmental effects observed in the CCCEH study based on advice from the 2016 SAP. (Ref. 28) Although the 2016 HHRA found that risks from food alone exceeded the safe level for chlorpyrifos, EPA also issued a revised drinking water assessment (2016 DWA). (Ref. 29) This refined drinking water assessment served to combine, update, and complete the work presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. Even with the additional refinements, the results were consistent and suggested potential exposure to chlorpyrifos or chlorpyrifos-oxon in finished drinking water based on labeled uses. The assessment noted that depending on the drinking water level of concern, measured concentrations of chlorpyrifos and chlorpyrifos-oxon may exceed the level of concern in some locations across the country, which warranted comparison of EDWCs to the established drinking water level of concern. EPA issued a Notice of Data Availability seeking public comment on the 2016 HHRA and 2016 DWA. (81 FR 81049, November 17, 2016) (FRL–9954–65)

In September 2020, EPA issued the ''Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review'' (2020 HHRA) (Ref. 2) and the ''Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review'' (2020 DWA) (Ref. 30). In the 2020 HHRA, EPA utilizes the same endpoint and PoDs as those used in the 2014 HHRA. This was done because the Agency concluded that the unresolved nature of the science addressing neurodevelopmental effects warranted further evaluation of the science during the remaining time for completion of registration review. Due to the uncertainties concerning neurodevelopmental effects, the 2020 HHRA retained the default 10X FQPA safety factor; the 2020 HHRA also presented potential risk estimates at a reduced 1X FQPA safety factor to reflect the range of estimates possible, although it did not adopt or explain why the 1X FQPA safety factor would be safe for infants and children. While in the 2020 HHRA the Agency determined that risks from exposures to chlorpyrifos residues in food combined with residential exposures were not of concern, drinking water exposures significantly add to those risks. The 2020 DWA built upon the analysis in the 2016 DWA but focused on a subset of currently registered chlorpyrifos uses for high benefit crops to growers in specific areas of the country, *i.e.,* alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat. This assessment utilized new surface water model scenarios (*i.e.,* soil, weather, and crop data), integrated the entire distribution of community water system percent cropped area (PCA) adjustment factors and state-level percent crop treated (PCT) data, and considered the quantitative use of available surface water monitoring data. The 2020 DWA noted that concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water were not likely to exceed the drinking water level of comparison (DWLOC) even with the retention of the 10X FQPA safety factor for the subset of uses considered; however, that assessment noted that adding additional uses could change estimated drinking water concentrations, which could ultimately result in changes to the risk conclusion relative to the drinking water level of comparison(s).

In December 2020, EPA released the ''Proposed Interim Decision for the Registration Review of Chlorpyrifos'' (2020 PID) for a 60-day public comment period (85 FR 78849, December 7, 2020) (FRL–10017–1). The 2020 PID concluded that ''[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern.'' (Ref. 31 at pg. 19) However, the 2020 PID also noted that if one considered only the uses that result in EDWCs below the DWLOC, then aggregate exposures would not be of concern. (*Id.*) Accordingly, the 2020 PID proposed to limit applications of chlorpyrifos in this country to only 11 uses in certain regions of the United States; EPA had focused its review on those 11 geographically limited uses due to potential benefits from those uses and concluded that the EDWCs for those uses alone were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos, although as a proposal, it was not a final Agency determination and could be subject to change following public comment and stakeholder interest, perhaps in an Agency determination on a different subset of uses. Along with comments on the 2020 PID, EPA invited comments on the benefits assessments, the 2020 HHRA, draft ecological risk assessment, and 2020 DWA. EPA extended the 60-day comment period by 30 days, which then closed on March 7, 2021. EPA is currently reviewing public input and will respond to comments prior to issuing an interim decision.

3. Scientific Issues and SAPs

As noted previously, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated. The OPs have presented EPA with numerous novel scientific issues that the Agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration in 2006. (*Note:* The SAP is a federal advisory committee created by FIFRA section 25(d), 7 U.S.C. 136w(d), and serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides. EPA may convene an SAP meeting to present significant regulatory, science, or policy matters involving pesticides and request that the SAP provide comments, evaluations, and recommendations on the matters submitted for its review.)

These FIFRA SAP meetings, which have included the review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, and the evaluation of a chlorpyrifos-specific PBPK–PD model, have resulted in significant developments in EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. In particular, and partly in response to issues raised in the 2007 Petition (discussed in Unit III.B. of this document), EPA has conducted extensive reviews of available data to evaluate the possible connection between chlorpyrifos and adverse neurodevelopmental effects and to assess whether the neurodevelopmental effects could be used to determine PoDs for assessing chlorpyrifos. On this particular topic, EPA has convened multiple FIFRA SAP meetings.

In 2008, the Agency presented to the FIFRA SAP a preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action. (Ref. 32) The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the PoDs but noted that despite some uncertainties, the CCCEH epidemiologic studies ''is epidemiologically sound'' and ''provided extremely valuable information'' for evaluating the potential neurodevelopmental effects of chlorpyrifos.

The 2010 FIFRA SAP favorably reviewed EPA's 2010 draft epidemiology framework. (Ref. 33) This draft framework, titled ''Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments in Pesticides,'' (''Epidemiologic Framework'') described the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. As suggested by the 2010 FIFRA SAP, EPA did not immediately finalize the draft framework but instead used it in several pesticide evaluations prior to making revisions and finalizing it. EPA's Office of Pesticide Program's (OPP) finalized this Epidemiologic Framework in December 2016. (Ref. 19)

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to RBC AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the United States, including those from the CCCEH, Mount Sinai, and University of California, Berkeley. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies.

The 2012 FIFRA SAP described the Agency's epidemiology review as ''very clearly written, accurate'' and a ''very thorough review.'' (Ref. 21 at pgs. 50–52, 53) It went further to note that it ''believes that the [Agency's] epidemiology review appropriately concludes that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7 through 9 years, and attention and behavior problems at 3 and 5 years of age. . . .'' The 2012 FIFRA SAP concluded that the RBC AChE inhibition remained the most robust dose-response data, though expressed concerns about the degree to which 10% RBC AChE inhibition is protective for neurodevelopmental effects, pointing to evidence from epidemiology, *in vivo* animal studies, and *in vitro* mechanistic studies, and urged the EPA to find ways to use the CCCEH data.

Taking that recommendation into consideration, the Agency prepared a proposal for using cord blood data from the CCCEH epidemiology studies as the source of data for the PoDs, which it presented to the FIFRA SAP in April 2016. The 2016 SAP did not support the ''direct use'' of the cord blood and working memory data for deriving the regulatory endpoint, due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations, and lack of raw data from the epidemiology study. (Ref. 22) Despite its critiques of uncertainties in the CCCEH studies, the 2016 FIFRA SAP stated that it ''agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition (*i.e.,* toxicity at lower doses).'' (*Id.* at pg. 18)

B. FFDCA Petition and Associated Litigation

1. 2007 Petition Seeking Revocation of Chlorpyrifos Tolerances

As described previously, in 2006, EPA issued the Reregistration Eligibility Decision (RED) for chlorpyrifos, which concluded that chlorpyrifos was eligible for reregistration as it continued to meet the FIFRA standard for registration. In September 2007, Pesticide Action Network North America (PANNA) and Natural Resources Defense Council (NRDC) (collectively, the Petitioners) submitted to EPA a petition (the Petition) seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA. (Ref. 34) That Petition raised several claims regarding EPA's 2006 FIFRA reregistration decision for chlorpyrifos and the active registrations in support of the request for tolerance revocations and product cancellations. Those claims are described in detail in EPA's earlier Order denying the Petition (82 FR 16581, April 5, 2017) (FRL–9960–77).

2. Agency Responses and 2017 Order Denying Petition

Ultimately, EPA denied the Petition in full on March 29, 2017 (82 FR 16581, April 5, 2017) (FRL–9960–77). Prior to issuing that Order, however, EPA issued two interim responses and a proposed rule in response to the Petition.

EPA provided the Petitioners with two interim responses on July 16, 2012, and July 15, 2014, which denied six of the Petition's claims. EPA made clear in both the 2012 and 2014 responses that, absent a request from Petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request, and EPA therefore finalized its response to those claims in the March 29, 2017 Order Denying Petition.

As background, three of the Petition's claims all related to the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% RBC AChE inhibition). Because the claims relating to the potential for neurodevelopmental effects in children raised novel, highly complex scientific issues, EPA originally decided it would be appropriate to address these issues in connection with the registration review of chlorpyrifos under FIFRA section 3(g) and decided to expedite that review, intending to finalize it in 2015, well in advance of the October 1, 2022 registration review deadline. (Ref. 35) EPA decided as a policy matter that it would address the Petition claims regarding these matters on a similar timeframe. (82 FR 16581 at 16583)

As noted earlier in this Unit, the complexity of these scientific issues precluded EPA from finishing its review according to EPA's original timeline, and the Petitioners brought legal action in the Ninth Circuit Court of Appeals to compel EPA to either issue an Order denying the Petition or to grant the Petition by initiating the tolerance revocation process. The result of that litigation was that on August 10, 2015, the Court ordered EPA to ''issue either a proposed or final revocation rule or a full and final response to the administrative [P]etition by October 31, 2015.'' (*In re Pesticide Action Network N. Am.,* 798 F.3d 809, 815 (9th Cir. 2015))

In response to that Court's order, EPA issued a proposed rule in 2015 to revoke all tolerances for chlorpyrifos (80 FR 69080, November 6, 2015) (FRL–9935–92) (2015 proposed rule), based on its unfinished registration review risk assessment. EPA acknowledged that it had had insufficient time to complete its drinking water assessment and its review of data addressing the potential for neurodevelopmental effects. Although EPA noted that further evaluation might enable more tailored risk mitigation, EPA was unable to conclude, based on the information before EPA at the time, that the tolerances were safe, since the aggregate exposure to chlorpyrifos exceeded safe levels.

On December 10, 2015, the Ninth Circuit issued a further order, in response to additional legal challenge by Petitioners, requiring EPA to take final action on its proposed revocation rule and issue its final response to the Petition by December 30, 2016. *In re Pesticide Action Network N. Am.,* 808 F.3d 402 (9th Cir. 2015). In response to EPA's request for an extension of the deadline in order to be able to fully consider the July 2016 FIFRA SAP report regarding chlorpyrifos toxicology, the Ninth Circuit ordered EPA to complete its final action by March 31, 2017. *In re Pesticide Action Network of North America* v. *EPA,* 840 F.3d 1014 (9th Cir. 2016). Following that Court's order, EPA published a Notice of Data Availability (NODA), seeking comment on EPA's revised risk assessment and water assessment and reopening the comment period on the proposal to revoke tolerances. (81 FR 81049, November 17, 2016) (FRL–9954–65)

On March 29, 2017, the EPA issued the 2017 Order Denying Petition. (82 FR 16581, April 5, 2017) (FRL–9960–77) The specific responses are described in full in that 2017 Order Denying Petition (and summarized again in the Agency's denial of objections. (84 FR 35555, July 24, 2019) (FRL–9997–06) EPA's 2017 Order Denying Petition did not contain a determination concerning the safety of chlorpyrifos. Rather, EPA concluded that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. EPA therefore denied the remaining Petition claims, concluding that it was not required to complete—and would not complete—the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without resolution of those issues during the ongoing FIFRA registration review of chlorpyrifos.

3. Objections and EPA's Denial of Objections

In June 2017, several public interest groups and states filed objections to the 2017 Order Denying Petition pursuant to the procedures in FFDCA section 408(g)(2). Specifically, Earthjustice submitted objections on behalf of the following 12 public interest groups: Petitioners PANNA and NRDC, United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens (LULAC), Learning Disabilities Association of America, National Hispanic Medical Association and Pineros y Campesinos Unidos del Noroeste. Another public interest group, the North Coast River Alliance, submitted separate objections. With respect to the states, New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submitted a joint set of objections. (Ref. 34), These objectors asserted that EPA erred in not making the requisite safety finding in denying the Petition and that EPA should revoke all tolerances because the available record supported a conclusion that the tolerances were unsafe.

On July 18, 2019, EPA issued a final Order denying all objections to the 2017 Order Denying Petition and thereby completing EPA's administrative denial of the petition (2019 Order Denying Objections to Petition Denial) (84 FR 35555, July 27, 2019) (FRL–9997–06). Again, the 2019 Order Denying Objections to Petition Denial did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA denied the objections on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the Petitioners' burden to present evidence supporting the request for revocation.

4. Judicial Challenge to 2019 Order Denying Objections To Petition Denial and 2021 Ninth Circuit Order

On August 7, 2019, the objectors (LULAC Petitioners) and States petitioned the Ninth Circuit for review of the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial. The LULAC Petitioners and States argued that EPA was compelled to grant the 2007 Petition and revoke chlorpyrifos tolerances because: (1) EPA lacked authority to maintain chlorpyrifos tolerances without an affirmative finding that chlorpyrifos is safe; (2) EPA's findings that chlorpyrifos is unsafe in the Agency's 2014 and 2016 risk assessments compel revocation of the chlorpyrifos tolerances; and (3) The Petition provided a sufficient basis for EPA to reconsider the question of chlorpyrifos's safety and was not required to prove that a pesticide is unsafe.

On April 29, 2021, the Ninth Circuit issued its decision, finding that when EPA denied the 2007 Petition to revoke chlorpyrifos tolerances, it was essentially leaving those chlorpyrifos tolerances in effect, which, the Court noted, the FFDCA only permits if EPA has made an affirmative determination that such tolerances were safe. (*League of United Latin Am. Citizens (LULAC)* v. *Regan,* 996 F.3d. 673 (9th Cir. 2021)) Although EPA argued that it was not compelled to reconsider its safety determination because the 2007 Petition had failed to meet the threshold requirement of providing reliable evidence that the tolerances were unsafe, the Court found that the Petition provided the necessary ''reasonable grounds,'' which triggered EPA's duty to ensure the tolerances were safe. (*Id.* at pg. 695) Since the 2017 Order Denying Petition and 2019 Order Denying Objections to Petition Denial failed to make any safety determinations for chlorpyrifos, the Court concluded that EPA violated the FFDCA by leaving those tolerances in place without the requisite safety findings. (*Id.* at pgs. 678, 695 and 696 (declaring that EPA's action was a ''total abdication of EPA's statutory duty under the FFDCA'')) Moreover, in light of the record before the Court, including the 2016 HHRA indicating that the current chlorpyrifos tolerances were not safe, the Court found EPA's denial of the 2007 Petition to be arbitrary and capricious. (*Id.* at pg. 697) Based on the available record, the Court concluded that EPA must grant the Petition and issue a final rule modifying or revoking the tolerances under FFDCA section 408(d)(4)(A)(i). (*Id.* at pg.701)

The Court recognized that, since the litigation had commenced, EPA had been continuing to evaluate chlorpyrifos in registration review and had issued the 2020 PID and convened another FIFRA SAP; the Court noted that such information could be relevant to a safety determination. (*Id.* at pg. 703) The Court allowed that if the new information could support a safety determination, EPA might issue a final rule modifying chlorpyrifos tolerances rather than revoking them. But the Court warned that EPA was to act ''immediately'' and not engage in ''further factfinding.'' (*Id.*) The Court chided that taking ''nearly 14 years to publish a legally sufficient response to the 2007 Petition'' was an ''egregious delay'' and ''EPA's time is [ ] up.'' (*Id.*) As a result, the Court ordered EPA to: (1) Grant the 2007 Petition; (2) Issue a final rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances, provided that such modification is supported by a safety finding, and (3) Modify or cancel related FIFRA registrations for food use in a timely fashion. (*Id.* at 703 and 704) Since the mandate was issued on June 21, 2021, the deadline for issuing the final rule was August 20, 2021, less than four months from the date the Court issued its decision.

IV. The Final Rule

As noted in the previous Unit, the Ninth Circuit directed EPA to act on the 2007 Petition by granting it and issuing a final rule concerning the chlorpyrifos tolerances. The Court allowed that that rule could either revoke all tolerances or modify tolerances, as long as EPA issued, concurrently with such modification, a determination that such modified tolerances were safe. The Court, impatient with EPA's failure to comply with the FFDCA when it left chlorpyrifos tolerances in place without the requisite safety finding, directed EPA to issue that final rule very quickly, *i.e.,* 60 days after the issuance of the mandate.

Given the limited window for issuing the rule and the Court's directive not to engage in additional fact-finding or further delay, the Agency focused in its rulemaking on the data and completed assessments available at the time and whether they were adequate to support a safety finding for the chlorpyrifos tolerances. EPA did not conduct additional analyses or engage in any additional fact-finding or scientific review, due to the limited time. Thus, the rule was based on available information that EPA had already reviewed and incorporated into risk assessments and/or regulatory documents.

The most recent risk assessments and regulatory documents were the 2020 HHRA (Ref. 2), 2020 DWA (Ref. 30), and the 2020 PID (Ref. 31). These documents were not in the record before the Ninth Circuit, although as noted previously, the Court allowed that the new information could be used in support of a safety finding as appropriate. Thus, the Agency considered, in addition to other previously developed documents on chlorpyrifos as cited in the final rule (Ref. 1), whether the 2020 documents would support a safety finding for the chlorpyrifos tolerances.

EPA's final rule follows the Agency's practice of assessing risk described in Unit II.B. of this document. Relying on the Agency's existing analyses on chlorpyrifos, EPA examined the toxicological profile of chlorpyrifos to identify potential hazards and identify PoDs for assessing risk. The Agency considered the appropriate uncertainty factors, including the appropriate FQPA safety factor, for setting the level of concern. EPA also examined potential exposures of chlorpyrifos in food and drinking water, as well as from uses that might result in exposure to residues in residential settings. Finally, EPA aggregated all anticipated exposures to determine if the existing tolerances would meet the safety standard of the FFDCA. The rest of this Unit summarizes the analysis and conclusions of the 2021 final rule. For further detail, see Ref. 1.

In the 2021 final rule, EPA described the two primary toxicological effects associated with chlorpyrifos: Acetylcholinesterase inhibition and neurodevelopmental effects. These effects are discussed in greater detail in Unit III.A.1.b. of this document. As EPA noted, the mode of action of chlorpyrifos of affecting the nervous system through inhibition of AChE is well-established, as well as its use as the basis for PoD for assessing risks from chlorpyrifos as well as other OPs. In addition, EPA acknowledged and addressed the extensive body of information studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos. EPA recognized that available data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain and acknowledged the observed associations between prenatal chlorpyrifos exposure and neurodevelopmental outcomes in the epidemiological data. But EPA also noted that due to uncertainties in the data, including the lack of specific exposure information, EPA was precluded from being able to make a causal linkage between chlorpyrifos exposure and the outcomes found in the epidemiological studies. As a result, while there is a lot of information about the potential association between chlorpyrifos and neurodevelopmental outcomes in infants and children, there was insufficient information at the time of the final rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes.

As a result, EPA relied on the RBC AChE inhibition results from laboratory animals to derive PoD, consistent with the 2006 chlorpyrifos RED, the 2006 OP cumulative risk assessment, and other single chemical OP risk assessments. To account for the unresolved scientific uncertainties associated with the potential for neurodevelopmental effects—and to be protective of those effects—the Agency retained the default 10X FQPA safety factor. As noted earlier, EPA is required to apply this tenfold margin of safety to account for potential pre- and postnatal toxicity, unless it has reliable data to support a determination that a different margin of safety would be protective. (21 U.S.C. 346a(b)(2)(C)) EPA explained that the Agency's WOE analysis indicates there is qualitative evidence of a potential effect on the developing brain associated with chlorpyrifos exposures; however, uncertainties remain about the levels at which those neurodevelopmental outcomes may occur. Therefore, EPA retained the 10X FQPA safety factor in recognition of the fact that despite extensive analysis of the available data, the science concerning neurodevelopmental effects remains unresolved and thus presents an uncertainty concerning the potential pre- and postnatal toxicity. EPA did not believe it had sufficient reliable data to determine that a lower safety factor would be protective of infants and children.

To assess risk, EPA estimated exposures to chlorpyrifos from approved uses. As the FFDCA requires, EPA examined exposures for chlorpyrifos uses that resulted in residues of chlorpyrifos in or on food, in drinking water, and in residential (or non-occupational) settings. EPA's assessment of dietary (food only) exposures relied on the Agency's Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate exposure by combining data on human consumption amounts with residue values in food commodities. These food-only exposure assessments were highly refined, based both on field trial data and monitoring data.

In drinking water, EPA estimated exposures of chlorpyrifos and chlorpyrifos-oxon, a metabolite of chlorpyrifos. The most recent drinking water assessment that examined all approved uses of chlorpyrifos was conducted in 2016; thus, the Agency relied on that assessment in evaluating the safety of the chlorpyrifos tolerances. While a more recent drinking water assessment had been conducted in 2020, that newer assessment only evaluated a subset of the approved uses and thus was incomplete for purposes of assessing the aggregate exposures of chlorpyrifos. Based on the 2016 drinking water assessment then, EPA evaluated estimated concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water resulting from approved uses of chlorpyrifos.

There are few remaining uses of chlorpyrifos that result in residential or non-occupational exposures. EPA evaluated those uses and used estimated exposures from use on golf courses in the overall aggregate risk assessment since golf course uses result in the highest estimated exposures among remaining residential (non-occupational) uses.

In accordance with the requirements of the FFDCA, EPA considered aggregate exposures of chlorpyrifos in all food, drinking water, and residential settings. EPA used a DWLOC approach, in which EPA compared estimated drinking water exposures to a DWLOC, *i.e.,* a value corresponding to the maximum amount of chlorpyrifos exposures that may be present in drinking water without resulting in aggregate exposures of chlorpyrifos that would result in unsafe exposures. Where the estimated drinking water concentrations for chlorpyrifos exceed the DWLOC, the Agency concluded that aggregate exposures would be unsafe because the chlorpyrifos residues in drinking water, when combined with food and residential exposures, would exceed safe levels of chlorpyrifos exposure. For chlorpyrifos and chlorpyrifos-oxon, the Agency calculated DWLOCs for acute and steady-state exposures for several population subgroups. (Ref. 2 at pgs. 15, and 44 through 47)

As noted in the final rule, EPA's assessment concluded that exposures to chlorpyrifos from food and residential exposures individually or together did not exceed EPA's levels of concern. However, the Agency found that when combined with the exposures in drinking water from all registered uses of chlorpyrifos, the aggregate exposure to chlorpyrifos exceeded safe levels. The estimated drinking water concentrations calculated in the 2016 drinking water assessment exceeded the DWLOC. The Agency recognized that the 2020 PID proposed a subset of uses that might result in exposures below the Agency's level of concern if uses were eliminated and significant changes to the labels were made, including use cancellations and geographic limitations, among others. However, as no registration or label changes had been effectuated such that EPA could rely on them at the time of the final rule, EPA assessed aggregate exposures expected from all registered uses.

Ultimately, EPA concluded that, based on the information before the Agency and taking into consideration all the registered uses for chlorpyrifos at the time, it was unable to determine that the chlorpyrifos tolerances were safe, since aggregate exposures to chlorpyrifos exceeded safe levels. Therefore, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. The prepublication copy of the final rule was posted on the EPA website on August 18, 2021, and the final rule published in the **Federal Register** on August 30, 2021 (Ref. 1). The final rule became effective on October 29, 2021. EPA provided a grace period of six months to ease the transition for growers and accommodate international trade considerations, by setting an expiration date for the chlorpyrifos tolerances of February 28, 2022.

The final rule provided that, pursuant to FFDCA section 408(g), 21 U.S.C. 346a, any person could file an objection to any aspect of the regulation, request a hearing on those objections, and requests for stay of the final rule. The objections, requests for hearing, and requests for stay received are summarized in Units V. and VI. of this document.

V. Objections, Requests for Hearing, and Requests for Stay

The Agency received several filings of objections, four requests for hearing on those objections, and several requests seeking a stay or extension of the rule. EPA briefly summarizes the objections, hearing requests, and stay requests, and responds to them in the next three units of this document.

Individual objections were filed by the following: The Amalgamated Sugar Company; the American Crystal Sugar Company; the American Farm Bureau Federation; the American Soybean Association; the California Citrus Quality Council; the Cherry Marketing Institute; the Coalition of Organophosphate (OP) Registrants; Gharda Chemicals International, Inc.; the Michigan Vegetable Council. Inc.; the Minor Crop Farmer Alliance; the Republic of Colombia; the Southern Minnesota Beet Sugar Cooperative; and 99 independent growers of soybean, corn, wheat, cotton, rice, alfalfa, and sugarbeet. Several entities also filed objections jointly in response to the final rule as follows: American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, Sugarbeet Associations) CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) (collectively, CLA/RISE); two sugarbeet farmers filed a joint objection; numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders signed on to a set of objections (collectively, the Agricultural Retailers Association, *et al.*).

The Agency has grouped the objections submitted into the following five categories:

(i) *Objections to the scope of EPA's final rule revoking tolerances.* Several Objectors objected to the final rule revoking all chlorpyrifos tolerances. Rather than revoke all tolerances, the Objectors assert that EPA should have modified tolerances by retaining the tolerances for those 11 high-benefit crops identified in the 2020 PID. Some of those objectors also argued that EPA had an obligation to harmonize its tolerance revocations with action under FIFRA (*e.g.,* canceling uses) in order to allow for the retention of the 11 tolerances identified in the PID. Finally, a number of Objectors requested that EPA retain ''import tolerances'' for chlorpyrifos commodities, on the grounds that those tolerances would not contribute to drinking water exposures, which are driving risks.

(ii) *Retention of the 10X FQPA safety factor.* Several objectors assert that EPA should not have retained the 10X FQPA safety factor due to scientific uncertainties tied to epidemiological data that objectors believe is invalid, incomplete, and unreliable. Objectors argue that EPA should have reduced the FQPA safety factor to 1X based on the rest of the available data for assessing the toxicity of chlorpyrifos.

(iii) *Objections related to drinking water.* Several objectors assert that EPA erred in relying on the 2016 Drinking Water Assessment (DWA), instead of the more refined 2020 DWA for assessing drinking water exposures. Objectors believe the Agency's approach is highly conservative and inaccurate. In addition, Gharda asserts that the Agency erred in assessing chlorpyrifos-oxon in the aggregate assessment of chlorpyrifos.

(iv) *Procedural considerations.* A number of objectors argue that EPA has failed to provide adequate due process by not addressing comments submitted on the 2015 proposed rule to revoke chlorpyrifos tolerances, and in the chlorpyrifos registration review process. Moreover, an objector raised due process concerns with the delayed opening of the Agency's Federal eRulemaking Portal for submitting objections electronically. Finally, some objectors argued that the Agency failed to provide meaningful opportunity for interagency input under Executive Order 12866.

(v) *Objections that, as a matter of law, do not provide a basis for leaving the tolerances in place.* Several Objectors requested that EPA rescind the final rule due to the impacts on growers and the environment from the loss of the pesticide. One objector believes that EPA improperly considered occupational exposure in the final rule based on an Agency press statement. Other objectors assert that the final rule is improper because it deviates from an unspecified Codex Alimentarius international standard of 0.05 mg/kg for chlorpyrifos. Some objectors assert that the implementation timeline specified by EPA was too short and that the final rule should have provided guidance for chlorpyrifos products in the channels of trade and considered the implications for existing stocks of chlorpyrifos. Finally, Gharda objects that the final rule violates their substantive due process rights.

Four objectors also included requests for evidentiary hearings. Three of these requesters—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—each request evidentiary hearings to demonstrate that the best available science, including the 2020 PID, supports a finding that chlorpyrifos tolerances can remain in effect for soybeans, sugarbeets, and Michigan tart cherries, respectively. Gharda submitted the fourth request for an evidentiary hearing on its objection that the chlorpyrifos-oxon was not relevant to the Agency's aggregate risk assessment. While Gharda believes the Agency has all the evidence necessary to make this determination, it still requests a hearing ''[t]o the extent that EPA believes that a fact issue is presented by this data.''

Finally, EPA received written requests to stay the effective date of the final rule from several objectors. The Sugarbeet Associations and Gharda both argue that the criteria set out in the FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35 require that EPA stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. Several other Objectors do not specifically address the regulatory criteria set forth at 21 CFR 10.35, but request that EPA stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. Some objectors simply request an extension of the timeframe for implementation of the rule.

VI. Response to Requests for Hearing

EPA denies each of the four requests for evidentiary hearing on objections. Three objectors requested an evidentiary hearing on their objection that EPA should have retained tolerances for certain crops based on the conclusions of the 2020 PID; these requests are denied for failure to make a sufficient evidentiary proffer. Gharda also requested a hearing on its objection to EPA's assessment of chlorpyrifos-oxon exposures in drinking water; this request is denied as unnecessary for the purpose of receiving evidence and because the likely factual issue has no material impact on Agency's decision to revoke tolerances. EPA's substantive responses to the underlying objections follow in the next Unit, *i.e.,* Unit VII.C.1. and VII.C.3.b., respectively. Under EPA's regulations, EPA may treat these objections as a group and rule on them only after ruling on the request for an evidentiary hearing on that objection. 40 CFR 178.30(c)(2) Therefore, EPA is addressing these hearing requests before responding to objections in the next Unit.

A. The Standard for Granting an Evidentiary Hearing

EPA has established regulations governing objections to tolerance rulemakings and tolerance petition denials and requests for hearings on those objections. (40 CFR part 178; 55 FR 50282, December 5, 1990) (FRL–3688–4)) Those regulations prescribe both the form and content of hearing requests and the standard under which EPA is to evaluate requests for an evidentiary hearing.

As to the form and content of a hearing request, the regulations specify that a hearing request must include: (1) A statement of the factual issues on which a hearing is requested and the requestor's contentions on those issues; (2) A copy of any report, article, or other written document ''upon which the objector relies to justify an evidentiary hearing;'' (3) A summary of any other evidence relied upon to justify a hearing; and (4) A discussion of the relationship between the factual issues and the relief requested by the objection. (40 CFR 178.27)

The standard for granting a hearing request is set forth in 40 CFR 178.32. That section provides that a hearing will be granted if EPA determines that the ''material submitted'' shows all of the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought. (40 CFR 178.32(b))

This provision essentially imposes four requirements upon a hearing requestor. First, the requestor must show it is raising a question of fact, not one of law or policy. Hearings are for resolving factual issues, not for debating law or policy questions. Second, the requestor must demonstrate that there is a genuine dispute as to the issue of fact. If the facts are undisputed or the record is clear that no genuine dispute exists, there is no need for a hearing. Third, the requestor must show that the disputed factual question is material, *i.e.,* that it is outcome determinative with regard to the relief requested in the objections. Finally, the requestor must make a sufficient evidentiary proffer to demonstrate that there is a reasonable possibility that the issue could be resolved in favor of the requestor. Hearings are for the purpose of providing objectors with an opportunity to present evidence supporting their objections as the regulation states, hearings will not be granted on the basis of ''mere allegations, denials, or general descriptions of positions or contentions.'' (40 CFR 178.32(b)(2))

The Court in *National Corn Growers Ass'n* v. *EPA* noted that the FFDCA and EPA's regulations ''establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact.'' (613 F.2d 266, 271 (DC Cir. 2010)) In addition, the Court applied a ''necessarily deferential'' standard of review in determining whether an issue was material, looking to whether the agency ''has given adequate consideration to all relevant evidence in the record.'' (*Id.* at pgs. 271 and 272) ''Mere difference in the weight or credence given to particular scientific studies . . . are insufficient'' to overturn an agency conclusion regarding whether an objection raises a material issue of fact. (*Id.* at pg. 271)

EPA's hearing request requirements are based heavily on FDA regulations establishing similar requirements for hearing requests filed under other provisions of the FFDCA (53 FR 41126, 41129, October 19, 1988) (FRL–8372–5). FDA pioneered the use of summary judgment-type procedures to limit hearings to disputed material factual issues and thereby conserve agency resources. FDA's use of such procedures was upheld by the Supreme Court in 1972, (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973)), and, in 1975, FDA promulgated generic regulations establishing the standard for evaluating hearing requests (40 FR 22950, May 27, 1975). It is these regulations upon which EPA relied in promulgating its hearing regulations in 1990.

Unlike EPA, FDA has had numerous occasions to apply its regulations on hearing requests. FDA's summary of the thrust of its regulations, which has been repeatedly published in the **Federal Register** in Orders ruling on hearing requests over the last 24 years, is instructive on the proper interpretation of the regulatory requirements. That summary states:

A party seeking a hearing is required to meet a threshold burden of tendering evidence suggesting the need for a hearing.' [ ] An allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. [ ] FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. [ ] Stated another way, a hearing is justified only if the objections are made in good faith and if they 'draw in question in a material way the underpinnings of the regulation at issue.' Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy.

(49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007 (citations omitted) EPA has been guided by FDA's application of its regulations in this proceeding.

Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996. Although the statute had been silent on this issue previously, the FQPA added language specifying that when a hearing is requested, EPA ''shall . . . hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections'' (21 U.S.C. 346a(g)(2)(B)). This language grants EPA broad discretion to determine whether a hearing is ''necessary to receive factual evidence'' to objections (H.R. Rep. No. 104–669, at pg. 49 (1996)).

B. American Soybean Association, Sugarbeet Associations, and Cherry Marketing Institute Hearing Requests

1. Summary of Hearing Request

Three Objectors—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—requested evidentiary hearings based on their objections that EPA erred in revoking tolerances covering chlorpyrifos residues for their particular commodity, *i.e.,* soybean, sugarbeet, and cherry, respectively. (Refs. 36 through 38) These Objectors root this claim in statements made in the 2020 PID, in which EPA proposed a subset of 11 registered uses for retention as an option to mitigate dietary risks from uses of chlorpyrifos. The 2020 PID noted that if uses were limited in accordance with that proposal, EPA would be able to determine that such uses would ''not pose potential risks of concern.'' Because, at the time of the final rule, uses were not so limited, EPA revoked all tolerances. These Objectors assert that such a conclusion was inconsistent with the conclusions in the 2020 PID and thus not supported by factual evidence. As a result, these Objectors request a hearing on that objection to dispute the underlying factual basis for EPA's decision to revoke all tolerances and, in particular, for their tolerance of interest.

Specifically, the American Soybean Association notes that soybeans were included among the 11 high-benefit crop uses of chlorpyrifos that the 2020 PID described as ''not pos[ing] potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X.'' (Ref. 36 at pg. 4) In addition, the American Soybean Association asserts that EPA has determined ''elsewhere in its administrative record'' that it is reasonably certain soybean uses will not pose harm from aggregate dietary exposures. (*Id.*) Therefore, the American Soybean Association challenges EPA's determination in the final rule that soybean uses of chlorpyrifos might pose dietary risks of concern as factually inaccurate and contrary to the finding in the 2020 PID, and requests an evidentiary hearing ''to dispute this underlying factual inaccuracy.'' (*Id.*) Similarly, the Sugarbeet Associations argue that EPA's decision to revoke tolerances for the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID is arbitrary and capricious and request an evidentiary hearing ''to demonstrate that the best available science, including the 2020 PID, supports a finding that tolerances for sugarbeets can remain in effect.'' (Ref. 37 at pg. 6) Lastly, the Cherry Marketing Institute argues that EPA's decision to revoke tolerances for chlorpyrifos in the Michigan tart cherry industry due to dietary risks is factually inaccurate, in light of EPA's identification of tart cherries among the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID. (Ref. 38 at pg. 2) The Cherry Marketing Institute allege that an unspecified ''drinking water assessment and a dietary assessment'' provide that the Michigan tart cherry industry's use of chlorpyrifos meets FFDCA safety standards. (*Id.* at pg. 1) The Cherry Marketing Institute therefore requests an evidentiary hearing ''to further convey [its] concerns with EPA's determination'' to revoke chlorpyrifos tolerances. (*Id.* at pg. 2)

2. Denial of Hearing Request

The evidentiary hearing requests submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute do not meet the regulatory standard for granting an evidentiary hearing request set forth in 40 CFR 178.32 and are therefore denied.

As noted previously, the purpose for holding hearings is ''to receive factual evidence.'' (21 U.S.C. 346a(g)(2)(B); 53 FR 41126 at 41129 (''Hearings are for the purpose of gathering evidence on disputed factual issues . . . .'')) Therefore, at a bare minimum, a requestor must identify evidence relied upon to justify a hearing and either submit copies of that evidence or summarize it. (40 CFR 178.27)

None of these Objectors proffers any factual evidence to support their request for an evidentiary hearing. Other than offering that the Agency's determinations in the final rule were inconsistent with the 2020 PID, these Objectors refer to a hearing as an opportunity to dispute the Agency's factual conclusions regarding the risks posed by the use of chlorpyrifos on their particular commodity. As noted previously, ''[a]n allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.'' (49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007) (citing *Georgia Pacific Corp* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)) The statute requires that the objector identify actual evidence; however, the Objectors point to no additional factual evidence that they would offer for review in this evidentiary hearing. Failing to identify any factual evidence that the Objectors would like to be considered in a hearing, the Objectors' hearing request fails to proffer the requisite evidence.

Even viewed in the most favorable light, these Objectors merely proffer the Agency's own statements in its risk assessments and the 2020 PID and unspecified references to statements ''elsewhere in the administrative record.'' As a result, EPA concludes that this submission is sufficiently lacking to be considered an evidentiary proffer. Given that the purpose of a hearing is to gather or receive evidence, proffering evidence already considered and relied upon by EPA is not grounds for holding a hearing. Furthermore, EPA has already considered and found inadequate the evidence in the record to support retaining individual tolerances without a change in registrations, and it is difficult to understand, how, as a matter of law, this same evidence would justify the opposite conclusion, given the same underlying facts. At bottom, these objectors' proffer fails to ''identify'' evidence which would, if established, resolve an issue in the objectors' favor.

Moreover, the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute have all failed to demonstrate that there is a ''genuine and substantial issue of fact for resolution at a hearing.'' (40 CFR 178.32(b)(1)) Whether EPA was arbitrary and capricious in revoking the soybean, sugarbeet, and cherry tolerances is a question of law, not of fact. Contrary to what these objectors assert, EPA does not assess safety of tolerances based upon the risks posed by use on a single commodity. Under the FFDCA, EPA is required to assess aggregate exposures, *i.e.,* exposure to the pesticide from use on that particular commodity, as well as use on all other commodities, contributions to drinking water from all registered uses, and exposures in non-occupational settings. Furthermore, to the extent there is a factual question here, it is not in dispute. EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document. The problem is that at the time of the final rule, the Agency did not have a basis for assuming that uses would be limited in accordance with the 2020 PID mitigation proposal. Thus, as a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time of the final rule. Ultimately, this issue comes down to whether EPA properly interpreted its obligation under the FFDCA in assessing aggregate exposure to chlorpyrifos, and that is ultimately a question of law and not one of fact. Hearings are not granted on legal questions. (40 CFR 178.32(b)(1)) Accordingly, the hearing requests of the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute are denied.

EPA responds to the objection concerning whether EPA was justified in revoking all chlorpyrifos tolerances in Unit VII.C.1.a. of this document.

C. Gharda Chemicals International, Inc. Hearing Request

1. Summary of Hearing Request

In a footnote in a section of its objections alleging that EPA failed to adequately consider certain relevant scientific information, Gharda says, ''Gharda respectfully submits that EPA has all of the scientific data at its disposal to find that chlorpyrifos oxon is not relevant to EPA's aggregate exposure assessment under the FFDCA. To the extent that EPA believes that a fact issue is presented by this data, Gharda respectfully requests a hearing.'' (Ref. 39 at pg. 34) Although the first sentence of Gharda's footnote indicates that Gharda does not believe that a hearing is necessary, which should settle the matter, the second sentence introduces some ambiguity that compels a response as a matter of completeness. So, as discussed later in this document, EPA considers whether an evidentiary hearing on Gharda's objection to EPA's assessment of chlorpyrifos-oxon is warranted and determines that it is not.

On its face, Gharda's request for a hearing fails to proffer any evidence that Gharda believes warrants an evidentiary hearing. The specific request refers simply to ''scientific data'', which is so vague as to not be an evidentiary proffer at all. Nevertheless, taking into consideration the whole of Gharda's objection concerning the assessment of chlorpyrifos-oxon, EPA notes that Gharda references two documents: (i) A drinking water study submitted to EPA by Corteva in December 2020 (*Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days* (MRID 51392601) (''Corteva Oxon Study'')) and (ii) A Declaration of Dr. Richard Reiss, dated October 21, 2021 and included as an exhibit attached to Gharda's Objections to the final rule, offering opinions on the meaning of the Corteva Oxon Study (''Reiss Declaration''). (*Id.* at pg. 32) Also mentioned within the same section of Gharda's submission as its objection relating to chlorpyrifos-oxon are two other documents: (i) Comments filed by Dow AgroSciences LLC (DAS) (now doing business as Corteva Agriscience) on January 17, 2017 on the *Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment* (81 FR 81049) and its accompanying assessments, including the 2016 DWA; and (ii) A Response to Objections document filed by DAS on April 18, 2019 regarding objections submitted by PANNA, NRDC, and others to EPA's March 29, 2017 Order denying the 2007 Petition. (*Id.* at 31) Because Gharda refers to these documents only in the context of challenging the Agency's use of the 2016 DWA in general and not with regard to the chlorpyrifos-oxon objection specifically, EPA concludes that Gharda is not proffering those documents in support of its objection on the assessment of chlorpyrifos-oxon.

Gharda points to the Corteva Oxon Study as support for its objection that the chlorpyrifos-oxon was not relevant to, and should not have been included in, EPA's aggregate risk assessment. Gharda asserts, quoting from the Reiss Declaration, that the Corteva Oxon Study found ''(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure,'' and therefore nullified EPA's assumption in the 2020 DWA ''that chlorpyrifos oxon is more toxic that the parent chlorpyrifos for drinking water exposure purposes.'' (*Id.* at pg. 32) As a result, Gharda argues that this study shows that ''drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos.'' (*Id.* at pgs. 32 and 33) According to Gharda, EPA has received this study but has failed to review it. Gharda argues that EPA's failure to consider this study means that the final rule rests on incomplete information and is arbitrary and capricious. (*Id.* at pgs. 33 through 34) Therefore, giving Gharda the benefit of the doubt, EPA finds that the Corteva Oxon Study is being proffered by Gharda for the Agency's consideration in determining whether a factual issue is raised that warrants an evidentiary hearing. Similarly, because Gharda relies heavily on the Reiss Declaration for its allegations concerning the Corteva Oxon Study, EPA finds that Gharda is proffering that declaration as evidence as well.

2. Denial of Hearing Request

EPA denies Gharda's hearing request under both its broad discretionary authority found in FFDCA section 408(g)(2) and under the regulatory standard in 40 CFR 178.32. As an initial matter, the equivocating and vague nature of Gharda's hearing request makes it difficult to discern whether Gharda has submitted a request for an evidentiary hearing that meets even the basic form and content criteria of EPA's regulations. (40 CFR 178.27) First, EPA's regulations require a specific request for an evidentiary hearing and a statement of the factual issue on which the hearing is requested. (40 CFR 178.27(a) and (b)) While Gharda ''respectfully requests a hearing,'' it is only to the extent EPA finds a factual issue warranting one. (Ref. 39 at pg. 34) Gharda asserts many things in this particular objection concerning what Gharda believes is EPA's failure to consider relevant scientific data, including failure to consider the Corteva Oxon Study, which Gharda asserts would support a conclusion that chlorpyrifos-oxon in drinking water is not relevant for chlorpyrifos risk assessment purposes. That is not a clear statement of the factual issue on which EPA should evaluate the request for a hearing. (40 CFR 178.27(b)) Moreover, as discussed previously, it is difficult to discern exactly what evidence Gharda is proffering—''all scientific data'' in EPA's files or just the Corteva Oxon Study. (40 CFR 178.27(c)) Finally, Gharda makes no attempt to ''include a discussion of the relationship between the factual issues and the relief requested by the objection.'' (40 CFR 178.27(e)) Gharda seems to be arguing that if the chlorpyrifos-oxon was not relevant to the Agency's assessment, it would somehow change the outcome of the final rule, but Gharda fails to explain how consideration of that study would ultimately impact the Agency's conclusions concerning the safety of chlorpyrifos. In order to evaluate this ''hearing request'', EPA has had to discern from context what the factual issue is and what Gharda specifically hopes to accomplish with this evidence. This is contrary to EPA's regulations, which place the burden of presenting evidence upon which the objector relies to justify an evidentiary hearing on the objector, not on EPA. (40 CFR 178.27(c) and (d)) It appears that Gharda in its comment is trying to flip the burden for demonstrating whether an evidentiary hearing is necessary onto EPA; as such EPA believes that Gharda has failed to meet a threshold burden of submitting a hearing request that meets the basic criteria for such submissions under 40 CFR 178.27.

Significantly, by its own terms, Gharda does not believe that a hearing is necessary for the Agency to receive factual evidence, since the Agency already ''has all of the scientific data at its disposal'' to evaluate this objection. (Ref. 39 at pg. 34) As noted previously, FFDCA directs EPA to ''hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections'' (21 U.S.C. 346a(g)(2)(B)) This language was added to the FFDCA by the FQPA in 1996, after EPA promulgated its evidentiary hearing regulations, and EPA views it as providing broad discretion to evaluate whether a hearing is necessary, even if the requirements in 40 CFR 178.32 are met. EPA does not interpret this language as requiring it to hold a hearing in any instance where factual evidence relevant to a material issue of fact is proffered (essentially the standard set forth in 40 CFR 178.32); rather, EPA construes the statutory language as requiring it to hold a hearing only where it determines a hearing is necessary to receive such proffered evidence. In other words, a party wishing to obtain a hearing must not only satisfy the requirements of 40 CFR 178.32, it must also show that an evidentiary hearing is necessary for the presentation of proffered evidence to the Agency.

In this particular instance, Gharda states that EPA already has all the scientific data necessary to evaluate this issue and thus does not believe that a hearing is necessary to address the relevance of the oxon issue. EPA agrees. Because EPA already has the Corteva Oxon Study in its files, EPA has determined that a hearing is not necessary to receive that evidence. This conclusion is bolstered by EPA's determination that ultimately, consideration of this study would not materially impact EPA's conclusions regarding the safety of chlorpyrifos, since (as discussed later in this unit) EPA could not support a safety finding for chlorpyrifos based on consideration of only the chlorpyrifos (and not the oxon) concentrations in drinking water.

Moreover, in examining the evidentiary proffer of the Reiss Declaration, EPA concludes that a hearing would not be appropriate for receiving that evidence. ''An evidentiary hearing will not be granted on the basis of mere allegations . . . or general descriptions of positions and contentions. . . .'' (40 CFR 178.32(b)(2)) The Reiss Declaration contains a composite of conclusory statements of interpretation of the Corteva Oxon Study, with no elucidation of how Dr. Reiss arrived at those conclusions. (Ref. 39 at pgs. 113 through 132) One paragraph simply refers to a ''prior study'' to illustrate an example of the oxon causing lower levels of brain AChE inhibition than chlorpyrifos, but no citation to that study is provided. (*Id.* at pg. 120, paragraph 26) Paragraph 27, which Gharda quotes for its objections, concludes that the Corteva Oxon Study ''found (a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure.'' (*Id.* at pg. 121, paragraph 27) But that is it. There is no explanation of how Dr. Reiss came to those conclusions based on the study or what information provided in the study that supports these conclusions. Therefore, with regard to the Corteva Oxon Study, EPA finds that a hearing is not warranted to receive the Reiss Declaration, since the statements contained therein appear to contain mere allegations and conclusions.

In applying the criteria for granting a hearing, EPA looks first to the question of whether there is a genuine and substantial issue of fact. (40 CFR 178.32(b)(1)) As noted previously, Gharda has failed to provide a clear statement of the factual issue to be resolved at an evidentiary hearing. However, EPA recognizes Gharda's assertion that chlorpyrifos-oxon is not relevant for risk assessment purposes due to the lack of toxicity allegedly demonstrated in the Corteva Oxon Study is at odds with EPA's assessment of chlorpyrifos-oxon residues in drinking water and in the aggregate risk assessment. Whether there is valid scientific data supporting a different conclusion about the toxicity of chlorpyrifos-oxon is likely to be a factual question, rather than one of law or policy.

Nevertheless, EPA's hearing regulations also require that the ''[r]esolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action request.'' (40 CFR 178.32(b)(3)) Under this prong, Gharda's request for a hearing fails. As noted previously, Gharda has failed to provide a discussion of how resolution of this factual issue would assist in granting the relief of their objection. For that matter, Gharda has not even clarified how their objection (*i.e.,* failure to consider relevant scientific information) supports a change to the Agency's safety determination in the final rule.

Assuming *arguendo* that Gharda (and Dr. Reiss) has correctly interpreted the Corteva Oxon Study and assuming also that chlorpyrifos-oxon is less toxic than chlorpyrifos and is not therefore the relevant exposure measurement for assessing risks of chlorpyrifos in drinking water as EPA had assumed, Gharda's request for an evidentiary hearing still fails. This is because this assumption would not ultimately change the outcome of the final rule; EPA would still be unable to conclude that the chlorpyrifos tolerances were safe because the estimated concentrations of chlorpyrifos itself (rather than chlorpyrifos-oxon) in drinking water still exceed the relevant DWLOC.

In the 2020 PID, EPA calculated a DWLOC for both chlorpyrifos and chlorpyrifos-oxon. The DWLOCs used for comparison to residues of chlorpyrifos in drinking water in the final rule were associated with chlorpyrifos-oxon, as that was considered the residue of concern: 4.0 ppb for steady-state exposures and 23 ppb for acute exposures. Based on the 2016 DWA, EPA determined that there were likely to be estimated concentrations of chlorpyrifos-oxon in drinking water that exceeded those DWLOCs. As indicated in Unit II.B.1.d., where the concentrations of pesticide in drinking water exceed the DWLOC, the Agency concludes that the aggregate exposures are not safe. If, as Gharda asserts, the chlorpyrifos-oxon residues are not relevant, there would still be exposures to chlorpyrifos in drinking water, and EPA would need to consider whether those exposures to chlorpyrifos would be safe. The DWLOCs calculated for chlorpyrifos were 17 ppb for steady-state exposures and 100 ppb for acute exposures. (Ref. 31 at pg. 15) Relative to the DWLOCs for chlorpyrifos-oxon, the DWLOCs for chlorpyrifos are larger, providing slightly more room in the risk cup for residues of chlorpyrifos, relative to chlorpyrifos-oxon. Nevertheless, the 2016 DWA indicates that for the majority of HUC regions assessed, the estimated concentrations of chlorpyrifos alone in drinking water still exceed the higher DWLOC of 17 ppb, *i.e.,* Table 25 of the 2016 DWA indicates that the range of chlorpyrifos concentrations in drinking water have the potential to exceed the DWLOC for all HUC regions except one (HUC 16b). (Ref. 29 at pgs. 73–74) As long as there are certain vulnerable watersheds where the concentrations of chlorpyrifos exceed the maximum amount allowed for residues in drinking water to ensure that aggregate chlorpyrifos exposures stay below safe levels, the Agency cannot make a safety finding to support the chlorpyrifos tolerances. Thus, Gharda has failed to raise a material factual issue for which an evidentiary hearing would be appropriate. ''An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.'' (40 CFR 178.32(b)(3))

The absence of a material issue of fact here is fatal to Gharda's request for a hearing. As noted previously, the Corteva Oxon Study, even if it supported Gharda's assertion that chlorpyrifos-oxon residues were not relevant for EPA's risk assessment, does not ultimately support a finding that the chlorpyrifos tolerances are safe. Therefore, EPA concludes that a hearing is not justified to receive that evidence for the purposes of evaluating Gharda's claim concerning the consideration of chlorpyrifos-oxon in the Agency's risk assessment. This conclusion also reinforces EPA's earlier determination that a hearing is not necessary to receive the evidence since the study is already in the Agency's files. Furthermore, because the Reiss Declaration offers nothing more than conclusory statements about how to interpret the Corteva Oxon Study, it also fails to provide a basis for determining that the chlorpyrifos tolerances are safe and changing the final rule. Conclusory statements indicating a potential difference of scientific interpretation of a study that, even in the most favorable light, is not outcome determinative, does not create a material issue of fact. (*See National Corn Growers Ass'n,* 613 F.3d at 274 (finding that ''[m]ere differences in the weight or credence given to particular scientific studies'' would not be a sufficient basis to overturn an Agency conclusion that there is no material issue of fact)) Therefore, EPA has determined that Gharda has failed to proffer evidence warranting an evidentiary hearing on its objection concerning the Agency's assessment of chlorpyrifos-oxon.

D. Summary of Reasons for Denial of Hearing Requests

EPA is denying the requests for evidentiary hearing submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute because those entities failed to proffer any evidence for which a hearing would be appropriate. The statute clearly states that a hearing is appropriate when ''necessary to receive material evidence.'' (21 U.S.C. 346a(g)(2)(B)) Moreover, these Objectors ultimately disagree with EPA's application of the FFDCA statutory standard for assessing exposures, which is a legal question, rather than a factual one, and thus not appropriate for a hearing. (40 CFR 178.32(b)(1))

EPA is denying Gharda's request for an evidentiary hearing for lack of necessity since, as Gharda concedes, EPA already has the evidence proffered and for lack of materiality, since even if Gharda's factual assertions are correct and supported by the evidence proffered, those issues are not determinative with regard to the Agency's conclusions in the final rule, *i.e.,* they would not provide a basis for leaving the chlorpyrifos tolerances in place at this time.

VII. Response to Objections

A. Overview

EPA denies each of the objections to the final rule. As noted in Unit V. of this document, EPA received several objections from many different entities, including trade associations, farm bureaus, individual growers, and registrants. EPA has grouped these objections into five different categories, which are described later in this unit. After a brief description of each objection or objection subissue, EPA responds to each in this unit.

B. Denial of Objections Not Properly Filed

As a preliminary matter, EPA notes that several parties submitted documents to the Federal eRulemaking Portal that are styled as objections but that do not comply with the requirements of 40 CFR 178.25. As EPA noted in the final rule—and as required in EPA's regulations—objections must be submitted in writing and filed with the Office of the Hearing Clerk in accordance with the procedures in 40 CFR 178.25. While the regulations specify that objections are to be mailed or hand-delivered to the Hearing Clerk, due to the pandemic the Office of Administrative Law Judges (OALJ), where the Office of the Hearing Clerk is housed, is directing parties to file electronically. (Ref. 40) The final rule provided instructions for filing online as well as what to do in the event that online filing was not available. (Ref. 1 at pgs. 48315–16)

The following parties did not submit their objections to the Office of the Hearing Clerk either through the OALJ e-filing system or through mail or hand delivery as required by 40 CFR 178.25(b): The Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador. (Refs. 41 through 45) EPA also notes that the National Association of Wheat Growers submitted two sets of objections: One as a standalone document, which was not properly filed with the Office of the Hearing Clerk (Ref. 46), and one as a signatory to objections submitted by numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders (which EPA is referring to as the Agricultural Retailers Association, *et al.* objections (Ref. 47)), which was properly filed with the Office of the Hearing Clerk. EPA's regulations require EPA to deny each objection that is found not to conform with 40 CFR 178.25. (40 CFR 178.30(a)(1)) As a result, EPA denies the previously-described objections that were not submitted to the Office of the Hearing Clerk and will not be considering them in this Order.

C. Responses to Specific Issues Raised in Objections

1. Objections to the Scope of EPA's Final Rule Revoking Tolerances

One theme running through several objections was an assertion that EPA's revocation of all chlorpyrifos tolerances was unlawful and unnecessary. Some Objectors argued that EPA should have retained some of the chlorpyrifos tolerances, rather than revoking them all, based on EPA's mitigation proposal in the 2020 PID to limit uses to 11 high-benefit crops in certain geographic locations. Relatedly, some Objectors believed that EPA should have coordinated the tolerance revocations with actions under FIFRA to cancel uses in order to avoid revoking all tolerances. Finally, some Objectors asserted that EPA should have retained import tolerances since imported commodities would not contribute to drinking water exposures, which were driving risk concerns. These objections and EPA's responses are discussed in further detail in this sub-unit.

a. EPA's Proposal for Limiting Uses to 11 High-Benefit Crops in the 2020 Proposed Interim Decision (PID) for Chlorpyrifos

i. Objection. Nearly all Objectors assert that revoking all chlorpyrifos tolerances was unlawful and unnecessary based on statements in the 2020 PID where EPA proposed a subset of chlorpyrifos tolerances for retention, provided certain restrictions were implemented. (The objections, requests for hearing on objections, and stay requests submitted in response to the final rule are available at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.) Some Objectors' claims are general, asserting that EPA should have retained all 11 tolerances, and some are specific to their own commodity of interest (*e.g.,* the American Soybean Association focuses on EPA's determination in the 2020 PID as it relates to soybeans, specifically). (Ref. 36 at pg. 4) In each case, however, these Objectors rely on EPA's proposed finding in the 2020 PID to demonstrate that EPA's record contains sufficient information to determine that at least some tolerances and uses satisfy the FFDCA safety standard. The objectors conclude that, therefore, revocation of all tolerances was inconsistent with the FFDCA requirement to consider aggregate exposure from all ''anticipated dietary exposures''.

The Objectors point to the Ninth Circuit's April 29, 2021, decision for support that EPA was not required to revoke all chlorpyrifos tolerances. The Objectors note that the Court gave EPA the option to ''either revoke all chlorpyrifos tolerances or modify chlorpyrifos tolerances,'' as long as the modification was supported by a safety determination, as well as a direction to ''modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of [FFDCA 408(a)].'' (*LULAC,* 996 F.3d at 703–04) Consequently, the Objectors assert that EPA should have modified tolerances by retaining the 11 uses rather than revoking all.

ii. Denial of objection. EPA denies this objection. The Objectors' claim is primarily based on a misunderstanding of the FFDCA's requirement to consider aggregate exposure, a misreading of the 2020 PID, and a disregard of the facts at the time of the final rule. When one corrects for each of those factors, it is clear that EPA's revocation of all chlorpyrifos tolerances was entirely consistent with the Agency's obligations under the FFDCA.

Before diving into the rationale for why the Objectors' argument is legally flawed, it is worth providing context for the PID, or proposed registration review decision. Under EPA's regulations, a proposed (interim) registration review decision lays out the Agency's proposed findings, identifies proposed risk mitigation measures or other remedies as needed, identifies any missing or needed data, specifies proposed labeling changes, and identifies any anticipated deadlines. (*See* 40 CFR 155.58(b)) EPA publishes notice of the availability of this proposed decision and provides for at least a 60-day comment period. (40 CFR 155.58(a)) After consideration of those comments, EPA will issue an interim or final registration review decision, which can be very similar to the proposed decision or incorporates changes based on those comments. (40 CFR 155.58(c)) As noted in Unit II.A., the purpose of registration review is to determine whether the registered pesticide continues to meet the standard for registration. Where EPA identifies potential unreasonable risks from use of a pesticide, EPA considers whether there are any options or measures for reducing or mitigating those risks that would enable the pesticide to meet the standard for registration. Where such mitigation measures are available, EPA will propose those in the proposed registration review decision in conformance with its regulations. But consistent with the nature of any proposal, the findings in the proposed decision are just proposals and subject to change based upon public comment or other developments that may occur before the final decision is issued.

For the 2020 PID for chlorpyrifos, EPA followed the process laid out in its regulations. EPA summarized the findings of its aggregate risk assessment and concluded that ''[w]*hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos,* aggregate exposures are of concern. *If considering only the uses that results in DWLOCs below the EDWCs,* aggregate exposures are not of concern.'' (Ref. 31 at pg. 19 (emphases added)) In other words, EPA found that the universe of currently registered chlorpyrifos uses presented aggregate exposures that exceeded the Agency's determined safe level of exposure. As a result, EPA proposed mitigation to address the dietary and aggregate risks of concern that were posed by use of chlorpyrifos as currently registered. (*Id.* at pg. 40)

To mitigate these risks, EPA proposed that chlorpyrifos applications be limited to the following 11 specific uses in only those specific geographic areas where the estimated concentrations of chlorpyrifos in drinking water from those uses were lower than the DWLOC, *i.e.,* the maximum amount of chlorpyrifos residues that could be present in water and still ensure that aggregate exposures would be safe: Alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and spring and winter wheat. (*Id.* at pgs. 40 and 41) For this mitigation proposal to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos that contribute to aggregate exposures (*i.e.,* food, drinking water, and residential exposures) would need to be cancelled and the labels for products containing the identified subset of uses would need to be amended to ensure that applications would be limited to those specifically identified geographic areas. Moreover, some revisions to labeled application rates would also be required since the conclusions in the 2020 PID that drinking water contributions were safe in these areas from these uses was based on usage data rather than maximum labeled application rates. It is also important to emphasize that the act of proposing to limit chlorpyrifos applications to this subset of uses did not, in fact, automatically result in the elimination of all uses beyond those identified uses; that would require separate actions under FIFRA to cancel uses and to amend labels, which has not occurred.

EPA proposed this particular list of uses as critical and high-benefit uses of those uses currently registered for chlorpyrifos. (Ref. 30, Attachment 2) Although the ''reasonable certainty of no harm'' standard in the FFDCA, which is strictly a risk-based standard, allows no consideration of benefits, except in one very limited circumstance not relevant here (*see* 21 U.S.C. 346a(b)(2)(B)), FIFRA's ''unreasonable adverse effects'' standard incorporates a consideration of economic costs or benefits, which EPA took into consideration when identifying this proposed list of retainable uses as part of the FIFRA registration review process. But this is likely not the only combination of uses that could have resulted in safe levels of aggregate exposure. To conserve resources (and because previous analyses had indicated risks of concern when considering all chlorpyrifos uses), EPA's 2020 DWA focused solely on the areas where these particular crops were grown that had the highest benefit to growers to determine if there were areas where the EDWCs were below the DWLOC; it is possible that a different set of crops and a different range of geographic areas could also result in safe aggregate exposures. The Agency expressly noted that it would ''consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if any other limited uses may be retained.'' (Ref. 31 at pg. 40) The 2020 PID was made available for public comment, and the Agency did, in fact, receive hundreds of comments, although none committed to making changes to the chlorpyrifos registrations necessary to implement the 2020 PID as proposed, nor were any requests for voluntary cancellation of registered uses submitted under FIFRA in response to the 2020 PID.

Turning now to the legal standard, as noted in Unit II.A., FFDCA section 408(b)(2)(A)(i) permits EPA to leave tolerances in place only if the Agency can determine that the tolerance is safe. If the Agency determines that the tolerances, which must be based on aggregate exposures, are not safe (or cannot determine that tolerances are safe), the Agency must modify or revoke them. (21 U.S.C. 346a(b)(2)(A)(i); see also *LULAC,* 996 F.3d at pgs. 693–94 (concluding that when EPA receives a petition raising substantive questions concerning safety, FFDCA provides no middle ground in which EPA can leave tolerances in place if EPA is unwilling or unable to make a safety finding)) The FFDCA also defines safe as requiring EPA to determine that ''there is a reasonable certainty that no harm will result from *aggregate exposure* to the pesticide chemical residue, including *all anticipated dietary exposures and all other exposures for which there is reliable information.*'' (21 U.S.C. 346a(b)(2)(A)(ii) (emphases added)) Congress understood the phrase ''aggregate exposure'' to include dietary exposures under all tolerances for the pesticide chemical residue, H.R. Rep. 104–669(II) at 1279, and codified that understanding among the factors EPA must consider when establishing, modifying, leaving in effect, or revoking tolerances. (21 U.S.C. 346a(b)(2)(D)(vi)) In FFDCA section 408(b)(2)(D)(vi), EPA must consider ''available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue,* and exposure from other non-occupational sources.'' (*Id.* (emphasis added))

The requirement to consider ''aggregate exposure'' was added to the FFDCA through the FQPA amendments in 1996. (Food Quality Protection Act of 1996, Pub. L. 104–170) Prior to the enactment of the FQPA, when assessing risk, EPA treated exposures from different pathways as independent events and made no concerted effort to evaluate potential exposures simultaneously. In reality, however, exposures to pesticides do not occur as single, isolated events, but rather as a series of sequential or concurrent events that may overlap or be linked in time and space. Congress, in enacting the FQPA, was concerned with ensuring that the Agency's assessments under the FFDCA would be strictly health-protective and risk-based, and as a result, made a number of significant amendments to the FFDCA, including the new risk-only safety standard, the FQPA children's safety factor, and, of most relevance here, a new requirement for EPA to consider exposures in the aggregate rather than independently.

Following the enactment of the FQPA, EPA developed guidance on how to conduct aggregate exposure and risk assessment. (Ref. 14) That guidance describes the aggregate exposure and risk assessment as involving ''the analysis of exposure to a single chemical by multiple pathways [food, drinking water, residential] and routes of exposure [oral, dermal, inhalation] . . . . All potential, relevant routes of exposure are analyzed with an aggregate exposure assessment.'' (*Id.* at pg. 4) That guidance also defines aggregate risk as ''[t]he likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to a single substance.'' (*Id.* at pg. 72) In describing how EPA intends to conduct such aggregate risk assessments, EPA states that ''[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide,'' which are determined by looking to labeled allowable use patterns. (*Id.* at pgs. 24, 44 and 45) Moreover, the guidance directs that aggregate exposure and risk should be estimated for major identifiable subgroups of the population, which the Agency typically does through considerations of demographics (*e.g.,* age, gender, racial/ethnic background) and temporal (season) and spatial (geographics) characteristics of potentially exposed individuals. (*Id.* at pgs. 12, 24)

The Aggregate Exposure Guidance describes an approach for assessing aggregate exposures that recognizes such exposures to hypothetical individuals in the population: ''(1) may occur by more than one route (*i.e.,* oral, dermal and/or inhalation); (2) may originate from more than one source and/or pathway (*i.e.,* food, drinking water, and residential); (3) may occur within a time-frame that corresponds to the period of exposure required in an appropriately designed toxicity study to elicit an adverse toxicological effect; (4) should occur at a spatially relevant set of locations that correspond to an individual's potential exposure; and (5) should be consistent with the individual's demographic and behavioral attributes.'' (*Id.* at pg. 26) In practice, this means that the Agency might consider whether different populations of individuals are more or less likely to eat different kinds of food over different time periods; whether pesticide concentrations in drinking water vary temporally due to the growing season calendar or spatially due to the nature of applications generally being localized or regional; and/or whether different populations are likely to use or be exposed to pesticides in non-occupational settings. Generally, EPA would utilize upper-end estimates to ensure protection for the most vulnerable populations, unless other factors warranted a different approach.

From there, the Agency assesses the aggregate exposure through relevant routes of exposure for hypothetical individuals among these major identifiable subgroups (including food, drinking water, and residential exposures to which that individual is likely exposed), taking into consideration the various factors for co-occurrence of exposures in the various exposure pathways. (*Id.* at pg. 26) Where risks from aggregate exposures exceed safe levels, EPA will examine whether refinements can be made to the assessment. (*Id.* at pg. 13)

In the final rule, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance. That assessment considered exposure through oral, dermal, and inhalation routes of exposure that could result from exposures in food, drinking water, and residential uses. Taking into consideration the registered use patterns for chlorpyrifos, EPA assessed the universe of potential exposures from all currently approved uses of chlorpyrifos because no formal steps had been taken to limit those uses.

In demanding that EPA retain tolerances for the 11 uses, the Objectors essentially argue that EPA should have presumed that individuals would only be exposed to chlorpyrifos from the 11 uses because EPA proposed those 11 uses as an option for mitigation in the 2020 PID proposal. However, that argument ignores the premise in the PID that the safety finding for those uses is contingent on all other uses being cancelled and the remaining 11 uses being restricted both geographically and with lowered use rates. Exposures from those uses alone could not reasonably be considered as ''anticipated'' since they did not yet (nor did EPA have reason to believe that they would) reflect the exposures people would be exposed to in the real world. The FFDCA requires EPA to determine whether tolerances *are* safe, requiring consideration of aggregate exposures, including ''anticipated dietary exposures''; it does not allow EPA to leave tolerances in place if they *would be* safe at some unspecified time in the future based on certain mitigation that may not be implemented.

At the time of the final rule, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: No uses had been cancelled, nor had any labels been revised to geographically limit applications or limit maximum application rates. Although there were discussions with registrants and indications of a willingness to mitigate uses (see discussion in next sub-unit), the Agency had not received prior to the issuance of the final rule from registrants any formal requests under FIFRA for voluntary cancellation or applications to amend labels, to which the Agency could point as directionally supportive for a conclusion that exposures would at some future time be limited to that subset of chlorpyrifos applications. Until such uses cease—or at least until EPA has a reasonable basis to believe that they will cease—the Agency could not ignore the exposures from those uses. In sum, the 2020 PID proposal, without more, is just a proposal; it does not support an EPA assumption that aggregate exposures would be limited to that subset of uses instead of an assessment based on the actual registered uses and ongoing real-world applications of chlorpyrifos.

While the Objectors claim that EPA could have modified tolerances, as per the Court's order, by leaving in place only those identified in the 2020 PID, doing so, without accompanying registration actions under FIFRA, would have put EPA in the position of picking ''winners and losers'' among the tolerances. While, under FIFRA, EPA might be able to make an argument that some uses contribute relatively lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment whereas others may not, considerations of those relative benefits is not a factor for consideration under the FFDCA when determining which tolerances are safe or not. As noted previously, the 2020 PID proposal reflected one possible subset of uses that might warrant retention based on economic considerations. In circumstances where aggregate exposures exceed safe levels, there are potentially multiple variations of the potential subset of tolerances that might meet the safety standard and that EPA did not analyze. As such, EPA's general policy is to defer to the pesticide registrant and the public to determine which of the various subsets of tolerances are of sufficient importance to warrant retentions since not all parties might agree on the particular combination that should be retained. For example, one comment submitted on the 2020 PID requested that EPA retain tolerances on cranberries (Ref. 48), which was not listed among the 11 uses in the PID. Without some reasonable basis to believe that the uses would be limited as had been proposed, EPA did not have a basis to assume anticipated exposures would be limited to that particular subset of uses for purposes of modifying the tolerances.

Some Objectors made this same argument but focused more specifically on their crop of interest (*e.g.,* cherry, citrus, soybean, sugarbeet). These objectors assert that EPA could not have revoked the specific commodity tolerance because that crop was included in the list of crops EPA proposed to retain and thus EPA did not have a basis for concluding that those tolerances themselves were unsafe. However, the Agency does not assess tolerances for each crop in a vacuum; whether one tolerance is safe depends on whether aggregate exposure from that tolerance and all other tolerances in effect are safe. (21 U.S.C. 346a(b)(2)(D)(vi)) The consequence of the FFDCA requirement for EPA to assess the safety of tolerances as an aggregate is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels. At the time the final rule was issued, there were over 80 tolerances in effect, which the Agency was required to consider in its aggregate exposure assessment, unless there had been a reasonable basis to exclude exposures from those tolerances. The list in the 2020 PID was only a proposed mitigation measure, necessary because the aggregate exposures from chlorpyrifos, which included exposures from use of chlorpyrifos on these three commodities, exceeded safe levels.

It is also worth noting that tolerances themselves are broadly applicable rules that regulate the amount of pesticide residues on a food commodity. As such, they are not limited in geographic scope, and the Agency must be able to determine that all aggregate exposures from any registered uses (including all relevant geographic areas) that would be covered by a particular tolerance would be safe. For example, the tolerance covering residues of chlorpyrifos on cherry applies to the pesticide residues on the crop regardless of the location of application. In practice, this means that EPA needs to be able to determine that use of chlorpyrifos in any place permitted by the FIFRA label would be safe. For cherries, EPA's 2020 PID proposal only concluded that use on cherry could be safe in Michigan, if the other aforementioned mitigation measures were implemented; whether cherry use could be safe in other areas was not assessed. In order to conclude that cherry use was safe based on the 2020 PID proposal, the labels would need to restrict chlorpyrifos use to cherries only in Michigan. Since the uses on cherry were not so restricted under FIFRA at the time of the final rule, EPA could not assume that chlorpyrifos would be used only in the limited geographical regions without some progress being made on the label revisions.

In conclusion, while the 2020 PID proposed that there is at least one subset of chlorpyrifos uses that could be safe if additional restrictions were adopted and all other uses contributing to aggregate exposures were cancelled under FIFRA, that is not a basis for maintaining tolerances when the Agency does not have a reasonable basis to believe that the registrations would be so amended. Based on the factual realities at the time of the final rule, EPA was required to consider aggregate exposures resulting from approved labelling and all currently registered uses. The Objectors' claim incorrectly relies on the proposal in the 2020 PID as a basis for limiting the aggregate exposure assessment, and the request to limit EPA's safety assessment to a subset of actual exposures based on a proposal would reflect an incorrect application of the statutory standard under the FFDCA. EPA recognizes that the practice of identifying mitigation measures to address risks of concern in the proposed or interim decisions in registration review is common, and the expectation is that registrants will make adjustments to retain registrations. However, this is not always the case; some registrants may suggest alternative means of mitigating risks, which the Agency then needs to evaluate, or may refuse due to a disagreement with the Agency's underlying rationale for its decision. When mitigation measures are not implemented (or it is unclear that such risks will be mitigated), the risks that EPA initially identified remain. Therefore, the objection is denied.

b. Coordination With FIFRA Under FFDCA Section 408(l)(1)

i. Objection. Objectors assert that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA. The Sugarbeet Associations and Gharda argue that EPA had a statutory duty under section 408(l)(1) of the FFDCA to harmonize the chlorpyrifos tolerance revocation with necessary actions under FIFRA. (Refs. 37 and 39) They argue that EPA offers no explanation for why it was not practicable for EPA to cancel the FIFRA registrations and revoke tolerances for the food uses for which EPA would be unable to make a safety finding while maintaining the registrations and tolerances that the 2020 PID proposed for retention. The Sugarbeet Associations also argue that because the Ninth Circuit also ordered EPA to ''correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion,'' EPA's failure to harmonize its revocations with FIFRA actions is therefore also inconsistent with the Court's order. (Ref. 37 at pg. 7) Gharda acknowledges that EPA did engage in negotiations with registrants to attempt this harmonization but alleges that EPA was acting in bad faith in those negotiations and disregarded Gharda's commitment to modify its registration. (Ref. 39 at pgs. 28 through 31) The Minor Crop Farmers Alliance notes that EPA did not follow ''its traditional FIFRA/FQPA sequencing of taking the necessary tolerance actions only after first finalizing its decision in a cancellation action under Section 6 of FIFRA.'' (Ref. 49 at pg. 4) Finally, CLA/RISE requests guidance on how EPA intends to harmonize the tolerance revocation under FIFRA to reduce confusion among growers and industry. (Ref. 50)

ii. Denial of objection. EPA denies this objection on the following legal and factual grounds. FFDCA 408(l)(1) states that ''[t]o the extent practicable . . . , in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA].'' (21 U.S.C. 346a(l)(1)) While the statutory language includes the word ''shall,'' this provision clearly contemplates that there may be circumstances in which coordination is not practicable and thus such coordination is not required. Even when such coordination would be practicable, the statute does not require that this coordination be concurrent or occur in any predetermined order.

EPA has previously opined on this provision in a final rule revoking carbofuran tolerances in which this same comment was raised. (See 74 FR 23046, 23069–70, May 15, 2009 (FRL–8413–3)) In that rule, EPA found that the requirement to ''coordinate'' is a direction to ensure that the substance of actions taken under FIFRA and the FFDCA are consistent, and that the Agency make a determination as to the proper order of action under the two statutes. It cannot be read as a requirement that actions under FIFRA precede actions under the FFDCA, or that any particular order for EPA actions is necessarily required. Accordingly, there is no support for the notion that, as a matter of law, the Agency lacks the legal authority to revoke pesticide tolerances under the FFDCA that do not meet the safety standard of that statute unless the Agency has first canceled—or simultaneously cancels—associated pesticide registrations under FIFRA.

In this instance, the Ninth Circuit itself prioritized EPA's taking action on the chlorpyrifos tolerances above the action necessary under FIFRA, when it set a very short and specific deadline for addressing pesticide tolerances (*i.e.,* within 60 days of the issuance of the mandate) and allowed flexibility for EPA to ''modify or cancel related FIFRA registrations for food use in a timely fashion.'' (*LULAC,* 996 F.3d at 703–04) Under the Court's timeframe, it was not practicable for EPA to take action under FIFRA to cancel registered food uses of chlorpyrifos concurrently with the final rule. Cancellation of uses under FIFRA section 6(b) requires several steps, including drafting a notice of intent to cancel, interagency coordination and SAP review, as well as possible administrative hearings, and can take several years to complete. (See 7 U.S.C. 136d(b)) Even the process to obtain and act on voluntary cancellation requests can be a time-consuming process with statutorily set comment periods before a cancellation can be ordered. (7 U.S.C. 136d(f))

In any event, in this particular instance, EPA did attempt to harmonize its tolerance revocation actions with cancellation actions under FIFRA. As the Minor Crop Farmer Alliance pointed out, EPA traditionally, as part of the registration review process, identifies the relative risks and benefits of particular uses and works with registrants to eliminate uses that no longer meet the FIFRA standard, including for safety risks. Under that approach, EPA and the registrant(s) can mutually agree on terms for the smooth phase-out of the product, and the product or use cancellations can be coordinated with tolerance revocations under the FFDCA. After the Ninth Circuit's decision was issued, EPA engaged in discussions with the four registrants of technical chlorpyrifos products (*i.e.,* those that are used to manufacture the chlorpyrifos pesticide products sold to end users) to discuss possible voluntary use cancellations and label restrictions, although EPA did not initiate any discussions with the dozens of registrants of end-use products. (Ref. 51) Despite the progress made in those discussions, no registrant submitted under FIFRA a request for voluntary cancellation of any uses or application to amend existing chlorpyrifos labels to reduce application rates and geographically limit uses. One of those registrants, Gharda, asserts that EPA acted in bad faith in the negotiations with Gharda and disregarded a commitment from Gharda to modify its registration. EPA disagrees with Gharda's characterization of the negotiations.

Prior to the issuance of the final rule, EPA entered into discussions with Gharda, as well as several other registrants, in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. EPA held several meetings with each of the technical registrants, including Gharda, to discuss their interests and concerns as EPA considered its response to the Court's directive to issue a final rule. (*Id.*) The meetings with Gharda occurred on May 27, June 3, June 17, June 24, July

14, and August 16, 2021. As Gharda's objection filing indicates, there was an extensive amount of back-and-forth between EPA and Gharda concerning restrictions to the current registrations and an attempt to work out mutually agreeable terms (*e.g.,* uses to be retained, geographic limitations on uses, retention of import tolerances, timing for phase-out of existing uses) to provide a reasonable basis for assuming aggregate exposures could be limited to the 11 uses proposed for retention in the 2020 PID.

Gharda asserts, in its objection, that EPA disregarded a written commitment to voluntarily cancel uses and therefore, the Agency's decision to revoke all tolerances was arbitrary and capricious. (Ref. 39 at pgs. 28 and 29) EPA acknowledges that Gharda submitted two such letters to the Agency; however, the question is whether those letters provided a legal basis for any EPA regulatory determination, *e.g.,* whether to retain tolerances for the 11 uses assessed in the PID. EPA concludes that they did not.

On their face, Gharda's letters fall far short of actually requesting voluntary cancellation of their registered uses. Gharda's first letter says that it is ''willing to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users.'' Gharda requests that any agreement with EPA to voluntarily cancel uses include several key terms, including further discussion of the geographic restrictions set forth in the PID as to the 11 crops, allowing use on crops in addition to the 11 uses in the PID, phase-out schedules that would allow some uses to continue until 2026 (5 years after the Court ordered EPA to issue a final rule revoking or modifying tolerances), additional existing stocks orders that would allow additional time for phase-out, retention of all import tolerances, etc. (Ref. 39 at Exhibit B to Gharda's objection, Letter from Gharda to EPA (May 12, 2021)) Gharda's second letter states that ''Gharda commits to voluntarily cancel all currently approved agricultural uses of chlorpyrifos other than uses for the 11 high-benefit agricultural crops in select regions that the Agency has identified [in the PID] . . . . subject to [several] conditions.'' Those conditions included allowing use on cotton in Texas (which the Agency had not determined would be safe under the limited conditions presented in the 2020 PID), existing stocks terms that allowed for sale of all finished Gharda technical product in the United States and overseas to be processed and sold until stocks were exhausted, retention of all ''import tolerances,'' and allowing food treated with chlorpyrifos to clear the channels of trade. (*Id.* at Exhibit C, Letter from Gharda to EPA (June 7, 2021)) As Gharda's objection filing indicates, there were several other emails exchanged in which terms continued to be negotiated, and Gharda continued to seek agreement on various terms prior to submission of a voluntary cancellation request. (*Id.* at Exhibits D through J)

Contrary to Gharda's assertions, a conditional proposal does not provide a sufficient basis for EPA to conclude that uses will be cancelled and exposures will be reduced. By their terms the letters simply indicate an intent to keep discussing the issue and a willingness to initiate the process to cancel uses provided other conditions can be agreed upon. The implication in Gharda's letter was that if agreement could not be reached on the other conditions, then no such voluntary cancelation request would be forthcoming. And as indicated previously, Gharda's proposal was initially contingent upon EPA allowing use on crops beyond the 11 identified in the PID, which EPA had not assessed and proposed to find safe if other conditions were met. Although Gharda's subsequent email traffic indicated a willingness to drop those additional uses, given the Agency's safety concerns with the tolerances, EPA continued to express a concern about whether an extended existing stocks period would be considered consistent with the Ninth Circuit's order.

Typically, a formal request for voluntary cancellation of a pesticide registration or registered uses would involve the submission of a letter requesting cancelation of a product or uses and would also, in the case of deletions of certain uses, need to be accompanied with applications to amend relevant labels. (See *https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use*) While Gharda's letters indicate a willingness to continue negotiations with EPA, they do not constitute an actual request to cancel uses and thus do not provide a sufficient basis for EPA to conclude that aggregate exposures to chlorpyrifos would be limited to the 11 geographically limited uses identified in the 2020 PID proposal.

It should also be noted that Gharda's voluntary cancellation request alone would not be sufficient to support a conclusion that all registered uses would be cancelled since other products are registered for those uses as well. Other registrants would have also needed to submit voluntary cancellation requests and label amendments, and as indicated previously, that has not happened.

Unlike negotiations that are typically conducted as part of registration review, this situation involved a tight deadline for a final Agency rulemaking and thus a very short period of time to resolve differences and allow EPA to develop a final rule that incorporated any such resolution. In light of the Ninth Circuit's impending deadline for issuing a final rule and the lack of a mutually agreeable resolution to the remaining issues in a timely manner, it simply was not practicable for EPA to continue negotiating these terms.

While it is understandable for Gharda to be disappointed, Gharda erroneously asserts now, based on the lack of resolution in time for the final rule to be completed by the Court's deadline, that EPA's rule is arbitrary and capricious. This simply is not true. Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question. As noted in the denial of the previous objection, EPA determined that the tolerances were not safe, based on the assessments EPA had completed at the time and aggregate exposures resulting from the uses in place at the time of the final rule.

It is worth noting that, although the Agency/registrant negotiations prior to the final rule ended without resulting in use cancellations or label amendments under FIFRA, any registrant is authorized at any time, without prior EPA consent, to take initiative and submit a request to voluntarily cancel uses on its registration or to submit an application seeking amendments to its label to restrict uses. Upon submission of such a request, EPA would consider that request and publish a notice of receipt of a voluntary cancellation request, and for situations like chlorpyrifos, take into consideration whether that request would have an impact on the Agency's ability to support a safety finding, in light of uses remaining on other registered products. For chlorpyrifos, however, no such submissions were submitted to with the Agency prior to the issuance of the final rule. While there were communications from Gharda indicating an intent to amend registrations and cancel uses, with an extended existing stocks period to allow for continued sale and distribution of their chlorpyrifos inventory, no formal steps were taken under FIFRA to put those processes in action.

c. Import Tolerances

i. Objection. Gharda, the Agricultural Retailers Association, *et al.,* and CLA/RISE argue that EPA should have retained import tolerances (*i.e.,* tolerances covering pesticide residues for commodities that are imported into the United States) for chlorpyrifos commodities. (Refs. 39, 47 and 50) These Objectors assert that because EPA's final rule noted that food exposures and non-occupational exposures do not exceed levels of concern—rather, risks are driven by exposures to chlorpyrifos in drinking water—EPA could conclude that import tolerances, which would not contribute to drinking water exposures, would be safe. The Objectors assert that there is no science-based reason to revoke tolerances as they apply to food imported with chlorpyrifos residues. CLA/RISE cites to EPA's guidance entitled, ''Pesticides; Guidance on Import Tolerances & Residue Data for Imported Food'' ((65 FR 35069, June 1, 2000) (FRL–6559–3)), and legal precedent for support for the retention of import tolerances. (Ref. 50)

ii. Denial of objection. This objection is denied because, as a matter of law, where aggregate exposures from pesticide use exceed safe levels, EPA cannot leave tolerances in place, even if those tolerances just cover residues in imported foods.

As a legal matter, tolerances established under the FFDCA apply to pesticide residues in or on food moving through interstate commerce, regardless of whether those residues came from use of a domestically registered pesticide or from application of a pesticide overseas to a food that is then imported into the United States. As a matter of law, EPA does not separately establish ''import tolerances'' that apply exclusively to imported commodities. The term ''import tolerance'' is a term of convenience that refers to tolerances for pesticide residues in an imported food where there is no corresponding U.S. registration for that pesticide on that particular commodity; however, there is no statutory or regulatory distinction between a tolerance covering pesticide residues in imported commodities and tolerances covering pesticide residues from use of a pesticide product registered in the United States. Once established, that tolerance would cover pesticide residues in that particular commodity, regardless of how residues came to be present in the food.

It is correct that imported food treated with a pesticide would only contribute to aggregate exposures through the residues that are present on the imported commodity. Imported foods do not result in additional drinking water and residential contributions to exposure because the pesticides are used overseas, not domestically. Nevertheless, the pesticide residues on the imported food must be aggregated with all the other food, drinking water, and residential exposures to that pesticide that occur in the United States, as part of the safety determination and consideration of aggregate exposures for that pesticide. If the domestic uses of that particular pesticide already exceed safe levels, EPA would not be able to approve the new import tolerance, even if the relative contributions from the imported commodities was very minor because the safety assessment of that tolerance requires a consideration of ''aggregate exposures'' from all other tolerances in effect.

For chlorpyrifos, since domestic use of chlorpyrifos in accordance with currently approved labeling results in aggregate exposures that exceed safe levels, due to drinking water concerns, all tolerances, including those covering imported commodities, are unsafe and must be revoked. Until domestic use ceases—or EPA has a reasonable basis to believe that it will cease—the risks from drinking water need to be assessed in EPA's risk assessment. Once domestic uses are cancelled and aggregate exposures are reduced below the Agency's levels of concern for safety, EPA could consider whether risks from exposures in or on imported food would be safe. Again, this is a consequence of the requirement under the FFDCA to consider aggregate exposures from all uses; when one tolerance is unsafe, all are equally unsafe until aggregate exposures have been reduced to levels that are below the Agency's level of concern.

CLA/RISE cite EPA's *Guidance on Import Tolerances* to encourage EPA to consider and approve requests to retain import tolerances. This guidance, however, does not provide a legal basis for retaining import tolerances under the current circumstances. Rather the guidance document describes how EPA may consider requests for modifying or maintaining tolerances to allow the continue import of food treated with a pesticide, where ''domestic uses are canceled . . . for any other reason (other than dietary risk)'' as long as EPA can make the required safety finding. (65 FR at 35072) For chlorpyrifos, no domestic uses have been cancelled to date, which precludes EPA from making the required safety finding.

CLA/RISE also point to the D.C. Circuit Court's decision in *National Corn Growers Ass'n* v. *EPA,* 613 F.3d 266, as instructive here. In that case, the Court ordered EPA to reinstate import tolerances for the pesticide carbofuran because the Agency had received requests for retaining those tolerances and because EPA had concluded that exposure from imported foods alone was safe. (*Id.* at pg. 275)

This present case is distinguishable in that for the carbofuran situation, the import tolerances at issue had no domestic registrations for the commodities covered by those tolerances. This fact was specifically identified by footnotes to the tolerances for those commodities. For chlorpyrifos, there are no specifically designated import tolerances, although the Agency notes that there is a tolerance for chlorpyrifos on banana, for which there are no U.S. registrations. To the extent there were requests for retention of import tolerances prior to the issuance of the final rule, such requests were to leave *all* current tolerances in place, in order to accommodate chlorpyrifos use in other countries on any of the commodities for which tolerances were set. Because those uses would overlap with domestic uses, the Agency could not exclude other non-food exposures associated with those uses until those domestic uses were cancelled.

EPA recognizes that the Republic of Colombia, in its objections, requested the retention of the banana tolerance; however, EPA denies that request since EPA is unable, at this time with the existing domestic uses still being registered, to make a safety finding for the banana tolerance. While after *National Corn Growers Ass'n* was decided, the import tolerances were reinstated for commodities that had no domestic uses, that reinstatement occurred after the other domestic uses that had resulted in unsafe aggregate exposure levels had been cancelled, thus obviating the need to tackle a potential aggregate exposure issue involving residues from both domestic and imported food. (*See* Carbofuran; Product Cancellation Order ((74 FR 11551, March 18, 2009) (FRL–8403–6)) (announcing FMC Corporation's voluntary cancelation of its carbofuran registrations for all but six crops); Carbofuran; Reinstatement of Specific Tolerances and Removal of Expired Tolerances ((80 FR 21187, Apr. 17, 2015) (FRL–9925–70)) (EPA reinstatement of import tolerances for carbofuran for banana; coffee, bean, green; rice, grain; and sugarcane, cane))

Here, all registrations of chlorpyrifos remain intact and uses in accordance with the labels are still contributing to drinking water concentrations that result in aggregate exposures exceeding safe levels. Therefore, for chlorpyrifos, the Agency cannot make the safety finding for leaving tolerances in place to accommodate imports until sufficient uses are cancelled that reduce aggregate exposures to acceptable levels.

2. Retention of the 10X Food Quality Protection Act (FQPA) Safety Factor

a. Objection

Several Objectors (Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.,* Minor Crop Farmer Alliance, California Citrus Quality Council, and Coalition of OP Registrants) claim that EPA acted unlawfully in retaining the 10X FQPA safety factor based on the epidemiology data. (Refs. 37, 39, 47, 49, 52 and 53) Objectors assert that the epidemiological data was invalid and unreliable and should not been considered nor should it have been relied upon to introduce ''scientific uncertainties'' into the Agency's assessment of chlorpyrifos. In light of the alleged defects with the epidemiological studies, the Objectors assert EPA had no basis to retain the 10X FQPA safety factor, given the balance of toxicity data on chlorpyrifos.

b. Denial of Objection

As an initial matter, EPA points out that the Objectors have failed to identify an issue that supports a retention of the chlorpyrifos tolerances or changing the EPA's final rule, even if what the objectors assert is correct. Even if the Agency agreed that the epidemiological data should not have been considered by the Agency or that available data support a reduction of the FQPA safety factor to 1X, as indicated in the 2020 PID, EPA would not have been able to determine that chlorpyrifos tolerances were safe without some uses being cancelled and other uses being modified.

The 2020 PID provided estimates of potential risks based on retention of the 10X FQPA safety factor and on a reduced FQPA safety factor of 1X. The previous sub-unit discussed the need to cancel all uses besides the 11 uses identified for retention and the need for label amendments to geographically restrict applications and to reduce maximum application rates, if EPA retained the 10X FQPA safety factor. For the 1X scenario, EPA concluded that ''the majority of labeled chlorpyrifos uses result in drinking water concentrations below the DWLOC.'' (Ref. 31 at pg. 41) The ''majority,'' however, is not all, and thus, EPA noted that three uses still resulted in EDWCs above the DWLOC (peppers, trash storage bins, and wood treatment), and six uses would need to be restricted to certain states and application rates adjusted consistent with assessed usage data in order to ensure that concentrations of chlorpyrifos in drinking water did not exceed safe levels. (*Id.*) In other words, uses as registered at the time EPA issued the 2020 PID—and at the time of the final rule—still resulted in aggregate exposures that were not safe under a scenario in which EPA applied a 1X FQPA safety factor. Since some uses would result in exposures of chlorpyrifos that exceeded the Agency's safe levels, EPA would not have been able to determine that the tolerances were safe, even with the FQPA safety factor being reduced to 1X. If EPA had had a reasonable basis to assume that such uses resulting in exceedances would cease, EPA may have been able to aggregate only those uses that were expected to continue. As there was no such basis at the time the final rule was issued—and, indeed at this time, there is still no such basis, EPA was required to look at aggregate exposures from all currently registered uses, as those exposures were anticipated to continue. Therefore, since the Objectors have failed to state a claim upon which the relief they seek (leaving the tolerances in place) can be granted, this objection is denied.

Notwithstanding this denial, EPA disagrees with the assertions made by Objectors with regard to the Agency's decisions to rely on the epidemiological data and retain the 10X FQPA safety factor as discussed in this unit. For ease of addressing this claim, EPA is breaking this objection into two subissues: (1) Whether it was reasonable for EPA to use the epidemiology data as part of its weight-of-the evidence analysis for assessing the potential pre- and postnatal toxicity relating to neurodevelopmental effects and (2) Whether EPA had ''reliable data'' to support a different margin of safety to protect infants and children based on the available record.

c. Background

Before responding to these objections, it is helpful to provide some background on the FQPA safety factor EPA used in the final rule to clarify the statutory standard, and to provide some background on EPA's FQPA safety factor policy.

i. Final rule. In the final rule, EPA retained the 10X FQPA safety factor due to uncertainty around the levels at which potential neurodevelopmental outcomes may occur in infants and children exposed to chlorpyrifos. The decision was based on the Agency's weight-of-evidence (WOE) analysis, which took into consideration the totality of available information on the toxicity of chlorpyrifos and the potential for neurodevelopmental outcomes associated with chlorpyrifos exposure. That information included laboratory animal studies, epidemiological studies, and available mechanistic data, as described in Unit III.A.1.b. of this document.

In essence, the WOE analysis concluded that there was qualitative evidence of a potential effect on the developing brain; however, due to insufficient clarity on the levels at which these neurodevelopmental outcomes occur relative to levels at which cholinesterase inhibition occurs, the science addressing neurodevelopmental outcomes remained unresolved in a manner sufficient to quantify these effects. Due to the remaining uncertainties, EPA was unable to conclude at the time of the final rule that a different safety factor would be sufficient to protect infants and children from potential pre- and postnatal toxicity related to neurodevelopmental effects. (Ref. 1 at pg. 48327)

ii. FFDCA section 408(b)(2)(C) and EPA's FQPA safety factor policy. Through the FQPA, Congress significantly amended the FFDCA, to establish a new stringent health-based standard (''reasonable certainty of no harm'') and add a new provision providing heightened protections for infants and children. (21 U.S.C. 346a(b)(2)(C)) That provision directs EPA to consider available data on, among other things, the ''special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals.'' (21 U.S.C. 346a(b)(2)(C)(i)(II)) Moreover, EPA is required to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide. (21 U.S.C. 346a(b)(2)(C)(ii)(I)) When making that safety determination for infants and children, EPA is required to apply, in the case of threshold effects, an additional tenfold margin of safety ''to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)) This provision permits a different margin of safety ''only if, on the basis of reliable data, such margin will be safe for infants and children.'' (*Id.*) Thus, EPA interprets this provision as establishing a presumption in favor of applying the default 10X safety factor, which can be departed from only if reliable evidence show that a different factor would be protective of infants and children.

In 2002, EPA issued guidance on how OPP intends to make determinations regarding the FQPA safety factor when developing risk assessments for pesticides (''FQPA Policy Paper'') (Ref. 9) While not binding, that document provides helpful background and clarification on the process for determining the appropriate FQPA safety factor. Ultimately, the decision to retain the default 10X FQPA safety factor or use a different factor depends on level of confidence in the risk assessment and the degree of concern for any susceptibility or residual uncertainties in the toxicity and exposure databases. (*Id.* at 50) A lower level of confidence and a higher degree of concern will support retention of the default 10X FQPA safety factor. Because the chlorpyrifos 10X FQPA safety factor decision relates primarily to the concern for potential pre- and postnatal toxicity, this discussion focuses on those aspects of the guidance, although it also covers concerns related to the completeness of the toxicity and exposure databases.

Before making any determination on the FQPA safety factor, OPP will review all available and relevant toxicological data and determine whether the chemical has any potential to cause adverse effects in infants and children, *i.e.,* potential pre- and postnatal toxicity or special susceptibility. (*Id.* at pg. 8) The FQPA Policy Paper states, ''In general terms, there is increased susceptibility or sensitivity when data demonstrate unique effects (*e.g.,* a different pattern of effects of concern) or adverse effects in the young that are of a type similar to those seen in adults, but occur either at doses lower than those causing effects in adults, occur more quickly, or occur with greater severity or duration than in adults.'' (*Id.* at pg. 30) If the toxicity data indicate no concern for pre- and postnatal toxicity or special susceptibility, then the presumption for the 10X factor should be treated as obviated with respect to the potential for pre- and postnatal toxicity. In contrast, if the toxicity data indicate pre- and postnatal toxicity, then OPP will assess the level or degree of concern for the potential for those effects, taking into consideration the degree to which the traditional uncertainty factors provide protection for infants and children. (*Id.* at pg. 29)

EPA typically uses a WOE approach for making judgments about the degree of concern for potential pre- and postnatal toxicity, in the context of the entire database, taking into consideration the quality and adequacy of the data, and the consistency of responses induced by the chemical across different studies. (*Id.* at pg. 30) The FQPA Policy Paper notes that this integrative approach is important because ''for example, positive animal findings may be diminished by other key data (*e.g.,* toxicokinetic or mechanism of toxicity information), or likewise, a weak association found in epidemiological studies may be bolstered by experimental findings in animal studies.'' (*Id.* at pg. 31) Moreover, it is important to consider other factors concerning the biological responses observed in the young relative to the adult effects, such as ''progression, severity, recovery time or persistence, and dose-response . . . . For example, there would be greater concern for effects that were irreversible and of a greater potential consequence to the young compared to observed effects in adults that are of a transient and minimal nature, even when they occur at the same dose.'' (*Id.* at pg. 33) The FQPA Policy Paper notes that ''[w]hen sufficient human data are available to judge that an adverse developmental outcome is related to exposure, the degree of concern increases,'' although ''sufficient human evidence is very difficult to obtain.'' (*Id.*) Another factor influencing the degree of concern is the relationship between dose and response. Where the dose-response relationship is well-characterized, there is a lower degree of concern, whereas in cases where the opposite is the case, the degree of concern may increase. (*Id.* at pg. 34) Finally, mechanistic data can be helpful in evaluating the degree of concern. (*Id.*)

In some cases, concerns regarding pre- and postnatal toxicity can be addressed by calculating a protective reference dose or margin of exposure based on relevant endpoints in the offspring or through the use of traditional uncertainty factors. (*Id.* at pg. 35) OPP risk assessors will consider whether the developmental and offspring effects are well-characterized in the toxicity database and if other appropriate uncertainty factors are already applied for calculating a protective RfD; if so, then ''there would normally be no need for an additional FQPA safety factor to address potential pre- and postnatal toxicity.'' (*Id.*) However, in some instances, ''data may raise uncertainties or a high concern for infants or children which cannot be addressed in the derivation of an RfD or MOE''. (*Id.* at pg. iv) If so, ''those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor . . . .'' (*Id.* at pg. 35)

If there is a high level of confidence that the combination of the hazard and exposure assessments is adequately protective of infants and children, then the presumption in favor of the additional 10X default FQPA safety factor would be obviated and the risk assessor should recommend that a different FQPA safety factor be applied . . . . Conversely, if the risk assessor finds evidence of pre- or postnatal toxicity or problems with the completeness of the toxicity or exposure databases and these uncertainties have not been adequately dealt with in the toxicity and/or exposure assessments (through use of traditional uncertainty factors or conservative exposure assumptions), then the default additional 10X safety factor should be retained.'' (*Id.* at pgs. 51 and 52)

If the degree of concern for the potential pre- or postnatal uncertainty is high, the default 10X FQPA safety factor will typically be retained, unless there is ''reliable data'' to account for and describe the level of uncertainty regarding the potential for pre- or postnatal toxicity. (*Id.* at pg. 30) ''If the uncertainty can be addressed by reliable data, the risk assessor should recommend use of a different FQPA safety factor . . . to protect the safety of infants and children.'' (*Id.*) In the FQPA Policy Paper, EPA explains that ''reliable data'' must ''be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action.'' (*Id.* at pg. A–5) As part of determining whether a different margin of safety would be safe, the paper indicates that the risk assessment should focus on whether the ''combination of data and reasonable scientific judgment,'' taking into account relevant information and data, would lead to a conclusion that the ''hazard or exposure . . . will not be underestimated.'' (*Id.* at pg. A–8)

d. Reliance on Epidemiological Data

i. Objection subissue. The Objectors assert that EPA's retention of the 10X FQPA safety factor to account for scientific uncertainties in the epidemiological data was unlawful. Citing the lack of underlying data and EPA's inability to reproduce or verify the conclusions of the studies, the Objectors claim that the epidemiological data are incomplete, invalid, and unreliable. As a result, Objectors argue that the ''scientific uncertainties'' in those epidemiological data cannot be used to justify retention of the 10X FQPA safety factor. Gharda also asserts that the FFDCA does not allow application of the 10X FQPA safety factor based on unreliable epidemiological studies, ''particularly where a 10X safety factor results in the elimination of many important crop uses.'' (Ref. 39 at pg. 48) In essence, the Objectors are arguing that EPA acted arbitrarily and capriciously in considering the epidemiological studies in its WOE analysis.

ii. Denial of objection subissue. To the extent the Objectors are arguing that EPA cannot, as a matter of law, rely on epidemiological studies where the underlying raw data is unavailable or EPA cannot independently verify or reproduce the studies' conclusions, that objection is denied. There is no requirement for epidemiological studies to be supported by the raw data before the Agency can rely on them. On the contrary, a rule promulgated in January 2021, which would have required EPA to give heightened consideration to studies for which underlying data were publicly available, was judicially vacated one month after its issuance. (*EDF* v. *EPA,* 515 F. Supp. 3d 1135 (D. Mt. Jan. 27, 2021); 86 FR 29515, June 2, 2021 (FRL–10024–32–ORD) (removal of regulatory provisions from Code of Federal Regulations))

Significantly, the idea that these epidemiological studies are unreliable without the raw data was soundly rejected by the Ninth Circuit as applied to the chlorpyrifos studies. In a departure from its previous statements about the epidemiological studies, in the 2019 Denial Order and in the attendant litigation, EPA argued that the epidemiological data was invalid, incomplete, and unreliable due to the lack of underlying data and thus should not be considered by the Agency in assessing chlorpyrifos. The Ninth Circuit rejected EPA's reasoning as follows:

''[W]hile the EPA might reasonably conclude that divergences from international protocols and lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCA requires the EPA to consider the ''information'' that is ''available'' and to make a safety determination based on that information. In this case, live animal studies showing sex-linked, neurotoxic harms from *in utero* chlorpyrifos exposure are available—even if such studies are supposedly not perfectly aligned with (unspecified) international standards. And peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available—even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: Speculation. Such speculation ''runs counter to the evidence before the agency,'' so it cannot form the basis for denying the 2007 Petition.'' (*Id.* pgs. 699 and 700 (citations excluded))

Moreover, in its recent framework document concerning the use of epidemiology studies, EPA recognizes that it is quite common and understood that certain information may be unavailable in epidemiology studies or suffer some limitations that may impede their use in quantitative risk assessment. (Ref. 19 at pgs. 10 and 16) That does not mean EPA cannot rely on these studies or use them to inform risk assessment. Often, such studies can ''provide insight into the effects cause by actual chemical exposures in humans and thus can contribute to problem formulation and hazard/risk characterization.'' In addition, epidemiological data ''can guide additional analyses or data generations . . . , identify potentially susceptible populations, identify new health effects, or confirm the existing toxicological observations.'' (*Id.* at pg. 4) Epidemiology studies ''have the potential to help inform multiple components of the risk assessment'', *e.g.,* qualitative comparisons between outcomes in epidemiologic studies to those in *in vitro* and animal studies to evaluate the human relevance of animal findings or assessing the biological plausibility of epidemiologic outcomes. (*Id.* at pg. 16)

Turning to the epidemiology studies themselves, there is extensive evidence in the record to support EPA's scientific decision to include those studies as part of its WOE analysis. Until its statements in the 2019 Denial Order and attendant litigation, which was rejected by the Ninth Circuit, EPA had concluded that the three prospective cohort studies (CCCEH, Mt. Sinai, and CHAMACOS, as described in Unit III.A.1.b.ii. of this document) were ''strong studies which support a conclusion that chlorpyrifos likely played a role in these [neurodevelopmental] outcomes.'' (Ref. 20 at pg. 33) Having considered the strengths and limitations of the studies, EPA concluded that the observed positive associations between *in utero* chlorpyrifos exposures and adverse neurodevelopmental effects were unlikely the result of errors in the design of the study. (*Id.*) While EPA did identify limitations in the studies, overall, EPA found the studies to be sound and worthy of consideration as part of a WOE analysis of available data concerning the potential pre- and postnatal toxicity of chlorpyrifos.

Under EPA's Epidemiologic Framework, ''human health characterizations involve the consideration of all available and relevant data, including but not limited to human studies/epidemiology . . . .'' (Ref. 19 at pg. 12) In evaluating epidemiology studies for use in pesticide risk assessment, EPA considers the ''quality of epidemiologic research, sufficiency of documentation of the study (study design and results), and relevance to risk assessment.'' (*Id.* at pg. 21) EPA will take into consideration various aspects of the study, including, but not limited to, adequacy of the exposure assessment, sample population and statistical power of the study, reliability of identifying affected individuals, adequacy of method for identifying confounding variables, characterization of systematic biases, among others. (*Id.* at pgs. 22 through 36)

For the epidemiology studies incorporated into EPA's WOE analysis, EPA fully evaluated and characterized the strengths and limitations of those studies consistent with its Framework Document. (Ref. 20 at pgs. 32–49) Despite limitations in the studies, EPA found ''considerable strengths in study design, conduct, and analyses demonstrated'' in the three cohort studies, including using prospective birth cohorts as a strong study design; using several methods for measuring pesticide exposure; using well-established, validated analytical tools for ascertaining developmental outcomes; measuring, analyzing, and adjusting for potentially confounding variables. Balancing those strengths against the limitations (one-time measure of exposure to assess prenatal exposure, lack of assessment of influence of mixtures, and small sample size, as well as lack of understanding of a critical window of exposure), EPA concluded that ''these data present an informative body of evidence with some notable consistencies across studies.'' (*Id.* at pg. 34)

Therefore, there is no merit to the Objectors' claim that it was unlawful for EPA to rely on the epidemiological studies in its assessment of chlorpyrifos. There is no requirement for the underlying data to be made available before EPA can rely on these studies, and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children.

e. Whether There Are ''reliable data'' Supporting a Different FQPA Safety Factor

i. Objection subissue. By objecting to the retention of the 10X FQPA safety factor, the Objectors appear to assert that EPA had ''reliable data'' to support a different margin of safety than the default 10X FQPA safety factor. However, most Objectors (Sugarbeet Associations, Gharda, Minor Crop Farmer Alliance) argue that because the epidemiological data is allegedly unreliable, the data should not be utilized. (Refs. 37, 39, and 49) Thus, removing the epidemiological data from consideration erases ''uncertainties'' and removes the need to retain the default safety factor. As EPA has demonstrated, the epidemiological studies have been evaluated and have been determined to support the conclusion of a potential effect on the developing brain associated with chlorpyrifos exposure.

The Coalition of OP Registrants assert that the toxicological profile of chlorpyrifos and other OPs indicates that the acetylcholinesterase inhibition endpoint is protective of the neurodevelopmental effects and thus the 10X FQPA safety factor was unnecessary to protect infants and children. (Ref. 53) Moreover, although noting that work concerning the New Approach Methodologies (NAMs) is ongoing, the Coalition of OP Registrants and the Agricultural Retailers Association, *et al.,* assert that NAMs would also support the position that the acetylcholinesterase inhibition endpoint would be protective of adverse neurodevelopmental effects. (Refs. 47 and 53)

ii. Denial of objection subissue. As noted previously, the FQPA amended the FFDCA to include an additional tenfold margin of safety to ensure the protection of infants and children. EPA may use a different margin of safety ''only if, on the basis of reliable data, such margin will be safe for infants and children.'' (21 U.S.C. 346a(b)(2)(C)) Thus, the presumption is to retain the 10X FQPA safety factor, unless there are reliable data to support a conclusion that a different safety factor will protect infants and children, taking into consideration potential pre- and postnatal toxicity and any residual uncertainties in the toxicity and exposure databases. Rather than requiring EPA to justify why the default factor is retained, the statute puts the burden on EPA to ensure that there are ''reliable data'' supporting a conclusion that a different safety margin would be protective for infants and children. Contrary to Gharda's implication, the FFDCA provides no flexibility for EPA to consider impacts on registrants or users of a pesticide when determining whether the available data is sufficiently reliable; this determination, much like the ''reasonable certainty of no harm'' standard is a purely risk-only standard, intended to ensure protection of infants and children from the harmful impacts of a pesticide.

As discussed in the FQPA Policy Paper, where there is a high degree of concern for potential pre- and postnatal toxicity, where data raise uncertainties or a high concern for infants or children that cannot be addressed through traditional uncertainty factors or other tools, those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor. (Ref. 9 at pg. 35) If there are ''reliable data'' that can account for the uncertainty regarding the potential for pre- or postnatal toxicity, a different FQPA safety factor may be appropriate. (*Id.* at pg. 30) As noted previously, ''reliable data'' must ''be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action'' and would lead to a conclusion that the ''hazard or exposure . . . will not be underestimated.'' (*Id.* at pgs. A–5 and A–8)

As noted previously and in the final rule, acetylcholinesterase inhibition remains the most robust quantitative dose-response data in the chlorpyrifos toxicity database and thus, has been and continues to be the critical effect for quantitative risk assessment. Based on its historic experience and confirmation from the 2008 and 2012 SAPs, EPA used acetylcholinesterase inhibition as the endpoint for assessing chlorpyrifos risks. Despite the robustness of that dataset, the Agency's WOE analysis indicates that there is qualitative evidence of an association with potential effects on the developing brain and chlorpyrifos exposure. As EPA noted in the final rule and in the 2020 PID, despite several years of study, the science addressing neurodevelopmental effects remained unresolved. In the face of that uncertainty, and given the potential concerns for neurodevelopmental effects in infants and children, the Agency could not conclude that a different margin of safety would be safe to infants and children. The data considered at the time of the final rule did not resolve the uncertainty about the levels at which these effects may occur.

The purpose of the FQPA safety factor is to ensure the protection of infants and children against special susceptibilities identified in the toxicological database, including the potential for neurodevelopmental effects and effects occurring *in utero.* While the Agency's extensive database on the impacts of chlorpyrifos on acetylcholinesterase is well-established, the additional data—including animal studies, mechanistic studies, as well as epidemiological studies—concerning the special susceptibility of infants and children and the potential for neurodevelopmental effects raised additional questions, and residual uncertainties remain about the levels at which those effects may occur. Those uncertainties could not be ignored. In the face of unresolved uncertainties, EPA cannot determine that a different safety factor would ensure the safety of infants and children with regard to these effects. At the time of the final rule, EPA did not have sufficient ''reliable data'' to identify a different safety factor that would assure protection of infants and children.

At the time of the final rule, EPA acknowledged that ongoing work to develop NAMs may inform the assessment of the developmental neurotoxicity potential for chemicals, including chlorpyrifos and other OPs. EPA noted that it had convened a FIFRA SAP in September 2020 regarding the use of NAMs, and the SAP released its report and recommendations on EPA's proposed use of the NAMs data in December 2020. (Refs. 23 and 24) In the final rule, EPA stated that the advice of the SAP was being taken into consideration and thus ''analysis and implementation of NAMs for risk assessment of chlorpyrifos is in progress and was unable to be completed in time for use in this rulemaking.'' (Ref. 1 at pg. 48325) For purposes of the final rule then, EPA did not consider the NAMs data among the information available to inform its decision on the safety of chlorpyrifos.

As noted previously, the FFDCA permits the use of a different safety factor only if EPA has ''reliable data'' to support a determination that a different factor would be safe for infants and children. (21 U.S.C. 346a(b)(2)(C)) At the time of the final rule, under pressure to finalize a rule by a tight court-ordered deadline from a court that found EPA's delays to be ''egregious'' and a ''total abdication'' of its statutory duty, EPA relied heavily on data already reviewed. EPA did not conduct any new risk assessments for chlorpyrifos or incorporate any new data after the Court's decision was issued.

Courts have recognized that court-imposed deadlines can become a ''substantive constraint on what an agency can reasonably do.'' (*San Luis & Delta-Mendota Water Authority* v. *Jewell,* 747 F.3d 581, 606 (9th Cir. 2014); *see also Am. Iron and Steel Inst.* v. *EPA,* 115 F.3d 979, 1006–07 (D.C. Cir. 1997) (recognizing that EPA was not required to stop process due to new evidence; ''mentioning the new evidence'' in the guidance and subsequently announcing use of that new evidence satisfied the requirement to deal with the new evidence ''in some reasonable fashion'')) In this case, EPA did recognize the NAMs data and its relevance, but because the Agency's path for incorporating NAMs into risk assessments was not finalized by the Court's deadline, EPA did not consider the NAMs data in the context of chlorpyrifos nor incorporate that data into any of its risk assessments or risk management decisions.

Although the Objectors suggest that the NAMs data may support the conclusion that the AChE endpoint is protective of the potential for neurodevelopmental effects in infants and children and thus obviate the need to retain the 10X FQPA safety factor, at this time, such conclusions are merely speculative. EPA's work on responding to the SAP report and developing a path forward for incorporation of the NAMs data into risk assessment is ongoing; EPA has not yet finalized its approach. When EPA's analysis is complete, EPA will proceed, as appropriate, with its use of the NAMs data in accordance with that evaluation.

f. Conclusion

In summary, EPA's inclusion of the epidemiological studies in its WOE was reasonable and consistent with sound science and its FQPA Policy Paper and Epidemiological Framework. Moreover, given the uncertainties surrounding the potential for neurodevelopmental effects, EPA's retention of the default 10X FQPA safety factor was consistent with the standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children. In any event, as EPA explained at the beginning of this section addressing the objection concerning the retention of the 10X FQPA safety factor, the question of what FQPA safety factor to apply is ultimately not outcome determinative in light of aggregate chlorpyrifos exposures resulting from registered uses. Even if EPA were to reduce the FQPA safety factor to 1X, the currently registered uses still result in aggregate risks of concern, and thus would not change the Agency's determination that the tolerances were unsafe and needed to be revoked. Therefore, this objection is denied.

3. Objections Related to EPA's Assessment of Drinking Water Exposures

The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association, *et al.,* submitted objections concerning EPA's assessment of drinking water exposures. (Refs. 37, 39, and 47) Essentially, there were two objections related to drinking water: (1) Whether EPA had a rational basis for relying on the April 14, 2016, Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2016 DWA) (Ref. 29) in the final rule instead of the September 15, 2020 Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2020 DWA) (Ref. 30) and (2) whether it was reasonable for EPA to assess exposures to chlorpyrifos-oxon, a metabolite of chlorpyrifos that forms in drinking water, in its drinking water assessment. Both of these objections are denied for the reasons discussed in the following unit.

a. Reliance on 2016 DWA

i. Objection. For the objection concerning reliance on the 2016 DWA, the Objectors claim that because EPA had conducted a more updated and refined drinking water assessment in 2020, the Agency could no longer rely on the 2016 DWA, which the Objectors allege no longer reflected the ''best available science.'' (Ref. 37 at pg. 10) The Objectors identify no substantive problems with the analysis of the 2016 DWA itself but believe that it fails solely because it did not incorporate the following refinements that were used in the 2020 DWA: (a) New surface water modeling scenarios, (b) Presentation of the entire distribution of community water systems percent cropped area (PCA) adjustment factors and integration of state-level crop-treated data using percent crop treated (PCT) factors, and (c) Quantitative use of surface water monitoring data. (Ref. 47 at pg. 7) Gharda further claims that EPA could not rely on the 2016 DWA because EPA has failed to take into consideration comments submitted in response to the 2016 DWA. (Ref. 39 at pgs. 31 and 32) Gharda cites Dow AgroSciences LLC's Comments on the 2016 Notice of Data Availability, Revised Human Health Risk assessment and Refined Drinking Water Assessment for Chlorpyrifos and Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (Ref. 39). Again, Gharda points to no specific deficiencies about the 2016 DWA identified in the Dow comments on the 2016 DWA and Dow Response to Objections; rather, Gharda simply summarizes the Dow submissions as commenting that the 2016 DWA is ''an overly conservative, screening-level estimate that far over-estimates real world exposures and ignores science-based refinements submitted by'' Dow (now Corteva) and asserting that the 2016 DWA was ''incomplete and unrefined.'' (*Id.* at pgs. 31 and 32) In addition, Gharda states that there were ''significant limitations'' in the 2016 DWA, although those limitations seem, again, tied to the absence of the refinements in the 2020 DWA. (*Id.* at pg. 32)

ii. Background. As described in Unit II.B.1.c.ii.(d), EPA takes a tiered approach to assessing drinking water. Lower tiered assessments are more conservative based on the defaults or upper-bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations. (Ref. 13)

Over the years, EPA has conducted several drinking water assessments for chlorpyrifos and refined those assessments as new information and tools became available. In 2011, EPA completed a preliminary DWA. (Ref. 26) That assessment recommended use of surface water estimated drinking water concentrations (EDWCs) derived from modeling and concluded that a range of agricultural uses could lead to high levels of chlorpyrifos in surface water that could potentially be used by community water systems to supply drinking water. That assessment discussed the effects of drinking water treatment on chlorpyrifos and concluded that during the chlorination disinfection processes, chlorpyrifos can be readily converted to chlorpyrifos-oxon. Therefore, chlorpyrifos and its oxon were considered residues of concern in the preliminary assessment.

Taking into consideration public comments on the 2011 preliminary DWA, EPA updated that assessment in a 2014 DWA to include additional analyses focused on clarifying labeled uses, evaluating volatility and spray drift, revising aquatic modeling input values, comparing aquatic modeling and monitoring data, summarizing effects of drinking water treatment, updating model simulations, and proposing a strategy to refine the assessment using community water system-specific drinking water intake percent cropped area (PCA) adjustment factors. (Ref. 27) This 2014 DWA confirmed the findings of the 2011 preliminary DWA, concluding that there were a number of uses that may result in exposures to chlorpyrifos-oxon in drinking water at unsafe levels, although the 2014 DWA also noted that additional analyses would be needed in order to finish identifying specific geographical areas where exposures may be of concern. (*Id.* at pgs. 8 and 9)

In 2016, EPA conducted a refined drinking water assessment that estimated drinking water concentrations based on modeling of all registered uses, as well as all available surface water monitoring data. That assessment considered several refinement strategies in a two-step process to derive exposure estimates for chlorpyrifos and chlorpyrifos oxon across the country. The first step was an assessment of potential exposure based on the current maximum label rates at a national level. This indicated that the EDWCs could be above the DWLOC. The second step considered model estimates, as well as measured concentrations, at a more localized level and more typical use scenarios. This built on the approach presented in the 2014 DWA for deriving more regionally specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos-oxon. The results of this second-step analysis also concluded that there were high levels of chlorpyrifos and chlorpyrifos-oxon in drinking water. (Ref. 29)

Following the completion of the 2016 DWA, EPA developed refinement strategies to examine those estimated regional/watershed drinking water concentrations to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At that time, EPA was anticipating that a more refined drinking water assessment might allow EPA to better identify where at-risk watersheds are located throughout the country for the purpose of supporting more targeted risk mitigation through the registration review process. The refinements better account for variability in the use area treated within a watershed that may contribute to a drinking water intake (referred to as PCA or percent use area when considering non-agricultural uses) and incorporate data on the amount of a pesticide that is historically applied based on user surveys within a watershed for agricultural uses (referred to as PCT). These refinement approaches underwent external peer review and were issued for public comment in January 2020. (Ref. 54) In addition, EPA used average application rates, average numbers of annual applications for specific crops, and estimated typical application timing at the state-level based on pesticide usage data derived from Kynetec, a statistically reliable private market survey database; publicly available survey data collected by the USDA; and state-specific scientific literature from crop extension experts.

The recently developed refinements were integrated into the 2020 DWA. (Ref. 30) Because of how high the estimated drinking water concentrations were in the 2016 DWA, it was not expected that the exposures for all uses could be refined to a safe level; therefore, the Agency decided to focus its refinements for the 2020 updated drinking water assessment on a subset of uses in specific regions of the United States. The purpose of the focus on this subset of uses was to determine whether, if these were the only uses permitted on the label, the resulting estimated drinking water concentrations would be below the DWLOC. The subset of uses assessed were selected because they were identified as critical uses by a registrant or high-benefit uses to growers by EPA. That subset of currently registered uses included alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat, confined to specific areas of the country. (*Id.* at Appendix A) The updated assessment applied the new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state level PCT data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information. The results of this analysis indicated that the EDWCs from this subset of uses limited to certain regions would be below the DWLOC. (*Id.* at pgs. 16 and 17)

It is important to emphasize that the 2020 DWA ''focuse[d] on a subset of currently registered chlorpyrifos uses. . . . The exposure estimates reported in [the 2020 DWA] and associated conclusions drawn are solely for those uses. . . . Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).'' (*Id.* at cover memo) In other words, EPA recognized that the subset of assessed uses was only one combination of possible subsets that might be safe. Recognizing that in response to the Agency's proposal in the 2020 PID, registrants or growers could have advocated for a different subset of uses or to add different uses or geographic regions, EPA noted that additional analyses would need to be completed to determine the contributions to drinking water in those impacted regions and whether such uses would be safe.

iii. Denial of objection. The Objectors' primary argument is that EPA could not rely on the 2016 DWA (Ref. 29) because the subsequently developed refinements used in the 2020 DWA (Ref. 30) meant that the 2016 DWA, having been conducted without those refinements, did not represent the best available science. As EPA acknowledges in the background discussion, the 2020 DWA incorporated several refinements, including updated surface water scenarios, new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state-level PCT data, and a quantitative use of surface water monitoring data. (Ref. 30) The 2020 DWA represents one of, if not, the highest tiered, most refined drinking water assessment EPA has conducted to date. Nevertheless, the availability of the more refined 2020 DWA does not make it unlawful for EPA to rely on the 2016 DWA in the final rule, particularly where the 2020 DWA was confined to a scenario that did not exist at the time of the final rule.

In denying this objection, EPA finds the scope of the 2020 DWA to be determinative. As noted previously and in the final rule, the 2020 DWA evaluated only a subset of the currently registered uses. Specifically, the 2020 DWA evaluated only 11 of the over 50 agricultural use sites and non-agricultural use sites currently registered for chlorpyrifos. Moreover, those 11 uses were assessed only in specific geographic regions (not all geographic regions in which the pesticide is currently being used) based on typical use rates rather than maximum labeled application rates. The underlying presumption of the 2020 DWA was that chlorpyrifos would not be labeled for any other uses, including non-food uses, besides that limited subset. As such, it presented a highly refined evaluation of a particular subset of predicted uses only; it was not a complete and full assessment of the approved uses of chlorpyrifos and thus did not provide an accurate picture of aggregate exposures from all currently registered use patterns. Although the Sugarbeet Associations assert that EPA could have relied on the 2020 DWA since it tracks the proposal in the 2020 PID, that argument fails for all the same reasons why EPA could not rely on the conclusions in the 2020 PID to retain the 11 uses, as explained in Unit VIII.C.1. Since the FFDCA, in requiring consideration of aggregate exposure, required EPA to evaluate food, drinking water, and residential exposures from all registered uses, EPA could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations, unless all other uses were canceled. Doing so would have presented an incomplete picture of potential drinking water contributions from currently registered uses. Thus, the 2016 DWA, which is the most recent EPA assessment of contributions to drinking water from all registered uses of chlorpyrifos—and not the 2020 DWA—represented the most recent, most robust ''best available science'' for use by the Agency for the uses on current labels.

EPA also disagrees with the Objectors' implication that the mere existence of new refinement methodologies somehow impacts the reliability of the 2016 DWA. At the time the 2016 DWA was issued, it represented the most refined drinking water assessment EPA's OPP had conducted. It applied all available refinement techniques available at that time, including, as discussed previously, using modeled estimates and measured concentrations to drill down to drinking water contributions on a regionally specific level. The subsequent development of additional tools to refine drinking water assessments that show risks of concern does not render the 2016 DWA overly conservative or otherwise scientifically invalid and unreliable. The Agency simply has additional tools and methods that can be applied to refine drinking water assessments where appropriate. The Agency's Drinking Water Framework notes that moving to the higher tiers that were used in the 2020 DWA ''requires a large amount of resources and adds a great amount of complexity to the assessment.'' Therefore, rather than moving to the higher tiers automatically, ''advancement to Tier 4 should be done in consultation with the interdivisional chemical team.'' (Ref. 13 at pg. 51)

The question then is whether it was reasonable for EPA not to apply the 2020 refinements to all the uses assessed in the 2016 DWA; EPA concludes that it was. Following the issuance of the 2016 DWA, in which EPA identified EDWCs from registered chlorpyrifos uses that exceeded safe levels, EPA met with representatives of Corteva, a chlorpyrifos registrant, about whether additional information about critical uses to growers could be used to refine the 2016 DWA as part of the ongoing work in registration review to assess uses of chlorpyrifos. (Ref. 51) Given the large number of uses and high estimates across various vulnerable watersheds throughout the country, EPA focused its resources to apply the refinement strategies on assessing whether a subset of uses that were identified by Corteva as critical and considered by EPA to present high benefits to chlorpyrifos users could result in EDWCs lower than the DWLOC.

Once EPA determined the appropriate subset of uses to evaluate, EPA dedicated extensive resources to apply the newly developed methodologies, including gathering PCT data from states in which the specific crops to be retained were grown, to those uses to determine if the resulting uses would result in estimated drinking water concentrations of chlorpyrifos below the Agency's relevant level of concern, *i.e.,* the DWLOC. This approach is consistent with the Agency's standard practice during registration review; for pesticides that pose risks of concern, EPA will typically consider whether any mitigation is available that would allow the pesticide to meet the registration standard, including the FFDCA safety standard. (*See* 40 CFR 155.53 and 155.56) For chlorpyrifos, for which the Agency had identified high levels of risk in 2016, EPA decided to focus on whether there was a mitigation package that would allow some uses of chlorpyrifos to be considered safe.

Starting with a hypothetical ''blank label'' with no registered uses and adding back just the 11 geographically and application rate limited uses, *i.e.,* assuming all other current uses did not exist, EPA assessed the subset of aforementioned uses applying the new refinement techniques. That analysis resulted in estimates of chlorpyrifos concentrations in drinking water below the DWLOC, which provided a basis for EPA to propose that subset of uses for mitigation of risk in the 2020 PID. For some areas, the estimated drinking water concentrations from combinations of those 11 uses were close to the DWLOC, so there was not much room in the risk cup for adding more uses. For example, EPA concluded that use of chlorpyrifos on alfalfa, sugarbeet, and soybean in the Upper Mississippi region (HUC–07) or on alfalfa, sugar beet, soybean, and spring and winter wheat in the Souris-Red-Rainy region (HUC–09), the estimated drinking water concentrations were 3.2 ppb and 3.3 ppb, respectively; for comparison, a concentration of 4.0 ppb or above would exceed safe levels of chlorpyrifos in those areas. (Ref. 31 at pg. 16) Because EPA was trying to evaluate a specific subset of uses for purposes of providing a mitigation option in the proposed registration review decision and because that evaluation indicated that that subset alone would not pose risks of concern, EPA did not engage in further refinements of other uses from the 2016 DWA to determine if other hypothetical uses could be safe. EPA, however, recognized the possibility that additional or different uses might be requested following that proposal and cautioned that, if so, additional assessment would need to be conducted to support risk management decisions for those other uses.

Thus, at the time the 2020 DWA was conducted, it was reasonable that EPA did not expand the application of refinements beyond the 11 uses assessed. It was also reasonable that EPA did not engage in refinements of the rest of the uses in the 2016 DWA in preparation of the final rule. As EPA has indicated throughout this Order, given the time constraints imposed on the Agency by the court-ordered deadline, EPA did not conduct any new risk assessments, including any new drinking water assessments to further refine the 2016 DWA for all registered uses. To apply the refinements to all currently registered uses would have required an extraordinary investment of resources and time, which EPA did not have in light of the Court's deadline. Consequently, EPA relied on the best available science it had available to assess the currently registered uses as required at the time of the final rule—the 2016 DWA. This objection is denied.

b. Assessing Chlorpyrifos-Oxon

In addition to opposing the use of the 2016 DWA in the final rule, the Agricultural Retailers Association, *et al.,* and Gharda assert that EPA's assessment of aggregate exposure should not have considered chlorpyrifos-oxon, a metabolite of chlorpyrifos.

i. Objection regarding lack of exposure. (A) Objection. The Agricultural Retailers Association, *et al.* note that the 2016 DWA stated that there were ''no detections of chlorpyrifos-oxon degradates in any finished drinking water samples that people actually consume.'' (Ref. 47 at pg. 7) Thus, the Agricultural Retailers Association, *et al.* argue that it was arbitrary and capricious for EPA to assess the exposures of chlorpyrifos oxon in drinking water.

(B) Denial of objection. EPA has extensive reliable data supporting its

conclusion that chlorpyrifos-oxon will be present in at least some drinking water. It is well understood that chlorpyrifos rapidly oxidizes to form chlorpyrifos-oxon almost quantitatively (*i.e.,* nearly 100% conversion of chlorpyrifos into equal quantities of chlorpyrifos-oxon) during drinking water treatment with chlorination. While chlorination is the most common drinking water treatment, there are some areas that use different disinfection processes, such as those using chloramines, which are less effective at converting chlorpyrifos to its oxon, so, the resulting drinking water may contain combination of residues of chlorpyrifos and its oxon.

Currently, there are no data available on the removal efficiency of chlorpyrifos prior to chlorination or the removal efficiency of chlorpyrifos-oxon after formation. Stability studies indicate that once chlorpyrifos-oxon forms, little transformation is likely to occur between water treatment and consumption of the drinking water; the chlorpyrifos-oxon has been shown to be relatively stable following drinking water treatment (*i.e.,* with a half-life of 12 days). While some drinking water treatment procedures, such as granular activated carbon filtration and water softening, may reduce the amount of chlorpyrifos-oxon in drinking water, it is unlikely that these treatment processes completely remove chlorpyrifos-oxon from drinking water. In addition, these treatment methods are not typical practices across the country for surface water. For these reasons, it is reasonable for EPA to assume that drinking water will contain chlorpyrifos-oxon residues as a result of water treatment systems. (Ref. 26 at pgs. 2, 22 and 23)

The Agricultural Retailers Association, *et al.* point out that the 2016 DWA states that there have been no detections of chlorpyrifos oxon in finished water samples. (Ref. 47 at pg. 7; Ref. 29 at pg. 111) While it is correct that the 2016 DWA contains this statement, the lack of detections in finished water does not mean that chlorpyrifos-oxon is not present in some drinking water. There were several detections in the monitoring data of both chlorpyrifos and oxon in filtered and unfiltered surface water, and in surface water with known particulates (Ref. 29 at pgs. 97 through 113), so it is clear that chlorpyrifos and its oxon are present in at least some drinking water. Chlorpyrifos found in surface water that enters a drinking water treatment plant will be converted in most instances, as indicated previously, into chlorpyrifos-oxon before it leaves the plant and travels to consumers. There are several reasons why chlorpyrifos and chlorpyrifos-oxon may not have been detected in finished drinking water, including sample site location, sampling frequency, as well as drinking water treatment not involving chlorination that may lead to less oxon formation. There is insufficient data available to determine if the community water systems sampled for chlorpyrifos to date are located in watersheds vulnerable to chlorpyrifos contamination. (Ref. 29 at pg. 10) Due to the limitations of monitoring data, EPA cannot conclusively determine that chlorpyrifos-oxon will not be present in some drinking water, in light of the available science demonstrating conversion of chlorpyrifos to its oxon during chlorination, which occurs in the vast majority of major drinking water treatment systems throughout this country.

ii. Objection regarding lack of toxicity. (A) Objection. Gharda objects to EPA's assessment of chlorpyrifos-oxon residues in drinking water because Gharda believes that the ''drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos.'' (Ref. 39 at pgs. 32 and 33) Gharda bases this conclusion on its interpretation of the Corteva Oxon Study, which Gharda asserts found ''(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure,'' and therefore nullified EPA's assumption in the 2020 DWA ''that chlorpyrifos oxon is more toxic than the parent chlorpyrifos for drinking water exposure purposes.'' (*Id.* at pg. 32) Gharda argues that EPA's failure to consider this study makes EPA's final rule arbitrary and capricious.

(B) Denial of objection. As noted throughout this document, in light of the time constraints imposed on EPA by the Court and the direction to avoid further delay and fact-finding 14 years after the petition to revoke the tolerances had been filed, EPA focused on information already assessed to determine whether the chlorpyrifos tolerances were safe. The Agency did not conduct any additional analyses of other data, including review of the Corteva Oxon Study, due to the time constraints that were imposed on the Agency by the Ninth Circuit's deadline. That study had not been incorporated into any Agency's risk assessments at the time of the final rule, given that this study was submitted to EPA in December 2020, after the Agency's risk assessments on chlorpyrifos had been finalized (in September 2020). Due to the ongoing status of registration review, the Agency has not yet determined whether—and if so, how—to integrate this study into any risk assessment. Therefore, the final rule was not arbitrary and capricious for failure to incorporate this study into the completed risk assessments.

In any event, as EPA indicated in Unit VII.C.2., Gharda has failed to demonstrate how EPA could conclude that the tolerances are safe, even if EPA were able to incorporate this study into its assessment and agreed that the oxon was not relevant for risk assessment purposes. Also as discussed in Unit VII.C.2., EPA has concluded that even assuming that chlorpyrifos-oxon is not more toxic than chlorpyrifos and thus should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe. Based on a comparison of 2016 DWA estimates of chlorpyrifos residues in drinking water to the chlorpyrifos DWLOC, registered uses of chlorpyrifos result in levels of chlorpyrifos in drinking water that would exceed safe levels of chlorpyrifos exposure. Therefore, this objection is denied for failure to demonstrate that using the Corteva Oxon Study would have a material impact on the Agency's safety finding.

4. Procedural Considerations

A number of objections were filed raising a variety of process claims: Failure to consider public comments on the Agency's 2015 proposal to revoke chlorpyrifos tolerances in response to the 2007 Petition and on the 2020 PID; delayed opening of the portal for submission of objections; and failure to comply with requirements for interagency coordination under Executive Order 12866. These objections are denied for the reasons discussed in this unit.

a. Prior Comments

i. Objection. The Sugarbeet Associations and CLA/RISE assert that the failure to consider and respond to the more than 90,000 comments on the 2015 proposed rule and the comments submitted in response to the 2020 PID is inconsistent with the principles of due process and transparency. (Refs. 37 and 50)

ii. Denial of objection. EPA denies this objection for lack of specificity and relevance. EPA's regulations require that an objection ''[s]pecify with particularity the provision(s) of the . . . regulation . . . objected to, the basis for the objection(s), and the relief sought.'' (40 CFR 178.25(a)(2)) The objection claiming that EPA must consider the 90,000 comments on a prior proposed rule fails to meet this test. Other than objecting to EPA's not having considered those prior comments, the objections do not specify a particular aspect of the final rule that is problematic. Neither do the objectors point to anything specifically raised in the comments on the 2015 proposed rule that would support a particular objection they have to the rule. Without something specific to address, these comments as a general matter are not relevant to the Agency's final rule, for the reasons articulated directly following this discussion in this document. For this reason, this objection is denied as not conforming to the required form of objections. (40 CFR 178.30(a)(1))

Moreover, EPA does not believe that responses to the comments submitted on the 2015 proposed rule are required before proceeding with this final action, due to the unique regulatory structure provided under the FFDCA. The FFDCA sets up three options for EPA in responding to a petition seeking revocation of tolerances: (1) To issue a final rule establishing, modifying or revoking a tolerance; (2) to issue a proposed rule subject to public comment and thereafter issue a final rule; or (3) to issue an Order denying the petition. (21 U.S.C. 346a(d)(4)(A)(i), (ii), (iii)) The 2015 proposed rule was issued in response to the 2007 Petition under the second option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(ii)) Based on comments submitted in response to that proposed rule, EPA conducted additional risk assessments, which were also released for public comment. (*See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment (81 FR 81049, November 17, 2016) (FRL–9954–65)) No formal responses to those comments were ever finalized, as soon thereafter, EPA abandoned the proposed rule and issued the 2017 Order Denying Petition under the third option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(iii)) EPA's final rule was issued under the first option provided by the statute—to issue a final rule establishing, modifying, or revoking a tolerance without public comment. In sum, the statute provides EPA with choices on how to act and does not constrain EPA's ability to follow any of the statutory paths.

After EPA denied objections to the 2017 Order Denying Petition in 2019, a lawsuit was filed, and the Ninth Circuit vacated the 2017 and 2019 Orders and directed EPA to ''publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate.'' (*LULAC,* 996 F.3d at pg. 703) Notably, the court also specifically ordered EPA to issue a final rule either revoking or modifying chlorpyrifos tolerances under the first option provided in the statute, which provides for the issuance of a final rule ''without further notice and without further period for public comment.'' (21 U.S.C. 346a(d)(4)(A)(i)) Since the Court directed EPA to proceed with a final rule without directing EPA to finalize the 2015 proposed rule, EPA interpreted the Court's mandate as requiring an independent final rule based on available information, not a finalization of the prior rule. The Court's strict deadline for finalizing the rule further suggests that the Court did not expect EPA to formalize responses to a large number of potentially stale comments. As such, EPA is not obligated to respond to comments on a rule that was never finalized.

With regard to the comments submitted in response to the 2020 PID, those comments were submitted in response to the separate registration review action. As a separate action, EPA is also not obligated to respond to those comments as part of its final rule. That registration review process for chlorpyrifos is ongoing, and EPA is still reviewing the comments received in connection with that process and was not in a position at the time of the final rule to have finalized its responses to those comments. It is also worth noting that, as alluded to earlier in Unit VIII.C.1.a. of this document, the scope of the registration review differs from that of the final rule, *i.e.,* registration review under FIFRA also includes consideration of environmental risks and benefits information that are not relevant to the Agency's final rule decision. As a result, several of the comments are not likely to be relevant to the final rule.

Finally, to the extent any objector believes that a comment on the 2015 proposed rule or the 2020 PID raises specific substantive challenges that should have been considered in the final rule, the FFDCA affords the exact due process they seek. Under the special administrative procedures provided in FFDCA section 408(g), ''any *person* may file objections thereto with the *Administrator,* specifying with particularity the provisions of the regulation or Order deemed objectionable and stating reasonable grounds therefor.'' (21 U.S.C. 346a(g)(1)) Any objector can take advantage of the due process allowed by the FFDCA and submit any specific comments for Agency consideration as an objection to the final rule. Because of the opportunity to provide such objections directly to EPA as part of the objections process, there is no due process violation for not responding to comments on a proposed rule that was never finalized or to comments submitted on a separate regulatory action that remains ongoing.

b. Objections Portal

i. Objection. The American Soybean Association argues that the final rule failed to provide adequate procedural due process as a result of technical delays in opening the Federal eRulemaking Portal for submission of objections. (Ref. 36 at pgs. 3 and 4) The American Soybean Association states that on October 12, 2021, its staff discovered that the docket for the final rule was not open to accepting comments. The American Soybean Association speculates that having the objections portal disabled for any portion of the objections period could have prevented individual growers from being able to submit objections, thus denying them the right to object to the final rule.

ii. Denial of objection. EPA denies this objection. EPA's regulations require that objections be filed with the Hearing Clerk no later than 60 days following publication of the final rule in the **Federal Register** in accordance with EPA's regulations in 40 CFR part 178. (*See* 40 CFR 178.25(a)(6) and (7)) This mandatory requirement, including the direction to submit filings through the Office of Administrative Law Judges' electronic filing system, was clearly laid out in EPA's final rule, as the American Soybean Association notes. In addition to the mandatory filing of objections with the Hearing Clerk, EPA also requests that objectors submit their filed objections online (redacting any Confidential Business Information (CBI)) ''for inclusion in the public docket''. This additional step allows submitters to ensure the protection of any sensitive information in what is uploaded as part of the public docket for the action. This additional request does not include a deadline for submissions. The American Soybean Association objects only to the delayed opening of this latter online public docket.

While EPA concedes that there were technical issues with the opening of the

Federal eRulemaking Portal, this appears to be a harmless error as there is no legal consequence from the delay, and there is no indication that anyone was deprived of the opportunity to submit objections. Promptly upon receiving notice that the docket for the final rule was not open to accepting comments, and well before the close of the objection period on October 15, 2021, this issue was resolved by EPA. The American Soybean Association and over 100 other Objectors were able to submit their objections, hearing requests, and requests for stay without issue. While the American Soybean Association speculates that individual growers seeking to object might not have had the opportunity to do so, EPA did not receive any information suggesting that might be the case. On the contrary, EPA received dozens of submissions to the Federal eRulemaking Portal from individual growers, which were filed as both standalone objections (see the objections filed by individual growers Chris Hill, Willard Jack, Steve Kelley, Andrew Lance, Alan Meadows, and Joel Schreuers, Ref. 1) and included in a transmittal of 93 independent comment letters submitted by the Sugarbeet Associations (Ref. 37, Attachment 4).

c. Interagency Review Process

i. Objection. The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association argue that EPA failed to comply with Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993), and thus deprived other federal agencies an opportunity to provide feedback on the final rule. (Refs. 37, 39, and 47) The Objectors argue that the final rule is a ''significant regulatory action'' as defined in the Executive order, noting that EPA estimated a high-end annual economic benefit of chlorpyrifos of $130 million, based on higher-cost alternatives and pest damage. (Ref. 56 at pg. 39) The Agricultural Retailers Association, *et al.* and Gharda both argue in the alternative that the final rule meets the definition of a significant regulatory action in that it is ''likely to adversely affect the entire agricultural economy, jobs, productivity, and our environment.'' (Ref. 39 at pgs. 47 and 48; Ref. 47 at pg. 4) In addition, Gharda and the Sugarbeet Associations assert that tolerance revocations are not covered by Office of Management and Budget's (OMB) guidance on Executive Order 12866, which excepts tolerance actions from OMB review, because that guidance excludes from the exemption only ''those [tolerance actions] that make an existing tolerance more stringent.'' (Ref. 39 at pg. 47; Ref. 47 at pg. 12)

ii. Background. Executive Order 12866 provides that ''significant regulatory actions'' must be submitted for review to the Office of Information and Regulatory Affairs in OMB. A significant regulatory action is generally any regulatory action that is likely to result in a rule that might, among other things, have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. After the issuance of Executive Order 12866, OMB issued *Guidance for Implementing E.O. 12866,* which exempted tolerance actions under the FFDCA from Executive Order 12866 review, ''except those that make an existing tolerance more stringent.'' (Ref. 55)

iii. Denial of Objection. As an initial matter, EPA notes that Executive Order 12866—like most, if not all, executive orders—explicitly says that it ''does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.'' (58 FR 51744) Thus, not submitting the final rule to OMB cannot constitute a violation of any law, such that a reviewing court could reasonably be expected to find that EPA's action was ''not in accordance with law'' under 5 U.S.C. 706(2)(A) or ''without observance of procedure required by law'' under 5 U.S.C. 706(2)(D). Therefore, this is not a judicially reviewable issue. Moreover, EPA notes that resolution of this particular objection has no bearing on any substantive issues with the final rule that are raised separately in other objections. Thus, this objection is denied.

In any event, EPA disagrees that the final rule revoking chlorpyrifos tolerances triggers the Executive Order 12866 interagency review requirements. EPA believes the OMB guidance regarding Executive Order 12866 and its application to pesticide tolerance actions can be interpreted to mean that a pesticide tolerance is made ''more stringent,'' and thus subject to Executive Order 12866 requirements, when EPA does not make accommodations for affected parties to adjust to the impacts of the rule. With respect to the revocation of tolerances for chlorpyrifos, however, the final rule provided a meaningful period of time for affected parties to adjust to the rule's impact, in light of the identified safety concerns. Specifically, EPA provided six months between the publication of the final rule and its effective date, which far exceeds the 30-day effective date requirement contained in the Administrative Procedure Act. In addition, this approach is both consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures and, in the Agency's view, generous in light of the Agency's conclusion that chlorpyrifos tolerances were not safe. Finally, this approach is consistent with the Agency's approach for other pesticide tolerance revocations that EPA determined were not subject to Executive Order 12866; *see, e.g.,* EPA's revocations of tolerances for carbofuran in 2009 (74 FR 23045), butylate, clethodim, dichlorvos, dicofol, and isopropyl carbanilate, et al. in 2012 (77 FR 59120), and tebufenozide in 2017 (82 FR 53423).

For all the foregoing reasons, the objection regarding Executive Order 12866 and interagency review is denied.

5. Objections That, As a Matter of Law, Do Not Provide a Basis for Leaving Tolerances in Place

Many Objectors suggested that EPA's final rule was inappropriate on grounds that are immaterial to the question of whether tolerances can be maintained under the FFDCA. The FFDCA and EPA's regulations require that objections identify a particular aspect of the final rule deemed objectionable and specify with particularity the provision of the regulation objected to and the relief sought. (21 U.S.C. 346a(g)(2), 40 CFR 178.25(a)(2)) In addition, the objection must seek relief that is consistent with the FFDCA. (40 CFR 178.30(a)(2)) Objections that do not meet these conditions will be denied. The objections discussed in this sub-unit provide no reliable information pertaining to the FFDCA safety standard in section 408(b)(2) that could support leaving the tolerances in place. Because these complaints are meritless on their face, these objections are denied. EPA provides further discussion in this unit.

a. Economic and Environmental Impacts

i. Objection. A majority of Objectors, including the Agricultural Retailers Association, *et al.,* the Sugarbeet Associations, American Soybean Association, Cherry Marketing Institute, and 93 sugarbeet growers as part of a mass mailer, allege that the revocation of chlorpyrifos tolerances will have detrimental impacts on their crops due to increased pest pressure, force growers to use more expensive and less efficacious alternatives, and result in harmful effects on the environment. (Ref. 1)

ii. Denial of objection. EPA appreciates that the revocation of chlorpyrifos tolerances will have an impact on growers who use the pesticide and the agricultural industry. Chlorpyrifos is a widely used pesticide that has been registered for many uses since 1965. As part of the registration review process under FIFRA, the Agency did evaluate the benefits of chlorpyrifos to growers by crop. (Ref. 56) EPA is aware that IPM and resistance management are critical pest management benefits of many pesticides, and where benefits considerations are permitted by law, the Agency takes these aspects into serious consideration. However, consideration of information on pesticidal benefits to growers or impacts on the environment from loss of a pesticide, while relevant considerations under FIFRA (*see* 7 U.S.C. 136(bb)), are not factors for consideration under the FFDCA, with one exception not applicable here. (*See* 21 U.S.C. 346a(b)(2)(B))

The safety standard under the FFDCA is strictly a human-health risk-based standard, which does not permit consideration of benefits or environmental information, in determining whether a tolerance is safe. Invariably, FFDCA section 408 directs EPA to consider factors relevant to the safety of the pesticide residue in food (aggregated with other sources of exposure to the pesticide residue), placing particular emphasis on human dietary risk. (*See, e.g.,* 21 U.S.C. 346a(b)(2)(B) (addressing an exception to the safety standard for pesticide residues as to which EPA ''is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health''); 21 U.S.C. 346a(b)(2)(C) (requiring special safety findings as to ''infants and children'' regarding their ''disproportionately high consumption of foods'' and their ''special susceptibility * * * to pesticide chemical residues''); 21 U.S.C. 346a(b)(2)(D)(iii) (requiring consideration of the relationship between toxic effects found in pesticide studies and human risk); 21 U.S.C. 346a(b)(2)(D)(iv), (vi), and (vii) (requiring consideration of available information on ''dietary consumption patterns of consumers,'' ''aggregate exposure levels of consumers,'' and the ''variability of the sensitivities of major identifiable subgroups of consumers''); 21 U.S.C. 346a(b)(2)(D)(vi) (requiring consideration of ''non-occupational'' sources of exposure); 21 U.S.C. 346a(b)(2)(D)(viii) (requiring consideration of information bearing on whether a pesticide ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects''); 21 U.S.C. 346a(l)(2) and (3) (requiring revocation or suspension of tolerances where associated FIFRA registration is canceled or suspended ''due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food'')) Thus, under section 408, EPA has no discretion to insert economic or environmental considerations into its decisions on the chlorpyrifos tolerances.

Therefore, objections that EPA should have taken economic and environmental impacts into consideration in issuing the final rule are denied, as EPA has no authority to do so as part of its safety evaluation under the FFDCA.

b. Consideration of Occupational Exposure by EPA

i. Objection. Gharda and the Sugarbeet Associations assert that EPA unlawfully considered occupational exposures as a reason for revoking the tolerances. In support of this objection, they point to an EPA press release regarding the final rule dated August 18, 2021, which mentioned that the tolerance revocation will result in protections for farmworkers. (Ref. 37 at 13; Ref. 39 at 33)

ii. Denial of Objection. The August 18, 2021 press release announcing the publication of the final rule included statements that EPA was stopping the use of chlorpyrifos on food ''to better protect human health, particularly that of children and farmworkers,'' and that ending the use of chlorpyrifos on food ''will help to ensure children, farmworkers, and all people are protected'' from potentially dangerous consequences of chlorpyrifos. (Ref. 57) Based on these statements alone, the Objectors argue that these references to farmworkers suggest that EPA impermissibly considered occupational exposures in its decision to revoke chlorpyrifos tolerances. However, the Objectors' arguments are not supported by the final rule itself, which specifically affirms that the FFDCA standard does not include occupational exposures to workers and which explicitly and repeatedly emphasizes that EPA's review included food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but did not include occupational exposures to workers. (*See, e.g.,* Ref. 1 at pgs. 48318, 48332 through 48333) The fact that the press release cited by the Sugarbeet Associations discusses the potential for incidental benefits to farmworkers from the final rule does not mean that such potential benefits were considered by EPA in the final rule. The Objectors' claim is meritless and is denied.

c. Compliance With Relevant International Standards

i. Objection. The Republic of Colombia objects to the final rule on the basis that the final rule's revocation of chlorpyrifos tolerances deviates from the Codex Alimentarius (Codex) international standard of 0.05 mg/kg for chlorpyrifos. (Ref. 58) Colombia requests that EPA reconsider the final rule's revocation of chlorpyrifos tolerances in light of the Codex MRL for chlorpyrifos, which it alleges is based on conclusive scientific evidence, although Columbia does not provide that scientific evidence with its objection for EPA to consider. In addition, Colombia requests that EPA consider, in its assessment of chlorpyrifos tolerances, the factors identified for consideration under Article 5, paragraphs 2 and 3 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Those paragraphs require Members to the SPS Agreement to ''take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest—or disease—free areas; relevant ecological and environmental conditions; and quarantine or other treatment'' and ''relevant economic factors.'' (Ref. 59 at art. 5, paragraphs 2, 3)

ii. Denial of objection. The Codex is a collection of internationally adopted food standards and related texts published by the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. (*See https://www.fao.org/fao-who-codexalimentarius/en/*) The Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, establishes Codex Maximum Residue Limits (MRLs) for pesticide products, which are similar to tolerances in that they set the limit for allowable pesticide residues in food. Although the Objector seems to be referring to a single universal Codex MRL of 0.05 mg/kg for chlorpyrifos residues, in actuality, Codex has promulgated several MRLs ranging from 0.01 mg/kg to 20 mg/kg for chlorpyrifos residues on a variety of commodities. (Ref. 60) It is unclear why Colombia is pointing the Agency to a generic MRL of 0.05 mg/kg.

The FFDCA requires consideration of Codex MRLs when EPA is making a decision to *establish* a tolerance. (21 U.S.C. 346a(b)(4)) Notably, the statute does not require the same consideration in revoking tolerances. That is because revocation is required when a tolerance is unsafe, (21 U.S.C. 346a(b)(2)(A)(i)), regardless of whether another international body, including Codex, is maintaining the same determination. In the final rule, EPA determined that current tolerances for chlorpyrifos are not safe under FFDCA and must therefore be revoked. Columbia has not provided any reliable information to support a reconsideration of that conclusion.

As far as the request to consider the factors under Article 5, paragraph 2 of the SPS Agreement is concerned, EPA reiterates its earlier arguments, that it is bound by its domestic statute, which requires that unsafe tolerances be revoked (21 U.S.C. 346a(b)(2)(A)(i)) and which does not permit consideration of environmental or economic factors. (See Unit VIII.C.5.a.) EPA does not have discretion to retain tolerances, based on consideration of the factors listed in SPS Agreement, where the Agency has determined those tolerances do not meet the FFDCA safety standard. For these reasons, the Republic of Colombia's objection with respect to the Codex MRLs and the SPS Agreement is denied.

d. Implementation Timeframe

i. Objection. While EPA received many requests for an extension of the phase-out period, this section address the single objection asserting that the Agency's six-month expiration date for the tolerances was unlawful. The requests EPA received for extensions of the tolerance expiration date are addressed in Unit IX, along with other requests seeking a stay of the final rule.

Seeking a ''gradual, multi-year phase-out of crop uses'' to mitigate economic injury to itself and growers, Gharda argues that EPA's selection of a six-month grace period was arbitrary and capricious because it did not provide for use in another growing season nor sufficient time for Gharda, distributors, or growers to phase out their inventories and exhaust existing stocks of chlorpyrifos. (Ref. 39 at 40) Nor, Gharda alleges, does the SPS Agreement requirement for a ''reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force'' mandate that EPA select six months as the reasonable interval. (*Id.* at 38)

ii. Denial of objection. Section 408(g)(1) of the FFDCA states that a rule issued under section 408(d)(4) of the FFDCA, which the final rule revoking chlorpyrifos tolerances was, ''shall take effect upon publication'', unless otherwise specified in the rule. (21 U.S.C. 346a(g)(1)) The Agency's authority to specify a different effective date or to set an expiration date for the tolerances is entirely discretionary. Moreover, there is no requirement in the FFDCA for EPA to accommodate, through delays in the effective date or any other way, economic hardships and transitions away from a pesticide that the Agency has found to be unsafe and for which tolerances must be revoked. Indeed, the FFDCA is entirely focused on whether the tolerance is safe, and so it would subvert the intent of the statute to allow all tolerances the Agency has deemed unsafe to remain effective for significant periods of time.

As stated in the final rule, EPA set a six-month expiration date for the chlorpyrifos tolerances, rather than requiring revocation immediately, to accommodate the SPS Agreement requirement to ''allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force.'' (Ref. 59 at Annex B, paragraph 2) The World Trade Organization (WTO) has interpreted the phrase ''reasonable interval'' to mean normally a period of not less than six months, although shorter durations could be justified under ''urgent circumstances.'' (Ref. 61 at paragraph 3.2) In the SPS Agreement, there are some procedural exceptions allow for urgent health concerns. (Ref. 59 at Annex B, paragraph 5; *see also* Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes,* WTO Doc, WT/DS406/AB/R (April 4, 2012) (finding that deviations from the TBT Agreement requirement to provide ''reasonable interval'' may be justified in cases of urgent safety or health concerns))

In light of EPA's inability to conclude that chlorpyrifos tolerances meet the FFDCA safety standard, the Agency determined that a six-month expiration date for the chlorpyrifos tolerances would provide a reasonable interval for importers and growers to adapt to the change in regulation. EPA also notes that the Ninth Circuit's decision directed EPA to act ''immediately,'' and chastised EPA for its ''egregious delay'' in publishing a sufficient response to the 2007 Petition, which ''exposed a generation of American children to unsafe levels of chlorpyrifos.'' (*LULAC,* 996 F.3d. at 703) It simply was not tenuous to leave tolerances in place to allow for additional growing season(s), given the Agency's lack of a safety finding for the chlorpyrifos tolerances in light of the Ninth Circuit's expressed impatience with EPA's delay in acting on the 2007 Petition and the accelerated timeframe provided by the Ninth Circuit for the issuance of the final rule. Consequently, EPA determined that six months was a reasonable period to accommodate growers and importers while minimizing any continued harm.

For these reasons, Gharda's objection with respect to the implementation timeframe of the final rule is denied.

e. Existing Stocks

i. Objection. The following Objectors argue that the final rule should have addressed the treatment of existing stocks of chlorpyrifos products and seek additional clarification on how existing stocks will be addressed: The Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.,* CLA/RISE, and the Michigan Vegetable Council. (Refs. 37, 39, 47, 50, and 62) These Objectors allege that the revocation of the tolerances is likely to leave millions of gallons of chlorpyrifos in the hands of growers or in storage in the United States and that the lack of clarity from EPA regarding the use and/or disposal of these existing stocks of chlorpyrifos places a financial and logistical burden on users and retailers and could inadvertently lead to inappropriate disposal of chlorpyrifos products. Several Objectors argue that guidance published by EPA on its website after publication of the final rule titled ''Frequent Questions about the Chlorpyrifos 2021 Final Rule'' (Ref. 63), fails to clarify this issue, and that the legal status of products with labels and registrations that contain both food and non-food uses remains unclear.

Gharda also argues that EPA, in issuing the final rule without concurrently addressing existing stocks in the final rule or issuing an existing stocks order pursuant to FIFRA section 6(a)(1) (7 U.S.C. 136d(a)(1)), has abdicated its responsibility under FIFRA to ensure the safe, lawful, and orderly phase-out and disposal of chlorpyrifos products. (Refs. 39 at 41 through 45) Gharda asserts that an existing stocks order is necessary to allow end users and others wishing to return existing stocks to the manufacturers or pursue other safe disposal options to avoid violating FIFRA. Gharda also asserts that because the practical effect of the final rule is to render previously registered products unregistered, EPA would have no enforcement authority over misuse of those pesticides.

ii. Denial of objection. As an initial matter, EPA notes that while the Objectors use the term ''existing stocks,'' existing stocks is a FIFRA term that applies to products that have been released for shipment upon cancellation of a registered pesticide. (*See* Existing Stocks of Pesticide Products; Statement of Policy, 56 FR 29362, June 26, 1991 (FRL–3846–4)) Since the final rule does not cancel any pesticide registrations, it has not created any ''existing stocks'' under FIFRA.

Nevertheless, EPA reads the majority of objections on this particular issue to be seeking clarity and guidance for users of chlorpyrifos on what to do with chlorpyrifos products that have been purchased but cannot be used on food crops following the expiration of the tolerances. As such, these objections are more akin to comments and requests concerning implementation of the final rule, than objections to the final rule itself; thus, they are denied as objections for failure to raise particular concerns with the final rule that can be resolved under the FFDCA. Nevertheless, EPA recognizes the confusion among the agricultural industry as a result of the final rule and the fact that tolerances will be revoked before any registrations for chlorpyrifos products are cancelled under FIFRA. Consequently, EPA will continue to update the FAQ page to provide guidance to assist growers and the agricultural industry with the implementation of this final rule.

Turning to Gharda's objection next, EPA denies that it has somehow abdicated its responsibilities under FIFRA by taking action to revoke unsafe tolerances under the FFDCA. EPA finds that Gharda is essentially making the same argument that EPA rejected in Unit VIII.C.1.b. Gharda's argument boils down to an assertion that EPA was required to take action concurrent with the final rule to cancel chlorpyrifos registrations under FIFRA, to provide for the use and disposition of existing stocks in that cancellation order, and then to revoke tolerances consistent with the existing stocks provisions of that cancellation order; thus, for the same reasons articulated in that previous Unit, Gharda's objection is denied. As noted previously, nothing in the FFDCA compels EPA to take action under FIFRA to cancel pesticide registrations and provide for existing stocks concurrently with or prior to revoking tolerances for that same chemical. Moreover, there is no requirement in the FFDCA, when revoking a tolerance, to resolve questions regarding existing stocks in the final rule itself.

Gharda appears to conflate the EPA's issuance of a rule revoking tolerances under the FFDCA with EPA's cancellation of registered pesticides under FIFRA. Gharda argues that because EPA's revocation of the tolerances under the FFDCA essentially renders the product unregistered, EPA was obligated to address the issue of existing stocks under FIFRA. However, Gharda misstates the effect of the final rule. The revocation of tolerances does not have the effect of rendering the chlorpyrifos products unregistered. Registered products only become unregistered once they are cancelled under FIFRA section 6. (7 U.S.C. 136d) EPA has no authority to issue a cancellation order under the FFDCA, only under FIFRA, and as discussed in Unit VIII.C.1.b., EPA is not required to cancel pesticides under FIFRA prior to taking action to revoke tolerances under the FFDCA. Because the actual remedy Gharda is seeking with this objection—a cancellation order with instructions on how to handle existing stocks—is only available under FIFRA, this is not a proper objection to the final rule.

f. Channels of Trade

i. Objection. The American Soybean Association and Willard Jack (an individual grower) submitted objections arguing that the final rule fails to provide adequate guidance for food or feed treated with chlorpyrifos that is or will be in the channels of trade when the tolerances are set to expire on February 28, 2022. (Refs. 36 and 64) The Objectors express concern that growers will be adversely impacted by this rule due to a lack of guidance and the potential of having adulterated food seized by the FDA.

ii. Denial of objection. To the extent this objection asserts that lack of guidance is a fatal flaw with the final rule, this objection is denied. This issue does not provide a basis for reversing the Agency's position on the safety of chlorpyrifos and changing the final rule. Nevertheless, EPA recognizes the need for guidance for farmers and food processors following the revocation of the chlorpyrifos tolerances. As EPA indicated in the final rule, section 408(l)(5) of the FFDCA governs commodities treated with pesticides and in the channels of trade following the tolerance revocations. Under that provision, chlorpyrifos residues in or on food in the absence of a tolerance will not render that food adulterated, as long as it is shown to the satisfaction of the U.S. Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. (21 U.S.C. 346a(l)(5))

The FDA, which is responsible for enforcing tolerances and implementing this provision, has developed guidance for growers and food processors for foods treated with chlorpyrifos. (Ref. 65) That guidance, which covers residues of chlorpyrifos in human food commodities, clarifies the FDA's planned enforcement concerning those foods containing chlorpyrifos residues after the tolerances expire. Animal feed items, which are regulated by FDA's Center for Veterinary Medicine, and various livestock commodities, which are regulated by USDA, are not covered by this guidance. EPA intends to work with those other agencies to assist with questions of compliance as they arise.

g. Substantive Due Process Concerns

i. Objection. Gharda argues that it and other registrants have a fundamental property right in their chlorpyrifos registrations, which is protected by the substantive due process doctrine provided for under the U.S. Constitution. (Ref. 39 at 36 through 37) Gharda claims that the economic value of its chlorpyrifos registration for food use crops is dependent on having tolerances for chlorpyrifos in place. Gharda argues that because the Agency revoked those tolerances ''without a reasoned explanation or valid scientific basis, and in disregard of scientific data,'' the Agency improperly deprived Gharda of economic value of its registration and violated its substantive due process rights.

ii. Denial of objection. Whether Gharda has a substantive due process right to its registrations and the revocation of tolerances somehow infringes that right is immaterial to the question EPA must answer when leaving a tolerance in place—whether the tolerance is safe. The FFDCA is clear: When a tolerance is not safe, it must be modified or revoked. Whether the revocation of that rule has implications for registrants of products or growers of crops is outside the scope of considerations in the FFDCA. Since nothing about this objection provides information bearing on the safety of chlorpyrifos, this objection is denied.

In any event, EPA disagrees with Gharda's claim that the final rule has infringed substantive due process rights.

"To state a substantive due process claim, a plaintiff must allege: (1) That it had property or a property interest; (2) the government deprived it of that property interest; and (3) the government's actions fall so far beyond the outer limits of legitimate governmental action that no process could cure the deficiency. . . . [S]ubstantive due process concerns governmental action which is so arbitrary and irrational, so unjustified by any circumstance or governmental interest, as to be literally incapable of avoidance by any pre-deprivation procedural protections or of adequate rectification by any post-deprivation . . . remedies. . . . Thus, a substantive due process claim is warranted only where *no process* could cure the deficiencies in the governmental action." (*Syngenta Crop Protection, Inc.* v. *EPA,* 444 F.Supp.2d 435, 447 (M.D.N.C. 2006) (internal citations and quotations omitted)) EPA disagrees that Gharda has a property interest in the food uses here since "there is no property interest in using property in a manner that is harmful to the general public." (*American Vanguard Corp.* v. *United States,* 142 Fed. Cl. 320, 328 (Jan. 28, 2019) (citing *Mitchell Arms, Inc.* v. *United States,* 7 F.3d 212 (Fed. Cir. 1993))) Moreover, Gharda has failed to allege any activity by EPA that would implicate the "outer limits of legitimate governmental action" or that is "so arbitrary and irrational, so unjustified by any circumstance or governmental interest," as to be incapable of remedy. Gharda alleges no activity that is "so arbitrary or irrational" other than a general claim that the final rule is "without a reasoned explanation or valid scientific basis, and in disregard of scientific data."

EPA notes that the final rule includes significant explanation for its finding that EPA is unable to determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos residues for which there is reliable information. For example, the final rule includes, among other key information, an overview of the numerous human health risk assessments EPA has conducted and FIFRA SAPs that were convened to discuss chlorpyrifos, a detailed summary of EPA's risk assessment for chlorpyrifos, EPA's hazard assessment of chlorpyrifos, EPA's exposure assessment for chlorpyrifos, and EPA's process for assessing aggregate risk based on the aforementioned assessments. To the extent that this assertion is intended to refer to or incorporate Gharda's other objections—such as Gharda's argument that EPA's explanation for not retaining the eleven uses proposed for retention in the 2020 PID or fails to consider the Corteva oxon study—EPA has already provided responses to those more detailed objections elsewhere in this Order.

In any event, it cannot be said that EPA taking action to revoke an unsafe tolerance under its statutory mandate to ensure that pesticide residues in food are safe for public consumption is outside the bounds of a legitimate governmental action. Congress tasked EPA specifically with the responsibility to ensure that tolerances are only left in place if they are safe and to revoke or modify tolerances if they are not. (*See* 21 U.S.C. 346a(b)(2)(A)) Upon concluding that aggregate exposures were not safe, EPA revoked the tolerances in accordance with the statutory mandate, which is clearly within the bounds of a legitimate government action to ensure that residues of pesticides in or on food are safe for consumption. It is necessarily the case that when EPA revokes a tolerance on the basis of dietary risks for pesticides that are registered under FIFRA, there are going to be impacts to the registrants of those pesticides. Leaving tolerances in place to avoid impacts to pesticide registrants would be inconsistent with the FFDCA. Finally, Gharda is not without process for curing any deficiencies in EPA's actions, including procedures afforded by FIFRA, the APA, and judicial review. Therefore, Gharda's claim that its substantive due process rights have been infringed by EPA's final rule fails.

D. Summary of Reasons for Denying Objections

EPA is denying the objections submitted by the Objectors for several reasons. EPA is denying the objections of the Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador, because these parties did not submit their objections to the Office of the Hearing Clerk, as required by 40 CFR 178.25(b). As discussed in Unit VIII.A. of this document, EPA grouped the other Objectors' objections into five different substantive categories and addressed each in turn.

Regarding the first category—objections to the scope of the final rule—EPA is denying the objections asserting that revoking all chlorpyrifos tolerances was unlawful and unnecessary in light of the proposal in the 2020 PID for limiting uses to 11 high-benefit crops, because the FFDCA requires that EPA assess aggregate exposure based on all currently registered uses of chlorpyrifos, not on a hypothetical subset of those uses. EPA also denies the objections arguing that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA, because FFDCA 408(l)(1) does not require that actions under FIFRA precede or occur concurrently with actions under the FFDCA, and because in any event it was not practicable for EPA to first modify of cancel any registrations in light of the Ninth Circuit's deadline for issuing a final rule. Lastly, EPA denies the objections arguing that EPA should retain import tolerances for chlorpyrifos commodities, because EPA is unable to make the safety finding for leaving in place tolerances for imports until enough uses are canceled to reduce aggregate exposures to acceptable levels.

Regarding the second category—objections to the retention of the 10X FQPA safety factor—EPA is denying the objections that EPA's final rule was arbitrary and capricious for retaining the 10X FQPA safety factor. As an initial matter, EPA has determined that whether the Agency retains the 10X FQPA safety factor or uses a different margin of safety does not ultimately have a determinative impact on the Agency's conclusions regarding the safety of chlorpyrifos in the final rule; therefore, this objection is denied for lack of materiality. Nonetheless, EPA concludes that its consideration of the epidemiological studies was reasonable and consistent with EPA's policy for consideration of all available data. EPA notes there is no requirement that the underlying data must be made available before EPA can rely on these studies, and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children. Furthermore, given the uncertainties surrounding the potential for neurodevelopmental effects at the time of the final rule, EPA's retention of the default 10X FQPA safety factor was consistent with the statutory standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children.

Regarding the third category—objections relating to EPA's assessment of drinking water exposures—EPA is denying the objections that EPA did not have a rational basis for relying on the 2016 DWA, because, unlike the 2020

DWA, the 2016 DWA considered contributions from all registered uses of chlorpyrifos, and so represented the most recent and robust ''best available science'' for use by the Agency in its final rule. EPA is also denying the objections that it was unreasonable for EPA to assess exposures to chlorpyrifos-oxon in its drinking water assessment, because EPA has reliable data that chlorpyrifos-oxon will be present in at least some drinking water, and because EPA concluded that even assuming chlorpyrifos-oxon is not more toxic and should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe.

Regarding the fourth category—objections relating to procedural matters—EPA is denying the objections that EPA acted inconsistently with the principles of due process and transparency in failing to consider and respond to comments previously submitted on the 2015 proposed rule and in response to the 2020 PID. EPA notes that these objections do not identify a specific element of the final rule that is problematic, and so do not conform to the required form of an objection per 40 CFR 178.30(a)(1). EPA also notes that EPA is not obligated to respond to comments on a rule that was never finalized (*i.e.,* the 2015 proposed rule), or on separate albeit parallel regulatory activities (*i.e.,* the 2020 PID). EPA is also denying the American Soybean Association's objection that the final rule failed to provide adequate procedural due process due to technical delays in opening the Federal eRulemaking Portal, because EPA's regulations only require that objections be filed with the Hearing Clerk, with the Portal serving as an additional means of protecting any CBI, and because the delayed opening of the Portal is harmless error. Lastly, EPA is denying the objections that EPA failed to comply with Executive Order 12866, because this is not a judicially reviewable issue and resolution of these objections has no bearing on any substantive issues with the final rule that could be raised separately.

Regarding the fifth and final category—objections that, as a matter of law, do not provide a basis for leaving tolerances in place—EPA is denying these assorted objections because they provide no reliable information pertaining to the FFDCA safety standard that could support leaving chlorpyrifos tolerances in place.

VIII. Response to Requests for Stay

A. The Standard for Granting a Stay

FFDCA section 408 provides that a regulation issued under subsection 408(d)(4) shall take effect upon publication in the **Federal Register** unless the regulation specifies otherwise. (21 U.S.C. 346(g)(1)) The effective date of the final rule was October 29, 2021, and tolerances for residues of chlorpyrifos on all commodities expire on February 28, 2022. However, section 408 also grants the Administrator the discretion to stay the effectiveness of a regulation if objections are filed. (21 U.S.C. 346a(g)(1))

The statute is silent on the standard to apply in granting a stay. The FFDCA gives EPA unlimited discretion to determine when it might be appropriate to issue a stay, requiring only that objections be filed before EPA may exercise that authority. EPA believes the discretionary nature of this authority gives EPA flexibility in any given case to determine whether and how to stay a rule or order issued under FFDCA section 408(d). EPA has indicated that it will consider the criteria set out in FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35, in determining whether to grant a stay. (*See, e.g.,* Carbofuran; Final Tolerance Revocations, 74 FR 23045, May 15, 2009; *cf.* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 FR 3422, Jan. 19, 2011 (evaluating stay request based on an amalgam of the 21 CFR 10.35 factors and a judicial stay factors)) Under 21 CFR 10.35, a stay shall be granted if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. (21 CFR 10.35(e))

B. Requests for Stay and EPA Responses

1. Summary of Requests for Stay

EPA received written requests for EPA to either stay the effective date of the final rule or allow for a longer phase-out period from the following objectors: Amalgamated Sugar Company, American Crystal Sugar Company, the American Soybean Association, the Sugarbeet Associations, the California Citrus Quality Council, the Cherry Marketing Institute, CLA/RISE, Gharda, the Minor Crop Farmer Alliance, the Agricultural Retailers Association, *et al.,* the Republic of Colombia, and several independent sugarbeet growers. (These written requests are available in the final rule docket at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.)

The requests for stay of the final rule can be sorted into three groups based on the form of the requests and the duration of the stay requested. The first group consists of the requests submitted by the Sugarbeet Associations and Gharda, both of which apply the criteria set out in 21 CFR 10.35 to argue that EPA is required to stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. The Sugarbeet Associations and Gharda also request a stay ''until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections.'' (Refs. 66 and 67) The second group consists solely of the Republic of Colombia. Colombia requests a period of at least 12 months before chlorpyrifos tolerances expire so that it can ''make the necessary adjustments in the production of [its] crops to ensure compliance.'' (Ref. 58) While Colombia does not explicitly frame its request as a request for a stay of the final rule, and does not reference the criteria at 21 CFR 10.35, EPA's interpretation is that this is best understood and assessed by EPA as a request for stay. Finally, the third group consists of the remaining stay requests. These Objectors do not specifically address the regulatory criteria set forth at 21 CFR 10.35; they simply request that EPA stay the final rule until EPA can address the issues raised in their various objections.

2. Denial of Requests for Stay

As noted previously, only the Sugarbeet Associations and Gharda frame their requests for stay by reference to the regulatory criteria at 21 CFR 10.35, and until ''a final resolution'' can be obtained with respect to the issues raised in their objections. The other stay requests do not reference the regulatory criteria. The sole rationale provided by Colombia for its request for an additional 12-month period before tolerances expire is to enable unspecified parties to ''make the necessary adjustments'' to ensure compliance. Colombia does not include any information regarding any potential injury (irreparable or otherwise) that might otherwise be suffered, showing that their case is not frivolous and is being made in good faith, demonstrating sound public policy supporting a 12-month delay, or arguing that their desired 12-month delay is not outweighed by public health or other interests. EPA declines to speculate as to the bases for Colombia's request and denies Colombia's stay request due to the lack of supporting information. The other stay requests simply ask EPA to stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. These Objectors appear to contemplate a scenario in which EPA delays addressing their objections until well after the February 28, 2022, expiration date for chlorpyrifos tolerances specified in the final rule. Because EPA has addressed these objections via this Order, by the plain meaning of these stay requests, there is no longer any need to stay the final rule. As a result, EPA denies those requests for stay submitted by Objectors other than the Sugarbeet Associations and Gharda.

With respect to the requests for stay submitted by the Sugarbeet Associations and Gharda, EPA examines these parties' arguments in light of the four factors set forth in at 21 CFR 10.35.

a. Will the Sugarbeet Associations and Gharda suffer irreparable injury without the stay?

i. Summary of arguments concerning injury. The Sugarbeet Associations and Gharda each argue that they will suffer irreparable injury in the form of economic losses and reputational impacts due to the final rule, and Gharda also argues that the deprivation of its chlorpyrifos registration under FIFRA is a due process violation that constitutes irreparable harm. (Refs. 66 and 67) With respect to economic losses, the Sugarbeet Associations argue that due to the lack of similarly effective alternatives to chlorpyrifos, reduced crop yields could cause the sugarbeet industry significant economic harm. (Ref. 66 at pgs. 2 through 4) Similarly, Gharda claims that it could face significant economic losses if, due to the final rule, it is unable to formulate, distribute, and sell the significant volume of raw materials and U.S.-labeled product it has in inventory. (Ref. 67 at pgs. 6 and 7) With respect to reputational impacts, the Sugarbeet Associations argue that the sugarbeet industry is likely to suffer reputational harm as a result of the final rule and the August 18, 2021, press release announcing the final rule, including the potential for ill will against the sugarbeet industry from customers and the public that could affect the industry's ability to sell its products. (Ref. 66 at pgs. 4 and 5) Similarly, Gharda argues that it has suffered and will continue to suffer reputational harm, and that the final rule has strained and will continue to strain Gharda's relationships with its customers, who might not use Gharda products moving forward. (Ref. 67 at pgs. 6 through 8)

As described in more detail in this unit, EPA disagrees that any injuries to the Sugarbeet Associations and/or Gharda are in fact irreparable.

ii. Response to the Sugarbeet Associations' and Gharda's economic injury arguments. EPA disagrees that the Sugarbeet Associations and Gharda have established that they—or, in the case of the Sugarbeet Associations, the farmer-owners and beet sugar manufacturers they represent—will be irreparably harmed without a stay. As Gharda correctly notes, to establish irreparable harm, ''injury must be both certain and great; it must be actual and not theoretical and of such imminence that there is clear and present need for equitable relief.'' (*Olu-Cole* v. *E.L. Haynes Pub. Charter Sch.,* 930 F.3d 519, 529 (D.C. Cir. 2019) (internal quotation marks and citations omitted)) However, this already high ''barrier to proving irreparable injury is higher still'' for the economic losses asserted by the Sugarbeet Associations and Gharda, ''for it is well settled that economic loss does not, in and of itself, constitute irreparable harm.'' (*Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544, 555 (D.C. Cir. 2015)) ''Mere injuries, however substantial, in terms of money, time, and energy necessarily expended in the absence of a stay are not enough.'' (*Wisconsin Gas Co.* v. *FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985)) Instead, ''recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence'' of a company. (*Id.*)

The Sugarbeet Associations and Gharda include identical statements arguing that ''[l]osses for which an aggrieved party has no recourse, such as those caused by a governmental entity immune from suit for monetary relief, are 'irreparable *per se.*' '' (Ref. 66 at pg. 3 and Ref. 67 at pgs. 5 and 6, respectively (each citing *Feinerman* v. *Bernardi,* 558 F. Supp. 2d 36, 51 (D.D.C. 2008))) However, the Sugarbeet Associations and Gharda fail to note that subsequent caselaw expressly disagrees with that principle. In *ConverDyn* v. *Moniz,* the District Court for the District of Columbia acknowledges that while in *Feinerman* it ''characterized economic damages that are unrecoverable due to sovereign immunity as 'irreparable *per se'* . . . that characterization goes too far and the inability to recover economic losses can more accurately be considered as a factor in determining whether the movant has shown irreparable harm.'' (68 F. Supp. 3d 34, 49 (D.D.C. 2014) (internal citations omitted)) The Court observed that ''[o]therwise, a litigant seeking injunctive relief against the government would always satisfy the irreparable injury prong, nullifying that requirement in such cases.'' (*Id.; see also N. Air Cargo* v. *U.S. Postal Serv.,* 756 F. Supp. 2d 116, 125 (D.D.C. 2010) (''this Court is of the opinion that a party asserting such a loss is not relieved of its obligation to demonstrate that its harm will be great . . . [otherwise] prospective injunctive relief would often cease to be an extraordinary remedy in cases involving government defendants'') (internal quotation marks and citations omitted))

EPA finds that neither the Sugarbeet Associations nor Gharda have demonstrated that they or their member entities will suffer irreparable economic harm in the absence of a stay of the final rule. The Sugarbeet Associations provide a handful of statistics regarding the estimated financial impacts that they allege will result from the revocation of chlorpyrifos tolerances, and argue that because EPA estimated in the 2020 PID that the benefits of chlorpyrifos for sugarbeets in North Dakota and Minnesota *could* be up to $500 per acre, and there are over 140,000 acres of sugarbeets at risk from sugarbeet root maggots, the sugarbeet industry ''would face tens of millions of dollars in irreparable damages annually'' absent a stay. (Ref. 66 at pg. 4) EPA notes, however, that the Sugarbeet Associations omit key details, and that their conclusion is highly speculative.

The Agency included sugarbeets in its detailed economic analysis of agricultural uses of chlorpyrifos, which was conducted in 2020 to support the preliminary interim registration review decision. The analysis utilized proprietary pesticide usage surveys as well as publicly available pest management recommendations from extension crop experts. (Ref. 56) This analysis indicated that for most sugarbeet pests targeted with chlorpyrifos, several effective alternatives are available. The Agency found that for regions in the upper Midwest where populations of sugarbeet root maggot are very high, yield losses of up to 45% could occur without chlorpyrifos. The impacts of such yield losses are estimated at $498 per acre in

North Dakota and Minnesota, where an average of 61,200 acres were estimated to be affected. While EPA acknowledges that growers in these areas will be impacted, these areas represent about 20% of the sugarbeet acreage in Minnesota and 10% of the acreage in North Dakota. For purposes of comparison, the total national harvested sugarbeet acreage is approximately 1.1 million acres. Furthermore, effective alternatives to chlorpyrifos are available in other areas of the country. Thus, while there are likely to be impacts to some growers, EPA does not agree that the loss of chlorpyrifos will cause an irreparable injury to the sugarbeet industry overall.

EPA also notes that the Sugarbeet Associations fail to provide any context for the economic injuries they claim that they and their members will incur as a result of the final rule. As discussed previously, EPA acknowledges that sugarbeet yields in certain production areas could be reduced, and that some sugarbeet growers and/or beet sugar manufacturers may lose some portion of their revenue due to the final rule. However, even assuming that the figures provided by the Sugarbeet Associations are accurate, it is not clear to EPA what the specific implications of these figures might be for the Sugarbeet Associations or the growers and/or manufacturers they represent, and nowhere in their stay request do the Sugarbeet Associations assert that the failure to stay the final rule will threaten their or their member entities' very existence.

Finally, EPA notes that for many crops—including sugarbeets, as the Sugarbeet Associations acknowledge in their request for stay—alternatives to pesticides are readily available. While these alternatives may be more expensive than chlorpyrifos, or perhaps less effective than chlorpyrifos, the availability of alternatives to chlorpyrifos indicates that it is unlikely that sugarbeets will be left completely unprotected. This in turn suggests that any injury is likely to be temporary and reparable.

EPA also disagrees with Gharda's arguments regarding irreparable economic injury. Although EPA acknowledges that the revocation of tolerances will necessarily impact any registrant of chlorpyrifos products, EPA is not convinced that the economic injuries alleged by Gharda are in fact irreparable. Gharda argues that it will suffer certain economic losses due to the inability to formulate, distribute, and sell chlorpyrifos products, including a loss of future sales of chlorpyrifos products, and that Gharda and its customers will face a loss of their investments in chlorpyrifos. EPA finds that Gharda's claims regarding the loss of future sales of chlorpyrifos products are too speculative to satisfy the requirement that injury ''must be actual and not theoretical.'' (*Olu-Cole,* 930 F.3d at 529) Gharda does not provide any basis for its assumptions regarding future revenues from chlorpyrifos other than a declaration from its president that contains an identical assertion as in the stay request and offers no further evidence. To provide but a few examples, these assumptions regarding future revenues could be undercut by changes in customer preferences, supply chain complications, and/or price fluctuations. Crucially, and in any event, Gharda does not claim that a failure to stay the final rule will threaten either its or its customers' very existences.

EPA notes that the 2020 PID proposed a subset of chlorpyrifos uses that might result in exposures below the Agency's level of concern if significant changes to the labels were made, including use cancellations and geographic limitations, among others. EPA also notes that the final rule does not foreclose Gharda's ability to sell or distribute its products outside of the United States for food applications in other jurisdictions, provided any such treated products are not imported into the United States in a manner inconsistent with FDA's channels of trade guidance. These possibilities undermine Gharda's assertion that any and all economic harms it has suffered or might suffer are irreparable.

EPA also notes that any potential economic injury suffered by Gharda has been significantly exacerbated by Gharda's independent business decisions. Gharda notes that in 2021 it increased production to meet demand for chlorpyrifos after Corteva exited the market, and that it now stands to incur certain losses due to its inability to formulate, distribute, and sell chlorpyrifos products. However, Gharda should have recognized that there was some risk to expanding production in light of the Agency's proposed findings in the 2020 PID (which indicated that some changes to existing registered products would likely be required, including some potentially significant changes), and following the issuance of the Ninth Circuit's decision in April of 2021.

More generally, pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* EPA conducted a small business analysis to assess the economic impact of the final rule on small entities. (Ref. 68) That analysis was prepared consistent with other analyses that are prepared for rules subject to notice and comment pursuant to the RFA, which requires an agency to consider the economic impacts that rules subject to notice and comment rulemaking will have on small entities. Since the final rule was not subject to notice and comment, the analysis was not required, but it was prepared to present information on the potential impact to small farms and possible job losses for industry as a result of the revocation of chlorpyrifos tolerances. Based on the analysis in the 2021 SBA memo, EPA concluded that there was not likely to be a significant impact on a substantial number of small entities and that there are unlikely to be significant job losses as a result of the revocation of the rule. Of the approximately 2 million farms currently in the United States, only an estimated 43,430 farms are using chlorpyrifos each year. For about 25,100 affected farms, the impacts of tolerance revocation are less than 1% of gross revenue. Up to 10,500 small farms could see impacts of between 1 and 3% of gross revenue per acre for affected crops. This is less than 1% of all small crop farms. An estimated 1,900 farms would see per-acre impacts of greater than 3%, about 0.13% of small farms producing crops. (Ref. 68 at pg. 2)

iii. Response to the Sugarbeet Associations' and Gharda's reputational arguments. EPA also disagrees with the Sugarbeet Associations' and Gharda's arguments regarding irreparable reputational injury. With respect to Gharda's arguments, EPA notes as a preliminary matter that Gharda claims that it ''has suffered'' reputational harm as a result of the final rule, and that EPA's revocation of the chlorpyrifos tolerances ''has . . . strain[ed]'' Gharda's customer relationships. (Ref. 67 at pg. 7) Even if EPA were to concede that Gharda has incurred such reputational injuries, staying the final rule would not resolve injuries that have allegedly already occurred. As a result, EPA will not further evaluate any reputational injuries Gharda alleges that it has already incurred for purposes of this first factor.

EPA will take the Sugarbeet Associations' and Gharda's remaining reputational arguments in turn. First, Gharda argues that by revoking chlorpyrifos tolerances, ''EPA has directly attacked the safety of chlorpyrifos . . . and the credibility of Gharda in selling and distributing chlorpyrifos products.'' (*Id.*) While EPA has determined that aggregate exposures to chlorpyrifos from currently registered uses are not safe, EPA categorically rejects Gharda's claim that EPA directly attacked Gharda's credibility. EPA finds it noteworthy that Gharda is unable to cite to a single source for this claim, other than a declaration from its president that simply contains a verbatim assertion as in the stay request and offers no further evidence. EPA also notes that the final rule did not single out Gharda's registered chlorpyrifos products. The final rule itself did not address any specific chlorpyrifos registered products or registrants; rather, the final rule revoked chlorpyrifos tolerances due to safety concerns with the chemical, not concerns with any specific registered product or individual company. Therefore, EPA finds no basis whatsoever for Gharda's claim that EPA attacked its credibility and thereby injured Gharda's reputation.

Second, Gharda asserts that because the final rule disregarded written commitments by Gharda prior to the final rule to modify Gharda's label consistent with EPA's proposal in the 2020 PID, and because ''Gharda assured its customers that it was working cooperatively with EPA to reach agreement that would allow for many continued agricultural uses,'' Gharda suffered reputational injury and a loss of customer goodwill. (*Id.* at pgs. 7 and 8) As already discussed in Unit VII.C.1.b.ii. of this Order, EPA entered into such discussions with Gharda in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. However, it simply was not practicable for EPA to complete any modifications or voluntary cancelations in time to inform the final rule and meet the Ninth Circuit's deadline. Furthermore, at no point during its discussions with Gharda did EPA make a binding commitment to modify chlorpyrifos tolerances instead of revoking them altogether. To the extent that Gharda informed its customers that EPA would modify chlorpyrifos tolerances instead of revoking them, that was an independent business decision made entirely by Gharda, and EPA cannot be held accountable for any consequences of that decision. Any reputational injuries suffered by Gharda as a result of assurances they provided their customers that EPA would modify chlorpyrifos tolerances are wholly attributable to Gharda.

Third, Gharda argues that in light of the scientific record for chlorpyrifos, neither Gharda nor its customers expected EPA to revoke all tolerances, and that EPA's decision to do so ''has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill.'' (*Id.*) EPA's review of the scientific record is already extensively detailed in the final rule and elsewhere in this Order, and EPA has made clear that based on its review of that record, it is unable to conclude that chlorpyrifos tolerances are safe due to the extent of currently registered uses. EPA also notes that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that on October 28, 2015 ((80 FR 69080, November 6, 2015) (FRL–9954–65)), EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. EPA also reiterates that the 2020 PID made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled under that proposed scenario. Finally, EPA notes that the Ninth Circuit rejected EPA's previous attempt to leave tolerances in place based on an argument that the petitioners had failed to provide sufficient data to support revoking the tolerances and found that the burden was on EPA to demonstrate that the tolerances were safe in order to leave them in place. The Court ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and therefore, a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Also, as noted in the preceding paragraph, any injury arising from Gharda's speculative discussions with its customers is an injury of Gharda's own making and not EPA's rule.

Fourth, Gharda argues that the final rule could result in long-term harm to Gharda due to ''the stigma attached to the unfounded public statements by EPA that its action was taken 'to ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of [chlorpyrifos],' and 'follow[s] the science and put[s] health and safety first.' '' (*Id.* at pg. 8, citing Ref. 57) The Sugarbeet Associations make a similar argument, claiming that because the final rule revoked chlorpyrifos tolerances despite the proposal in the 2020 PID concerning the 11 uses of chlorpyrifos identified by EPA, the sugarbeet industry is likely to suffer reputational harm in the form of ''ill-will . . . from customers and the public.'' It is not clear to EPA why that would be the case. The final rule makes no mention of Gharda or the Sugarbeet Associations at all and includes only a single reference to sugarbeets in its discussion of the 2020 DWA. (See Ref. 1 at pg. 48331) Nowhere in the final rule does EPA disparage sugarbeets, or single out chlorpyrifos applications on sugarbeets as presenting a unique risk to the public. Quite the opposite: EPA revoked *all* chlorpyrifos tolerances due to its inability to conclude that aggregate exposures from all chlorpyrifos uses would be safe. Additionally, while it is not established that Gharda's, the Sugarbeet Associations' or the sugarbeet industry's reputations will suffer as a result of the final rule, EPA's view is that a stay might in fact lead to the reputational harm the Sugarbeet Associations and Gharda are seeking to avoid. As described in the final rule and reiterated throughout this Order, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA, and as of February 28, 2022, those tolerances will no longer be in effect. Assuming the Sugarbeet Associations and their member entities and Gharda comply with the revocation and abide by the guidance issued by the FDA and USDA, EPA sees no reason why customers or the public should have any ill will toward these entities for simply complying with the FFDCA. On the other hand, if EPA were to stay the final rule after concluding that tolerances are unsafe, customers and the public might have concerns about the safety of chlorpyrifos residues on food products, and Gharda's and the Sugarbeet Associations' members' roles in making these products available to the public. Therefore, EPA disagrees with Gharda and the Sugarbeet Associations that they and/or the sugarbeet industry will suffer irreparable reputational injury due to the final rule.

iv. Response to Gharda's due process argument. Finally, EPA disagrees with Gharda that EPA has infringed its due process rights via the final rule. As a preliminary matter, EPA notes that Gharda's stay request omits a key element of the due process analysis. Gharda's request characterizes ''the deprivation of a legally protectable property right (i.e., pesticide registration)'' as a due process violation. However, as Gharda itself makes clear in its Objections to the final rule, any such deprivation must also be ''unreasonable, arbitrary or capricious.'' (Ref. 67 at pg. 37 (*citing Nebbia* v. *New York,* 291 U.S. 502, 525 (1934))) As EPA explains in more detail in Unit VII.C.5.g. of this

Order, Gharda has failed to provide information sufficient to establish that the final rule unfairly or arbitrarily revoked chlorpyrifos tolerances. EPA also notes that as a legal matter, the final rule does not in fact effectuate a cancellation of Gharda's registrations. Instead, the final rule simply revokes chlorpyrifos tolerances. As a result, it cannot be said that the final rule infringed Gharda's substantive due process rights and thereby caused Gharda irreparable harm.

b. Were the Sugarbeet Associations' and Gharda's cases for a stay frivolous, and not pursued in good faith?

EPA generally believes that the Sugarbeet Associations' and Gharda's requests for a stay were made in good faith and reflect their concern about the potential implications of the final rule for their and their represented entities' business interests and/or ability to produce food (as the case may be). Chlorpyrifos has been an available insecticide for decades, and EPA recognizes that many growers have come to rely on it as a tool for controlling insect pests. Nor is there any indication in their requests for stay that the Sugarbeet Associations or Gharda are making frivolous arguments; EPA's impression is that the Sugarbeet Associations' and Gharda's requests for stay appear to reflect their good-faith interpretation of 21 CFR 10.35. As discussed in Unit VIII.B.2.a.iii., EPA note that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that in 2015 EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. The 2020 PID also made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled. Finally, the Ninth Circuit ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and that a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, the Sugarbeet Associations and Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Notwithstanding this fair warning, however, EPA generally agrees with these Objectors that their cases for a stay are not frivolous and are being pursued in good faith.

c. Have the Sugarbeet Associations and Gharda demonstrated sound public policy grounds supporting a stay?

The Sugarbeet Associations and Gharda each argue that public policy grounds support their stay requests, though EPA notes that the Sugarbeet Associations combined this factor and the fourth factor into a single discussion. Both of these Objectors' arguments on this point incorporate several of the arguments raised in their objections, which were submitted under separate cover: That good public policy does not support regulatory decisions that are at odds with EPA's "best available science" and the 2020 PID; that EPA issued the final rule in a process that was fundamentally unfair and marked by bad faith; that EPA disregarded cancelation procedures, prior public comments, and interagency review processes, and abdicated its responsibility to oversee a lawful and orderly phase-out of chlorpyrifos products; and that the final rule will result in economic harms to U.S. growers and environmental harms from increased application of chlorpyrifos alternatives. Gharda also argues that the timeframe imposed by the final rule "will result [in] the needless waste of safe and wholesome food," (Ref. 67 at pg. 11) and the Sugarbeet Associations include a general assertion that chlorpyrifos "is used only when and only as much as necessary." (Ref. 66 at pg. 9)

EPA finds that the Sugarbeet Associations and Gharda have failed to demonstrate sound public policy grounds supporting a stay of the final rule. First, EPA notes that most of the arguments marshaled by the Sugarbeet Associations and Gharda on this point are simply restatements of their objections to the final rule, and that these Objectors frequently fail to explain how exactly any particular public policy is furthered by these objections. For example, the Sugarbeet Associations argue that EPA's alleged failure to consider relevant scientific information, as indicated by its decision to revoke chlorpyrifos despite the 2020 PID, is itself a reason that the public interest supports a stay. However, the Sugarbeet Associations do not elaborate on how or why that alleged failure relates to sound public policy or furthers the public interest or in this particular case, supports a conclusion that EPA erred in concluding that chlorpyrifos tolerances were unsafe. Similarly, Gharda argues that the final rule will cause significant hardship to U.S. growers who might need to rely on more expensive and/or less effective alternatives to chlorpyrifos but does not explain in its stay request why that is a matter of public interest, rather than an issue of concern particular to those growers.

Second, EPA notes by requesting a stay "until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections," while failing to define what exactly constitutes a "final resolution," the Sugarbeet Associations and Gharda are essentially asking for the final rule to be stayed indefinitely. Even if EPA interprets "final resolution" as being limited to the conclusion of judicial review of the final rule—which EPA notes is a much narrower interpretation than the plain language of these Objectors' request—it is extremely unlikely that this matter would be fully and finally resolved by the courts for at least two or three years. FFDCA section 408(h)(1) provides that any person who will be adversely affected by the final rule may obtain judicial review in the relevant U.S. Court of Appeals. Review in the Court of Appeals may, by itself, take several years; for example, over a year and a half elapsed between the LULAC Petitioners' and States' August 7, 2019, petition in the Ninth Circuit for review of the Denial Order and Final Order and the Ninth Circuit's decision on April 29, 2021. However, the process could take still longer, since FFDCA section 408(h)(4) provides that the judgment of the court affirming or setting aside the final rule is subject to review by the Supreme Court of the United States. Even if the Supreme Court denies certiorari, significant time will have elapsed before it could reasonably be said that there has been a "final resolution" in terms of judicial review of the final rule. Furthermore, EPA is confident in its legal and scientific analyses, and sees no compelling policy rationale for staying the final rule and leaving chlorpyrifos tolerances in place pending judicial review. Doing so would only perpetuate the public's exposure to the unsafe levels of chlorpyrifos that the Agency identified based on its review of the science and the aggregation of relevant exposures from all currently registered uses, all to mitigate the potential for impacts to Gharda and/or the sugarbeet industry. EPA's position is that there are no sound public policy grounds supporting such a course of action.

It is also clear to EPA that the Sugarbeet Associations' and Gharda's ultimate goal with respect to their stay requests is the rescission or revocation of the final rule. This is evident from the fact that the Sugarbeet Associations and Gharda incorporate many of the arguments made in their objections, which request that the final rule be immediately or summarily reversed, and from Gharda's stay request, which discusses the economic losses Gharda will allegedly face if the final rule is not ''reversed or rescinded.'' To the extent the Sugarbeet Associations and Gharda are seeking to utilize the stay process to rescind the final rule, EPA notes that there is no need for EPA to stay the final rule simply to give the Sugarbeet Associations and Gharda more time to file litigation seeking rescission. EPA has outlined the relevant judicial review process in the preceding paragraph, and notes that there is no barrier to the Sugarbeet Associations and Gharda deciding to pursue judicial review of the final rule through a challenge to this Order. Nor does EPA believe that any public policy interest is furthered by such a course of action.

In light of the foregoing, EPA has significant concerns that the Sugarbeet Associations and Gharda are seeking to use the stay process to compel the consideration of factors not permitted by the FFDCA, thereby keeping chlorpyrifos tolerances in place despite EPA's inability to make the safety finding required by the FFDCA and the Ninth Circuit. By arguing that public policy grounds favor an effectively indefinite stay of the final rule due to the potential for economic harm, the Sugarbeet Associations and Gharda are asking EPA to keep chlorpyrifos tolerances in place despite EPA's inability to make a statutorily required safety finding for these tolerances and despite the fact that the FFDCA safety standard does not permit consideration of economic costs or benefits. This is a significant request, and EPA expects any party making such a request to demonstrate in detail how it furthers the public interest. However, as noted in the preceding paragraph, the Sugarbeet Associations and Gharda fail to sufficiently explain how the stay request is in the public interest at all, much less how any such public interest warrants deviating from the plain language of the FFDCA. EPA's position is that there are in fact overwhelming public policy grounds supporting EPA's reliance on the plain language of the FFDCA, particularly given the public health concerns underlying that statute.

Specifically, there is a significant public policy argument in favor of the Agency fulfilling its statutory obligation to follow the law as it was enacted by Congress. As enacted by Congress, section 408 of the FFDCA is clear that in order to leave tolerances in place, EPA must determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos, including all anticipated dietary exposures and all other exposures for which there is reliable information. If the tolerances are not safe, EPA must modify or revoke them; any tolerances so modified, however, must also be safe. As discussed throughout this document, the FFDCA does not permit consideration of economic factors in the Agency's determination of safety. There is a compelling public policy argument that EPA must act in accordance with Congress' intent, as evidenced by the plain language of the statute. As a result, EPA's analysis in the final rule was necessarily limited to an assessment of aggregate exposures, including dietary, residential, and drinking water exposures, as instructed by the statute. Because EPA could not determine that such aggregate exposures were safe, EPA revoked tolerances for chlorpyrifos. Furthermore, EPA notes that to disregard the clear statutory language would also entail turning a blind eye to EPA's inability to find that chlorpyrifos tolerances are safe. That is, EPA taking action in direct contravention of the FFDCA is not only poor public policy from an administrative law standpoint, but also from a public health perspective. EPA considers the protection of public health to be a matter of overwhelming importance and is not inclined to so readily disregard its own inability to conclude that chlorpyrifos tolerances are safe.

Notwithstanding, EPA is not saying that it is precluded from ever delaying an effective date of a tolerance revocation rule. In a proposed order granting objections to revoke sulfuryl fluoride tolerances, EPA proposed to phase-out tolerances over varying periods of time due to lack of alternatives and the relatively low contribution of harm coming directly from the use of the pesticide itself as opposed to naturally occurring fluoride. (*See* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay (76 FR 3422, January 19, 2011 (FRL–8867–9))) But that is not the case here: For chlorpyrifos, the use of the pesticide itself is directly contributing to harmful aggregate exposures, there are some alternatives, and EPA has already delayed the expiration of the revoked tolerances. Therefore, EPA concludes that there are not compelling public policy grounds to further delay in light of the Agency's finding that the chlorpyrifos tolerances are not safe.

With respect to Gharda's argument that the final rule will ''result [in] the needless waste of safe and wholesome food,'' EPA notes that Gharda is incorrect. FFDCA section 408(l)(5) provides for the continued distribution of food treated with chlorpyrifos as long as the conditions in that provision are met. Moreover, FDA has developed guidance describing how FDA intends to monitor any foods containing chlorpyrifos residues and detailing intentions concerning enforcement. (Ref. 65) As a general matter, implementation of the FDA guidance will not result in the ''needless waste'' of food since foods treated with chlorpyrifos prior to the expiration of the tolerances on February 28, 2022, will continue to move through the channels of trade for the next few years consistent with the terms of section 408(l)(5) and the guidance. Therefore, as implemented, EPA does not anticipate that the final rule will result in the disposal of massive amounts of foods treated with chlorpyrifos, or in any ''needless waste.''

Finally, while the Sugarbeet Associations include a general assertion that chlorpyrifos ''is used only when and only as much as necessary,'' EPA again notes that the Sugarbeet Associations fail to demonstrate how that assertion supports a determination that sound public policy grounds support a stay of the final rule. EPA has provided significant detail in the final rule and in this Order describing the analysis supporting its revocation of revoking chlorpyrifos tolerances, which analysis included consideration of estimated exposures from all approved uses of chlorpyrifos.

d. Is the delay resulting from the stay outweighed by public health concerns or other public interests?

The Sugarbeet Associations and Gharda each argue that the delay resulting from a stay is not outweighed by public health concerns or other public interests, though as noted the Sugarbeet Associations combined this factor and the third factor into a single discussion. Gharda's arguments in support of this factor are brief and conclusory. Gharda argues that ''[t]here are no public health or other public interests that will be adversely impacted by granting a stay,'' referencing back to its arguments that the final rule is at odds with the 2020 PID, that EPA incorrectly applied the 10X FQPA safety factor, and that the final rule will result in economic and environmental harms. (Ref. 67 at pg. 11) Similarly, the Sugarbeet Associations state that the ''weighing of the public interest supports a stay'' based on the potential economic harm to growers if no stay is granted, as well as ''the corresponding lack of public health or public interest counseling against a stay.'' (Ref. 66 at pg. 9)

EPA disagrees with the Sugarbeet Associations and Gharda and finds that the delay resulting from an effectively indefinite stay of the final rule is outweighed by public health concerns and other public interests. First, EPA strongly disagrees with the Sugarbeet Associations and Gharda that there are no public health concerns or other public interests counseling against a stay. Most obviously, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA. Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe. While FFDCA section 408(l)(5) and the FDA's Channels of Trade guidance will continue to allow some foods treated with chlorpyrifos to move through the channels of trade, the revocation and expiration of the tolerances will ensure that no chlorpyrifos is used on food after the expiration, thus, limiting the ultimate universe of foods that may contain chlorpyrifos residues to less than what would be available if EPA stayed the rule. Moreover, the final rule's revocation of chlorpyrifos tolerances, which precludes continued application to food crops, would also prevent additional contributions of chlorpyrifos from ending up in drinking water due to its use on food. EPA does not take lightly the FFDCA's clear mandate that tolerances may only be left in place if they are safe and views the safety of pesticide chemical residues on food as a significant public health concern and a matter of overwhelming public interest.

Nor have the Sugarbeet Associations or Gharda presented any persuasive evidence in support of this position. The Sugarbeet Associations simply state that there is a ''lack of public health or public interest counseling against a stay,'' and provide no support whatsoever for this proposition. Gharda makes a similar assertion, and then includes a few sentences briefly referencing arguments made in its objections. However, Gharda does not identify how these points, which appear to be made almost in passing, support their argument that there is a complete absence of public health or other public interests that will be adversely impacted by granting a stay.

Second, EPA is unsettled by the open-ended nature of the Sugarbeet Associations' and Gharda's stay requests, which ask EPA to stay the final rule ''until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections.'' EPA notes that neither Objector defines or otherwise limits what exactly might constitute such a ''final resolution,'' particularly since their requests include, but are not limited to, potential judicial review. As a result, EPA views Objectors' request as at best an indefinite stay of the final rule, and at worst as an attempt to effectively rescind the final rule via the stay process—all in direct contravention of a statutory mandate that requires EPA to determine that tolerances are safe in order to leave them in place. While EPA does not necessarily require requests for stays to include a specific timeframe for the duration of the requested stay, EPA does not believe that the public interest is served by granting a stay with such ill-defined parameters. This is particularly true where, as is the case here, the subject matter bears directly on public health concerns. If EPA were to indulge Objectors' requests and stay the final rule on this basis, and after several years Objectors exhaust their judicial avenues for challenging the final rule, Objectors could nonetheless continue to assert that any or all of the specific issues raised in their objections have not been fully resolved and that the stay should continue. As a result, EPA would necessarily have to agree to a definable endpoint for the stay. EPA cannot agree to this indefinite postponement, particularly in light of its inability to conclude that chlorpyrifos tolerances are safe.

Finally, EPA recognizes that the Sugarbeet Associations' and Gharda's requests ask EPA to continue relying on the precise approach for which EPA was so recently and explicitly chastised by the Ninth Circuit. That is, EPA is asked to set aside the final rule in order to engage in ''further factfinding after thirteen years of interminable delay,'' which the Ninth Circuit stated, ''would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself.'' (*LULAC,* 996 F.3d at pg. 702) In light of the Ninth Circuit's clear frustration with EPA for its long delay, EPA is unwilling to return to an approach that would result in further delay for more study of chlorpyrifos tolerances, all in pursuit of an amorphous ''final resolution'' of the Sugarbeet Associations' and Gharda's various concerns. As reiterated several times herein, EPA is unable to conclude that chlorpyrifos tolerances are safe. The statute does not permit EPA to leave tolerances in place when it cannot conclude that they are safe. As a result, EPA refuses to further delay revoking chlorpyrifos tolerances.

e. Denial of the Sugarbeet Associations' and Gharda's Stay Requests

As stated in the regulation, the Agency shall grant a stay if all four of the criteria in 21 CFR 10.35(e) are satisfied. As explained previously, EPA find that the Sugarbeet Associations and Gharda have failed to satisfy three of the four criteria in 21 CFR 10.35(e). Consequently, EPA denies the Sugarbeet Associations' and Gharda's requests for a stay of the final rule.

IX. Earthjustice Feedback and Comments

A. Overview

On October 28, 2021, prior to the close of the objections period, Earthjustice submitted a document titled *LULAC Petitioners' Feedback on the Environmental Protection Agency's Chlorpyrifos Tolerance Revocation Rule and Comments on Growers' Objections* on behalf of the following 12 public interest groups: League of United Latin American Citizens, NRDC, PANNA, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers. (Ref. 69) Earthjustice previously submitted objections to the 2017 Order Denying Petition on behalf of these same 12 public interest groups in June 2017. Earthjustice also represented these 12 public interest groups in their lawsuit challenging the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial before the Ninth Circuit Court of Appeals, in which they sought to have the chlorpyrifos tolerances revoked.

Notably, Earthjustice does not object to the final rule's revocation of tolerances for chlorpyrifos. On the contrary Earthjustice's submission says that ''[t]he LULAC petitioners . . . celebrate EPA's action.'' (*Id.* at pg. 1) Rather, these comments are primarily focused on arguments that Earthjustice (on behalf of the advocacy groups) believes the Agency must consider and address in the event that chlorpyrifos tolerances would be retained or reinstated at a future time. For the most part, Earthjustice reiterates arguments that it has made previously in its objections to the 2017 Order Denying Petition, including that use of 10% cholinesterase inhibition as the regulatory endpoint, which EPA used in the final rule, is underprotective, even with the retention of the 10X FQPA safety factor, and should not be used as precedent in future registration review actions for non-food uses of chlorpyrifos or for other organophosphate pesticides.

Earthjustice asserts that, as a scientific and legal matter, EPA is unable to make a finding of reasonable certainty of no harm using 10% cholinesterase inhibition as the regulatory endpoint. Earthjustice alleges that not only does the science support the conclusion that neurodevelopmental harms occur below levels of this regulatory endpoint, but the record and the Ninth Circuit's decision in *LULAC* foreclosed EPA from making such a finding. Earthjustice also takes issues with certain EPA statements in the final rule, which Earthjustice argues are intended to ''disparage'' the causal link between chlorpyrifos exposure and neurodevelopmental harm to children. Earthjustice believes that these statements are at odds with the record and unsupported. Finally, Earthjustice reiterates arguments made previously in response to EPA's 2017 Order Denying Petition that the final rule's retention of the 10X FQPA safety factor is not sufficient to ensure reasonable certainty of no harm to children.

B. Response to Earthjustice's Feedback and Comments

Because EPA is leaving the final rule in place as promulgated in August 2021 and not leaving any tolerances in place, EPA does not believe the Earthjustice comments necessitate a response at this time. While the comments might be relevant in the event that tolerances were retained or in any future action in which EPA considers petitions to establish chlorpyrifos tolerances, they are not relevant to a final rule that revokes tolerances. EPA does not need to address any of these comments as part of this Order, as they are not ripe for consideration at this time.

X. Conclusion

For all of the reasons specified in Unit VI., VII., and VIII. of this document, EPA denies, in full, the objections and requests for hearing on those objections and requests for stay, respectively.

XI. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying objections filed under the FFDCA section 408. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

XII. Congressional Review Act (CRA)

The CRA, 5 U.S.C. 801 *et seq.,* does not apply to this Order because this action is not a rule for purposes of 5 U.S.C. 804(3).

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

1. U.S. EPA. Chlorpyrifos; Tolerance Revocations; Final Rule. **Federal Register**. 86 FR 48315, August 30, 2021 (FRL–5993–04–OSCPP).
2. U.S. EPA (2020). Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review. September 22, 2020. Available at *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944.*
3. U.S. EPA (2000). Available Information on Assessing Exposure From Pesticides In Food: A User's Guide. June 21, 2000. Available at *https://www.doh.wa.gov/Portals/1/Documents/4000/PASW_exposurefood.pdf.*
4. U.S. EPA, Office of Research and Development (2000). Benchmark Dose Technical Guidance Document. External Review Draft. October 2000. EPA Document ID. No. EPA/630/R–00/001.
5. FIFRA Science Advisory Panel (2002). Methods Used to Conduct a Preliminary Cumulative Risk Assessment for Organophosphate Pesticides. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 5–7, 2002. Report dated March 19, 2002. Available at *https://archive.epa.gov/scipoly/sap/meetings/web/pdf/final-4.pdf.*
6. FIFRA Science Advisory Panel (2005). Final Report on Preliminary N-Methyl Carbamate Cumulative Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of August 23–25, 2005. Report dated October 13, 2005. Available at: *http://www.epa.gov/scipoly/sap/2005/august/minutes.pdf.*
7. U.S. EPA (2018). Science in Action: Physiologically-Based Pharmacokinetic (PBPK) Models. February 2018. Available at *https://www.epa.gov/sites/default/files/2018-02/documents/pbpk_factsheet_feb2018_0.pdf.*
8. U.S. EPA (2014). Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation. September 2014. EPA Document ID No. EPA/100/R–14/002F. Available at: *https://www.epa.gov/sites/default/files/2015-01/documents/ddef-final.pdf.*
9. U.S. EPA (2002). Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Assessment. February 28, 2002. Available at: *https://www.epa.gov/sites/default/files/2015-07/documents/determ.pdf.*
10. U.S. EPA (1996). Residue Chemistry Test Guidelines: OPPTS 860.1500 Crop Field Trials. August 1996. EPA Document ID No. 712–C–96–183. Available at: *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0155-0013.*
11. U.S. EPA (2000). Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern. March 16, 2000. Available at: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/choosing-percentile-acute-dietary-exposure.*
12. FIFRA Scientific Advisory Panel (2020). Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments. Final Report from the FIFRA Scientific Advisory Panel Meeting of November 19–21, 2019. Report dated February 18, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2019-0417-0019.*
13. U.S. EPA (2020). Framework for Conducting Pesticide Drinking Water Assessments for Surface Water. September 2020. Available at: *https://www.epa.gov/sites/default/files/2020-09/documents/framework-conducting-pesticide-dw-sw.pdf.*
14. U.S. EPA (2001). General Principles for Performing Aggregate Exposure and Risk Assessments. November 28, 2001. Available at: *https://www.epa.gov/sites/default/files/2015-07/documents/aggregate.pdf.*
15. U.S. EPA (2020). Appendix B. Case Study for Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment. June 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0279-0002.*
16. U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment. October 2012. Available at: *https://www.epa.gov/sites/default/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.*
17. U.S. EPA (2000). Office of Pesticide Programs Science Policy on: The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides. August 18, 2000. Available at: *https://www.epa.gov/sites/default/files/2015-07/documents/cholin.pdf.*
18. U.S. EPA (2011). Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. June 30, 2011. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0025.*
19. U.S. EPA (2016). Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides. December 28, 2016. Available at: *https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.*

20. U.S. EPA (2014). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. December 29, 2014. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0195.*
21. FIFRA Scientific Advisory Panel (2012). Scientific Issues Associated with Chlorpyrifos. Final Report from the FIFRA Scientific Advisory Panel Meeting of April 10–12, 2012. Report dated July 11, 2012. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2012-0040-0029.*
22. FIFRA Scientific Advisory Panel (2016). Analysis of Biomonitoring Data. Final Report from the FIFRA Scientific Advisory Panel Meeting of April 19–21, 2016. Report dated July 20, 2016. Available at: *https://www.epa.gov/sites/default/files/2016-07/documents/chlorpyrifos_sap_april_2016_final_minutes.pdf.*
23. U.S. EPA (2020). The Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment. August 25, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0033.*
24. FIFRA Scientific Advisory Panel (2020). Peer Review of the Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of September 15–18, 2020. Report dated December 15, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0054.*
25. U.S. EPA (2006). Reregistration Eligibility Decision for Chlorpyrifos. July 31, 2006. Available at: *https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-059101_1-Jul-06.pdf.*
26. U.S. EPA (2011). Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment. June 20, 2011. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0026.*
27. U.S. EPA (2014). Updated Drinking Water Assessment for Registration Review. December 23. 2014. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0198.*
28. U.S. EPA (2016). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. November 3, 2016. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0454.*
29. U.S. EPA (2016). Chlorpyrifos Refined Drinking Water Assessment for Registration Review. April 14, 2016. *https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437.*
30. U.S. EPA (2020). Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review. September 15, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.*
31. U.S. EPA (2020). Chlorpyrifos Proposed Interim Registration Review Decision. December 3, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971.*
32. FIFRA Scientific Advisory Panel (2008). The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos. Final Report from the FIFRA Scientific Advisory Panel Meeting of September 16–18, 2008. Report dated December 17, 2008. Available at: *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0274-0064.*
33. FIFRA Scientific Advisory Panel (2010). Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 2–4, 2010. Report dated April 22, 2010. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2009-0851-0059.*
34. The Petition from NRDC and PANNA, EPA's various responses to it, and the objections submitted on the Petition denial are available in docket number EPA–HQ–OPP–2007–1005 at *https://www.regulations.gov.*
35. U.S. EPA (2009). Chlorpyrifos Final Work Plan. September 25, 2009. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0020.*
36. American Soybean Association. Objections, Request for Evidentiary Hearing, Request to Stay Tolerance Revocations. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0022.*
37. American Sugarbeet Growers Association, U.S. Beet Sugar Association. Objections to Decision Revoking All Chlorpyrifos Tolerances. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0029.*
38. Cherry Marketing Institute. Formal Written Objections and Request for Evidentiary Hearing for Chlorpyrifos Tolerance Revocation. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0024.*
39. Gharda Chemicals International, Inc.'s Objections to the Final Rule Revoking All Tolerances for Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0028.*
40. U.S. EPA, Administrative Law Judge (2020). Order Urging Electronic Service and Filing. April 10, 2020. Available at: *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.*
41. Columbia Ministry of Trade, Industry and Tourism. Comment. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0027.*
42. Drexel Chemical Company. Objections, Request for Stay, Request for Product Phase Out. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0021.*
43. International Pepper Community. Comment. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0014.*
44. Oregonians for Food & Shelter. Formal Objections and Request to Stay Tolerance Revocation of Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0023.*
45. Republic of Ecuador. Comments on Chlorpyrifos: Tolerance Revocations Rule by the EPA. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0026.*
46. National Association of Wheat Growers. Comment. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0016.*
47. Agricultural Retailers Association et al. Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0007.*
48. Cranberry Industry comments on EPA's Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1075.*
49. Minor Crop Farmer Alliance. Objections to the Revocation of Chlorpyrifos Tolerances Final Rule. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0018.*
50. CropLife America and Responsible Industry for a Sound Environment. Objections, Request for Stay, Request for Guidance. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0004.*
51. U.S. EPA (2021). List of External Meetings Between EPA and Chlorpyrifos Stakeholders. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0002.*
52. California Citrus Quality Council. Objections to the Revocation of Chlorpyrifos Tolerances Final Rule. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0019.*
53. Coalition of Organophosphate (OP) Registrants. Written Objection on Chlorpyrifos Tolerance Revocation Final Rule. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0003.*
54. U.S. EPA (2020). EPA Requests Comments on New Methodologies to Estimate Pesticide Concentrations in Surface Waters. January 15, 2020. See announcement at: *https://www.epa.gov/pesticides/epa-requests-comments-new-methodologies-estimate-pesticide-concentrations-surface-waters.*
55. Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (1993). Guidance for Implementing E.O. 12866. October 12, 1993. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/inforeg/eo12866_implementation_guidance.pdf.*
56. U.S. EPA (2020). Revised Benefits of Agricultural Uses of Chlorpyrifos s (PC#

059101). November 18, 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969.*

57. U.S. EPA (2021). EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health. Announcement. August 18, 2021. Available at: *https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.*
58. Republic of Columbia. Comment. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0020.*
59. World Trade Organization (WTO). The WTO Agreement on the Application of Sanitary and Phytosanitary Measures. Available at: *https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.*
60. The Codex website contains a listing of current chlorpyrifos MRLs. (Last viewed February 13, 2022). Available at: *https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=17.*
61. WTO (2001). Doha Decision on Implementation-Related Issues and Concerns. WT/MIN(01)/17 (2001).
62. Michigan Vegetable Council. Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0005.*
63. U.S. EPA (2022). Frequent Questions about the Chlorpyrifos 2021 Final Rule. (Last viewed February 13, 2022). Available at: *https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-10.*
64. Willard Jack. Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0013.*
65. U.S. FDA (2022). Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues. February 2022. Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities.*
66. Sugarbeet Associations. Request for Stay of Decision Revoking All Chlorpyrifos Tolerances. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0029.*
67. Gharda. Petition to Stay the Effective Date of the Revocation of All Tolerances for Chlorpyrifos. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0028.*
68. U.S. EPA (2021). Chlorpyrifos Revocation Small Business and Employment Analysis. August 12, 2021. Available at: *https://www.regulations.gov/docket/EPA-HQ-OPP-2021-0523.*
69. Earthjustice. LULAC Petitioners' Feedback on the Environmental Protection Agency's Chlorpyrifos Tolerance Revocation Rule and Comments on Growers' Objections. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0017.*

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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EXHIBIT 21

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)

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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).

References

Almond Board of California. 2015. Personal communication to EPA OPP BEAD in the summer of 2015.

Bakker, J. 2016. Comment submitted by John Bakker, Manager, Michigan Asparagus Industry Research Farm. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0308

Bean, B. 2019. Sugarcane aphid, how far we've come. *Sorghum Grower*. Spring 2019: 22-23. Available at: https://sorghumgrowers.com/wp-content/uploads/2019/05/Spring2019.pdf

Boetel, M. 2016. Comment submitted by Dr. Mark A. Boetel, Professor of Entomology, North Dakota State University (NDSU). Available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0364.

Bouchard, M. F., Chevrier, J., Harley, K. G., Kogut, K., Vedar, M., Calderon, N., *et al.* (2011). Prenatal exposure to organophosphate pesticides and IQ in 7-year-old children. *Environ Health Perspect*, 119(8), 1189-1195.

Bowling R., M. Brewer, S. Biles, and J. Gordy. 2015 Occurrence of Sugarcane Aphid in the U.S. and Mexico With Reference to Occurrence in 2013 and 2014. Texas Plant Protection Conference, Bryan, TX. Available at: http://agrilife.org/ccag/files/2015/12/2015-BowlingTPPA.pdf.

Bowling, R.D., M.J. Brewer, D.L. Kerns, J. Gordy, N. Seiter, N.E. Elliott, G.D. Buntin, M.O. Way. T.A. Royer, S. Biles, and E. Maxson. 2016. Sugarcane Aphid (Hemiptera: Aphididae): A New Pest on Sorghum in North America. *J. Integr. Pest Manage*. 7: 12 pp. https://doi.org/10.1093/jipm/pmw011

CDPR. 2019. California Department of Pesticide Regulation. Agreement Reached to End Sale of Chlorpyrifos in California by February 2020. Available at: https://www.cdpr.ca.gov/docs/pressrls/2019/100919.htm#:~:text=All%20sales%20of%20chlorpyrifos%20products,31%2C%202020.

Daane, K. M., G.Y. Yokota, and H. Wilson. 2019. Seasonal Dynamics of the Leaffooted Bug *Leptoglossus zonatus* and Its Implications for Control in Almonds and Pistachios. *Insects* Vol. 10: 255-266.

Dapsis, L. J. and D. N. Ferro. 1982. Crop loss assessment methods for the cabbage maggot, (Diptera: Anthomyiidae) in cabbage. *J. Econ. Entomol*. 75: 777-780.

Diepenbrock, L. M., L. Stelinski, J. Qureshi, and P. A. Stansly. 2019a. 2019-2020. Florida Citrus Production Guide: Soft-bodied Insects Attacking Foliage and Fruit. UF IFAS Extension Publication number ENY-604. Available at: https://crec.ifas.ufl.edu/media/crecifasufledu/production-guide/Soft-Bodied.pdf

Diepenbrock, L. M., P.A. Stansly, L.L. Stelinski, J.D. Burrow, and J.A. Qureshi. 2019b. Quick Reference Guide to Citrus Insecticides and Miticides. UF IFAS Extension Publication number ENY-854. Available on the web at https://edis.ifas.ufl.edu/pdffiles/IN/IN80700.pdf

Engel, S. M., Berkowitz, G. S., Barr, D. B., Teitelbaum, S. L., Siskind, J., Meisel, S. J., Wolff, M. S. (2007). Prenatal organophosphate metabolite and organochlorine levels and performance on the Brazelton Neonatal Behavioral Assessment Scale in a multiethnic pregnancy cohort. *Am. J. Epidemiol.* 165(12), 1397-1404.

Engel, S. M., Wetmur, J., Chen, J., Zhu, C., Barr, D. B., Canfield, R. L., & Wolff, M. S. (2011). Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood. *Environ Health Perspect*, 119(8), 1182-1188.

Eskenazi, B., Marks, A. R., Bradman, A., Harley, K., Barr, D. B., Johnson, C., Jewell, N. P. (2007). Organophosphate pesticide exposure and neurodevelopment in young Mexican American children. *Environ Health Perspect*, 115(5), 792-798.

FIFRA Scientific Advisory Panel (2002). "Organophosphate Pesticides: Preliminary OP Cumulative Risk Assessment." Information on how to obtain the meeting report is available on the web at http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings

FIFRA Scientific Advisory Panel (2008). "The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos." Report from the FIFRA Scientific Advisory Panel Meeting of September 16-19, 2008. Available on the web at http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.

FIFRA Scientific Advisory Panel (2012). "Scientific Issues Associated with Chlorpyrifos". Available on the web at http://www2.epa.gov/sap/meeting-materials-april-10-12-2012-scientific-advisory-panel.

Goodhue, R., K. Mace, J. Rudder, T. Tolhurst, D. Tregeagle, H. Wei, E. Grafton-Cardwell, I. Grettenberger, H. Wilson, R.t Van Steenwyk, and J. Steggall. 2019. Economic and Pest Management Evaluation of the Withdrawal of Chlorpyrifos: Six Major California Commodities. An analysis prepared for the Department of Pesticide Regulation by the California Department of Food and Agriculture's Office of Pesticide Consultation and Analysis and the University of California. Available on the web at https://www.cdfa.ca.gov/files/pdf/ChlorpyrifosReport.pdf.

Grafton-Cardwell, B. 2015, Comment submitted by J. Morse. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0138

Hebert, A., E. Blinka, J. Bacheler, J. VanDuyn, J. Greene, M. Toews, P. Roberts, and R.H. Smith, (2009). Managing Stinkbugs in Cotton: research in the Southeast Region. Publication # 444-390 of the Virginia Cooperative Extension Service. Available on the web at http://pubs.ext.vt.edu/444/444-390/444-390.html.

Hoepting, C.H., and B. Nault, (2012). New Seed Treatment Options for Onion Maggot: What Growers Need to Know. Available at: https://rvpadmin.cce.cornell.edu/uploads/doc_36.pdf

Hollingsworth, C.S., Editor. 2019. Pacific Northwest Insect Management Handbook [online]. Corvallis, OR: Oregon State University. http://pnwhandbooks.org/insect.

Horton, D.L., (2016). Comment submitted by Dan Horton, University of Georgia. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0054

Humfeld, T. 2016. Comment submitted by Terry Humfeld, Executive Director, Cranberry Institute (CI). Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0298

Ingels, C., D. Haviland, and S. Quashnick, (2012). Integrated Pest Management for Vine Mealybugs in Wine Grapes. Tree and Vine Newsletter, A publication of the Cooperative Extension Service for Sacramento County. Available on the web at http://cesacramento.ucanr.edu/news/Tree_-_Vine_News/.

James, S. 2015. Comment submitted by S. James, University of Georgia Extension Services Agriculture and Natural Resources Agent for Meriwether County, Georgia. Available on the web at www.regulations.gov using Comment ID epa-hq-opp-2015-0653-0239.

Jesse, W. and A.J. Dreves. 2020. Biology and Control of the Garden Symphylan. Pacific Northwest Insect Management Handbook. Available on the web at https://pnwhandbooks.org/insect/ipm/garden-symphylan.

Kahn, M. 2016. Comment submitted by M. Khan. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0178

Knutson, A. and B. Ree, (2015). Controlling the Pecan Nut Casebearer. Texas A&M University Extension Service Publication E-173. Available on the web at http://lubbock.tamu.edu/files/2015/06/PNC_Guide.pdf.

Korson, P. 2016. Comment submitted by Phil Korson, President, Cherry Marketing Institute. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0203

Kynetec USA, Inc. 2016. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 1998-2014.

Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 1998-2018.

LSU. 2016. Louisiana State University Ag Center. Sorghum Hybrids That Offer Some Protection from Sugarcane Aphid with Expected Availability in 2016. Publication # 3523 https://www.lsuagcenter.com/NR/rdonlyres/EF5A0F6C-B46D-4C16-9E8F-C355F5B7DE90/105488/Pub3523SorghumHybrids_FINAL.pdf

Morrison, W.R., S. Linderman, M.K. Hausbeck, B.P. Werling, and Z. Szendrei (2014). Disease and Insect Pests of Asparagus. Extension Bulletin E3219 of the Michigan State University. Available on the web at https://www.canr.msu.edu/resources/disease_and_insect_pests_of_asparagus_e3219_1.

Morse, J. 2015. Comment submitted by J. Morse. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0138

Mossler, M.A. 2012. Florida Crop/Pest Management Profiles: Strawberry. University of Florida, Florida Cooperative Extension Service Publication CIR1239. Available on the web at https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.574.7616&rep=rep1&type=pdf.

MSU. 2015. Insect Control Guide for Agronomic Crops. Available from Mississippi State University on the web at http://msucares.com/insects/cotton/index.html.

Murray, K. and J. DeFrancesco. 2014. Pest Management Strategic Plan for Pears in Oregon and Washington. Available on the web at www.ipmcenters.org.

Mulder, P.G. and R. Grantham. Undated. The pecan nut casebearer. Oklahoma State University Cooperative Extension Service EPP-7189. Available on the web at http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-1314/F-7189web+color.pdf.

Natwick, E.T., R.J. Mullen, W.E. Chaney, and C.B. Fouche (2012). UC IPM Pest Management Guidelines Asparagus: Insects. University of California Agricultural and Natural Resources Publication 3435. Available on the web at http://www.ipm.ucdavis.edu/PMG/selectnewpest.asparagus.html.

NWHC (2016). Personal communication from the Northwest Horticultural Council to C. Myers and Y. Guilaran, USEPA staff, on June 14, 2016.

Pest Management Strategic Plan for Pear Production in California, 2004. USDA Integrated Pest Management Center. Available on the web at www.ipmcenters.org.

Pest Management Strategic Plan for Winegrape Production in California, 2004. USDA Integrated Pest Management Center, available at: http://www.ipmcenters.org
PSU. 2013. Penn State University Tree Fruit Production Guide, 2012-2013. Available at https://polk.extension.wisc.edu/files/2014/02/Tree-Fruit-Production-Guide-Penn-State-2013.pdf.
Pscheidt, J.W., E. Peachey, and S. Castagnoli. 2015. Cherry: 2015 Pest Management Guide for the Willamette Valley. Publication # EM 8329 of the Oregon State University Extension Service. Available on the web at https://ir.library.oregonstate.edu/downloads/p2676v80j.
Pscheidt, J., Walton, V.M., and E. Peachey. 2015. 2015 Hazelnut Pest Management Guide for the Willamette Valley. Oregon State University Extension. Available on the web at https://catalog.extension.oregonstate.edu/em8328.
Rauh, V., Arunajadai, S., Horton, M., Perera, F., Hoepner, L., Barr, D. B., & Whyatt, R. 2011. Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide. *Environ Health Perspect*, 119(8), 1196-1201.
Rauh, V. A., Garfinkel, R., Perera, F. P., Andrews, H. F., Hoepner, L., Barr, D. B., Whyatt, R. W. 2006. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics*, 118(6), e1845-1859.
Rauh VA, Garcia WE, Whyatt RM, Horton MK, Barr DB, Louis ED., 2015. Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor. *Neurotoxicology* (2015) 51:80–6.10.1016.
Renquist and Thiemann. 2015. Pacific Northwest Insect Management Handbook: Hazelnut Pests. Available on the web at www.insect.pnwhandbooks.org/nut/hazelnut.
Rinehold, J. 2016. Mint Pests. In: Hollingsworth, C.S., editor. Pacific Northwest Insect Management Handbook [online]. Corvallis, OR: Oregon State University. Available on the web at https://pnwhandbooks.org/insect/vegetable/vegetable-pests.
Roberts, James R., and Reigart, J. Routt 2013. Recognition and Management of Pesticide Poisonings. Available on the web at https://www.epa.gov/pesticide-worker-safety/pesticide-poisoning-handbook-complete-document.
Salkever, D.S. 1995. Updated Estimates of Earnings Benefits from Reduced Exposure of Children to Environmental Lead. Environmental Research 70:1-6.
Salisbury, S.E. 2015. Letter from the Research and Regulatory Coordinator, Mint Industry Research Council. Comment # EPA-HQ-OPP-2015-0653-0102 submitted to the chlorpyrifos regulatory docket at www.beta.regulations.gov.
SEVEW. 2019. Southeastern Vegetable Extension Workers (SEVEW) 2020 Southeastern Vegetable Crop Handbook. J. M. Kemble, senior editor. A publication of North Carolina State Extension. Available on the web at https://content.ces.ncsu.edu/southeastern-us-vegetable-crop-handbook.
Shimat, J.V., and Zarate, J. 2015. Comparing efficacy of insecticides against cabbage maggot (Diptera: Anthomyiidae) in the laboratory. *Crop Prot*: 77: 148-56.
Sorghum Checkoff. 2016. Steps to managing sugarcane aphid in grain sorghum. Available at: https://www.sorghumcheckoff.com/news-and-media/newsroom/2016/05/23/steps-to-manage-sugarcane-aphid.
Stevenson, D. E. and M. A. Matocha, (2005). A Pest Management Strategic Plan for Cotton Production in Texas. Available on the web at www.ipmcenters.org.
Szendrei, Z. and W.R. Morrison, (2011). Asparagus Miner. Extension Bulletin E-3143 of the Michigan State University. Available on the web at

http://vegetables.ent.msu.edu/images/E3143-Asparagus-miner.pdf.
UC IPM. 2009a. University of California Pest Management Guidelines: Almond Ants. Revised March, 2009. Available on the web at www.ipm.ucdavis.edu/PMG/r3300411.html.
UC IPM. 2009b. University of California Pest Management Guidelines: Plum San Jose Scale. Revised April, 2009. Available on the web at www.ipm.ucdavis.edu/PMG/r611302111.html.
UC IPM. 2012a. University of California Pest Management Guidelines: Leaffooted Bug. Revised November, 2012. Available on the web at www.ipm.ucdavis.edu/PMG/r3301011.html.
UC IPM, 2012b. University of California Pest Management Guidelines: Pear San Jose Scale. Revised November, 2012. Available on the web at www.ipm.ucdavis.edu/PMG/r603301311.html.
UC IPM, 2013a. University of California Pest Management Guidelines: Walnut Husk Fly. Revised August, 2013. Available on the web at www.ipm.ucdavis.edu/PMG/r881301211.html.
UC IPM. 2014a. University of California Pest Management Guidelines: Peach Twig Borer. . Available on the web at www.ipm.ucdavis.edu/PMG/r3300211.html.
UC IPM. 2014b. University of California Pest Management Guidelines: Navel Orangeworm. Available on the web at https://www2.ipm.ucanr.edu/agriculture/walnut/navel-orangeworm/.
UC IPM. 2014c. How to Manage Pests: Strawberries. Available at: http://www.ipm.ucdavis.edu/PMG/selectnewpest.strawberry.html. Accessed: August 21, 2015.
UC IPM. 2015a. University of California Pest Management Guidelines: Alfalfa. Available on the web at http://ipm.ucanr.edu/PMG/selectnewpest.alfalfa-hay.html
UC IPM. 2015b. University of California Pest Management Guidelines: Citricola Scale. Revised August, 2015. Available on the web at www.ipm.ucdavis.edu/PMG/r107301511.html.
UC IPM. (2015c. University of California Pest Management Guidelines: California Red Scale and Yellow Scale. Revised August, 2015. Available on the web at http://www.ipm.ucdavis.edu/PMG/r107301111.html
UC IPM. 2015d. University of California Pest Management Guidelines: Citrus Katydids. Revised, August, 2015. Available on the web at www.ipm.ucdavis.edu/PMG/r107300411.html.
UC IPM. 2015e. University of California Pest Management Guidelines: Cotton Aphid. Revised, September, 2015. Available on the web at http://ipm.ucanr.edu/PMG/r114300111.html.
UC IPM. 2015f. University of California Pest Management Guidelines. Cherry: Obliquebanded Leafroller. In Publication 3440 of the University of California Division of Agricultural and Natural Resources. Available at http://ipm.ucanr.edu/PMG/r105302211.html
UC IPM, (2019a). University of California Pest Management Guidelines: Grape (Vine mealybug). Revised April 2019. Available on the web at http://ipm.ucanr.edu/PMG/r302301911.html.
UC IPM. 2019b. University of California Pest Management Guidelines: Citrus: Citrus Bud Mite (*Eriophyes sheldoni*). Available on the web at https://www2.ipm.ucanr.edu/agriculture/citrus/Citrus-Bud-Mite/.

UC IPM. 2012. Peppermint mint root borer. University of California Integrated Pest Management. Available on the web at http://ipm.ucanr.edu/PMG/r61300111.html. [Accessed November 2016].
UF. 2012. Featured Creatures: Citrus Mealybug. University of Florida Department of Entomology and Nematology, Fact Sheet. Available on the web at http://entnemdept.ufl.edu/creatures/CITRUS/Planococcus_citri.htm
UF. 2019. University of Florida IFAS Extension publication: Vegetable Production Handbook of Florida 2018-2019. Available on the web at http://edis.ifas.ufl.edu/pdffiles/cv/cv29200.pdf
UGA. 2019. Cotton Production Guide. A Publication of the University of Georgia College of Agricultural and Environmental Sciences Cooperative Extension. Available on the web at http://www.ugacotton.com/2019/03/uga-cotton-production-guide-for-2019/.
Unger, M. 2016. Comment submitted by Matt Unger, Chairman, Oregon Strawberry Commission. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0197.
USDA. 1999a. Crop Profile for Asparagus in Michigan. Available on the web at www.ipmcenters.org.
USDA. 1999b. Crop Profile for Sunflowers in North Dakota. Available at: www.ipmcenters.org.
USDA. 1999c. Crop Profile for Tobacco in North Carolina. Available at: http://www.ipmcenters.org/cropprofiles/docs/nctobacco.pdf.
USDA. 2000a. Crop Profile for Strawberries in Virginia. Available at: http://www.ipmcenters.org/cropprofiles/docs/vastrawberries.pdf.
USDA. 2000b. Pest Management in the Future: A Strategic Plan for the Michigan Asparagus Industry. Available on the web at: https://ipmdata.ipmcenters.org.
USDA. 2001. Crop Profile for Pecans in Georgia. Available on the web at: http://www.ipmcenters.org.
USDA. 2002. Crop Profile for Pecans in Texas. Available on the web at: http://www.ipmcenters.org.
USDA. 2003a. Crop Profile for Asparagus in New Jersey. Available on the web at www.ipmcenters.org.
USDA. 2003b. Crop Profile for Peanuts in Georgia. Available on the web at http://www.ipmcenters.org.
USDA. 2003c. Crop Profile for Pecans in Arkansas. Available on the web at http://www.ipmcenters.org.
USDA. 2008. Crop Profile for Tobacco in Tennessee. Available on the web at http://www.ipmcenters.org.
USDA. 2011. Tart Cherry Pest Management in the Future: Development of a Strategic Plan. Available on the web at www.ipmcenters.org. [Accessed August 2015].
USDA NASS 2010 – 2014. Data retrieved from USDA Quickstats database: https://quickstats.nass.usda.gov/
USDA NASS 2014. 2012 Census of Agriculture. National Agricultural Statistics Service, United States Department of Agriculture. May 2014. Available on the web at http://www.agcensus.usda.gov/Publications/2012/.
USDA NASS 2015. 2009-2013 Survey of Agriculture. National Agricultural Statistics Service, United States Department of Agriculture. http://quickstats.nass.usda.gov/.
USDA. 2016a. Data retrieved from USDA Quickstats database:

https://quickstats.nass.usda.gov/.
USDA. 2016b. Crop Production 2015 Summary. January, 2016. Available on the web at https://downloads.usda.library.cornell.edu/usda-esmis/files/k3569432s/kh04dr985/cc08hh91c/CropProdSu-01-12-2016.pdf
USDA. 2016c. Non-citrus Fruits and Nuts 2015 Summary. July 2016. http://usda.mannlib.cornell.edu/usda/current/NoncFruiNu/NoncFruiNu-07-06-2016.pdf.
USDA. 2020. Data retrieved from USDA Quickstats database: https://quickstats.nass.usda.gov/.
USDA OPMP. 2017. Personal communications via USDA's Office of Pest Management Policy (OPMP). Contains narratives in support of chlorpyrifos use and benefits in stone fruit and apples from Cornell University, Michigan State University, and Penn State University. Available in the chlorpyrifos docket at regulations.gov.
U.S. Environmental Protection Agency. 2012. Chlorpyrifos—Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures, June 20, 2012. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0114.
U.S. Environmental Protection Agency. 2014. Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review. December 29, 2014. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0196
U.S. Environmental Protection Agency. 2015a. Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0002
U.S. Environmental Protection Agency. 2015b. Review of Specific Exemption Request from Texas for the Use of Sulfoxaflor on Grain Sorghum to Control the Sugarcane Aphid (*Melanaphis sacchari*). (15-TX-01; DP#424135). February 10, 2015.
U.S. Environmental Protection Agency. 2016. Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment. November 17, 2016. Available on the web at https://www.federalregister.gov/documents/2016/11/17/2016-27552/chlorpyrifos-tolerance-revocations-notice-of-data-availability-and-request-for-comment
U.S. Environmental Protection Agency. 2020a. Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review. Official Agency memorandum available in the chlorpyrifos docket at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0944.
U.S. Environmental Protection Agency. 2020b. Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review. Available on the web at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0940.
U.S. Environmental Protection Agency. 2020c. Mallampalli, N. and C. Paisley-Jones. Chlorpyrifos Benefits Assessment for Non-crop Uses. Official Agency memorandum available in the chlorpyrifos docket at www.regulations.gov.
Utah State University, Cooperative Extension. 2011. The 2011 Onion Budget. https://cdn.sare.org/wp-content/uploads/20171204131809/944017onion-budget-2011.pdf
Varela, L. G., D. R. Haviland, W. J. Bentley, F. G. Zalom, L.J. Bettiga, R. J. Smith, and K. M. Daane, (2015). UC IPM Pest Management Guidelines: Grape [Insect and Mites subsection]. University of California Agricultural and Natural Resources publication # 3448. Available on the web at http://ipm.ucdavis.edu/PMG/selectnewpest.grapes.html .
Wiman, N. and N. Bell. 2020. Pacific Northwest Insect Management Handbook: Hazelnut Pest.

Available on the web at https://pnwhandbooks.org/insect/nut/hazelnut.
Wyatt, T.J. Screening Level Analysis of the Small Business Impacts of Revoking Carbofuran Tolerances. US EPA. June 26, 2008. https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2005-0162-0506&contentType=pdf
Young, J. G., Eskenazi, B., Gladstone, E. A., Bradman, A., Pedersen, L., Johnson, C., Holland, N. T. (2005). Association between in utero organophosphate pesticide exposure and abnormal reflexes in neonates. *Neurotoxicology*, 26(2), 199-209.
Zalom, F.G., M.N. Oliver, and D.E. Hinton, (1999). Alternatives to Chlorpyrifos and Diazinon Dormant Sprays. A publication of the State Water Resources Control Board of the California Environmental Protection Agency. Available on the web at https://www.waterboards.ca.gov/publications_forms/publications/general/docs/alternatives_chlorpyrifos_diazinon_dormantsprays.pdf.

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