## 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 rig*ht (i.e., pestic*ide 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).
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## List of Subjects in 40 CFR Part 180

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

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2022–04139 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P