IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

Petition for Review of Actions of the U.S. Environmental Protection Agency

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BRIEF OF RESPONDENTS

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GLOSSARY

APA	Administrative Procedure Act
EPA	Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

INTRODUCTION

Congress tasked EPA with establishing "tolerances," which allow maximum levels of pesticide residues in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. Under the FFDCA, EPA may establish or leave in place a tolerance for a pesticide *only* if it determines that the tolerance is "safe," and must revoke or modify an existing tolerance if EPA determines that the tolerance is not "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. "Safe" means a "reasonable certainty that no harm will result from aggregate exposure," including all anticipated dietary exposures. *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. The FFDCA's safety standard is strictly safety-based: EPA may not consider any other factors, such as economic costs or benefits, in determining whether tolerances are safe, and whether tolerances are "safe" is the exclusive basis for revoking, modifying, or setting tolerances.

In 2007, public interest groups petitioned EPA to revoke all chlorpyrifos tolerances based on neurodevelopmental impacts to infants and children, among other things. After years of administrative process and court rulings in response to the petition, the U.S. Court of Appeals for the Ninth Circuit concluded in 2021 that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 700–01 (9th Cir.

2021) (*"LULAC II"*). The Ninth Circuit chided EPA for "expos[ing] a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 702. The Court ordered EPA to, within 60 days, revoke all chlorpyrifos unless EPA could find by that time, based on the evidence regarding aggregate exposure to chlorpyrifos, that modified tolerances would be safe. *Id.* at 703.

On August 30, 2021, EPA promulgated a final rule revoking all chlorpyrifos tolerances. Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315 (Aug. 30, 2021) ("Final Rule"), AR 1, Pet'rs' Add. 1; *see also* Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222 (Feb. 28, 2022) ("Denial Order"), Pet'rs' Add. at 23. EPA determined that it could not make the safety finding necessary to leave in place the current tolerances for residues of chlorpyrifos because the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Specifically, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. In addition, there are laboratory studies and epidemiological data studying chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* Adhering to the

FFDCA's strict safety standard and the Ninth Circuit's mandate, EPA revoked all chlorpyrifos tolerances. AR 1 at 48316, Pet'rs' Add. at 2. Petitioners now ask this Court to do what both Congress and the Ninth Circuit forbade: leave *all* chlorpyrifos tolerances in place, even though the expert agency has concluded that they are not safe.

STATEMENT OF JURISDICTION

Petitioners have filed three petitions for review regarding EPA's revocation of chlorpyrifos tolerances. The Court dismissed Petitioners' first petition for lack of jurisdiction. *Red River Valley Sugarbeet Growers Ass'n v. Regan,* No. 22-1294, Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661. The Court has jurisdiction over the consolidated second and third petitions challenging EPA's Final Rule and Denial Order under FFDCA Section 408(h)(1). 21 U.S.C. § 346a(h)(1), Resp'ts' Add. at 12.

STATEMENT REGARDING ORAL ARGUMENT

Respondents agree with Petitioners that oral argument is appropriate and would be helpful to the Court. This case involves the application of important provisions of the FFDCA administered by EPA.

STATEMENT OF THE ISSUE

The Ninth Circuit ordered EPA to "immediately" revoke all chlorpyrifos tolerances unless the Agency could find, based on evidence available at that time, that modified tolerances were reasonably certain to avert harm from aggregate exposure to chlorpyrifos. EPA revoked all tolerances after determining that it could not make that finding. Was EPA's determination non-arbitrary and consistent with the FFDCA's strict-safety standard?

STATEMENT OF THE CASE

A. Statutory and regulatory background

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, Resp'ts' Add. at 1, and FIFRA, 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, EPA establishes "tolerances," which are rules establishing the maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a, Resp'ts' Add. at 1. As originally enacted, the FFDCA instructed EPA to set tolerances that are "safe for use, to the extent necessary to protect the public health" while giving appropriate consideration to "the necessity for production of an adequate, wholesome, and economical food supply" and "the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture." H.R. Rep. No. 104-669, pt. 2 at 40 (1996). With the passage of the

Food Quality Protection Act ("FQPA") in 1996, Congress replaced that standard with a pure safety standard. *See id.* As amended, the FFDCA permits EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). EPA "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* Thus, under current law, "FFDCA review is limited to the sole issue of safety" and "explicitly prohibit[s] the EPA from balancing safety against other considerations, including economic or policy concerns." *LULAC II,* 996 F.3d at 696.

"Safe" under the FFDCA means a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. Congress understood "aggregate exposure" to include "all dietary exposures." H.R. Rep. 104–669, pt. 2, at 40 (1996). In another provision of the FFDCA describing "aggregate exposure," Congress required EPA to consider "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue . . . , including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources." 21 U.S.C. § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5. Additionally, infants

and children are given special consideration: EPA must assess the risk of the pesticide residues to infants and children utilizing a presumptive tenfold (10X) margin of safety for threshold effects (the "FQPA safety factor"), unless "reliable data" shows that a lower margin will be safe. 21 U.S.C. § 346a(b)(2)(C), Resp'ts' Add. at 4-5.

Under Section 408(*l*), EPA is to coordinate the revocation of a tolerance with any related necessary action under FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. While EPA may establish, modify, or revoke tolerances under the FFDCA, it cannot require changes to pesticide registrations (like geographic or application restrictions) under the FFDCA.

2. The Federal Insecticide, Fungicide, and Rodenticide Act

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

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years, starting in 2006. *Id.* § 136a(g)(1)(A). During "registration review," EPA assesses all pesticide product registrations containing an active ingredient and must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account new scientific information and changes to risk-assessment procedures, methods, and data requirements. 40 C.F.R. §§ 155.40(c)(1), 155.53(a); 7 U.S.C. § 136a(g). EPA may propose measures to mitigate identified risks, including label or registration changes, in a proposed decision or proposed interim decision. *See* 40 C.F.R. §§ 155.56, 155.58(a)-(b). EPA may issue a final interim decision. *See id.* § 155.56. In addition, or instead of, a final interim decision, EPA will issue a proposed final decision. *Id.* EPA must issue a final registration review decision to conclude registration review. *See id.*

FIFRA registrations function as product-specific licenses. *See* 7 U.S.C. § 136a(a), (c)-(e). Registrants may submit a request to modify a pesticide registration, including labeling, under FIFRA. *See* 40 C.F.R. § 152.44. Registrants may submit requests to voluntarily cancel their pesticide registrations or terminate certain registered uses under 7 U.S.C. § 136d(f), or EPA may initiate cancellation proceedings under § 136d(b). The procedures for voluntary and involuntary cancellation differ dramatically. If a registrant wishes to voluntarily

cancel its registration or terminate a specific use, it may do so at any time by submitting a request to EPA, which following publication in the Federal Register for public comment, the Agency may approve or deny. 7 U.S.C. § 136d(f)(1). By contrast, if EPA initiates cancellation proceedings, it must first provide a draft Notice of Intent to Cancel to the Secretary of Agriculture and the FIFRA Scientific Advisory Panel at least 60 days before publishing the final Notice in the Federal Register. 7 U.S.C. §§ 136d(b), 136w(d).[1] Any person adversely affected by the notice may request a hearing before an Administrative Law Judge. 7 U.S.C. §§ 136d(b). The Administrative Law Judge's decision may be appealed to the Environmental Appeals Board. 40 C.F.R. § 164.101. Registrants and other interested persons may seek judicial review of a final cancellation order within 60 days. 7 U.S.C. § 136n(b).

B. Factual background

1. 2007 petition to revoke all tolerances

Chlorpyrifos is a broad-spectrum insecticide and miticide registered for use on over 50 different food crops as well as in non-food settings, including turf. AR 40 at 11. In the 2006 Reregistration Eligibility Determination for chlorpyrifos,

[1] EPA may also issue a notice of intent to hold a hearing on cancellation instead of publishing a Notice of Intent to Cancel. 7 U.S.C. § 136d(b).

EPA determined that chlorpyrifos tolerances were safe.[2] AR 33, Resp'ts' App. at 80.

In 2007, the Pesticide Action Network North America ("PANNA") and the Natural Resources Defense Council ("NRDC") filed a Petition to Revoke all Tolerances and Cancel All Registrations for Chlorpyrifos under 21 U.S.C. § 346a(d)(1)(A) (the "2007 Petition to Revoke"). AR 1 at 48318, Pet'rs' Add. at 4. Among other things, the petition argued that chlorpyrifos causes adverse neurodevelopmental effects in children. AR 1 at 48318–19, Pet'rs' Add. at 4-5. EPA believed that these neurodevelopmental claims raised important concerns and warranted further consideration in registration review, which EPA initiated in 2009. 87 Fed. Reg. at 11235, Pet'rs' Add. at 36. In the years that followed, EPA convened multiple meetings with the FIFRA Scientific Advisory Panel, and published multiple Human Health Risk Assessments, all of which analyzed these neurodevelopmental claims. AR 1 at 48320–22, Pet'rs' Add. at 6-8.

Dissatisfied with the pace of EPA's review, PANNA and NRDC filed a petition for mandamus in 2012, seeking an order requiring EPA to respond to the 2007 Petition to Revoke. The court denied the petition without prejudice, noting that EPA intended to issue a final response by February 2014. *In re Pesticide*

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[2] EPA issued decision documents called REDs for registered pesticides as part of the pesticide review program that predated registration review. *See* 7 U.S.C. 136a-1.

Action Network N. Am., 532 Fed. Appx. 649, 650–52 (9th Cir. 2013). After EPA failed to meet its self-imposed deadline, PANNA and NRDC filed a second petition. *In re Pesticide Action Network N. Am.*, 798 F.3d 809 (9th Cir. 2015). In that case, EPA told the court that due to its concerns about drinking water contamination, the Agency planned to issue a rule by April 2016 revoking all tolerances. *Id*. at 812–13. The Ninth Circuit granted the mandamus petition and directed EPA to issue, by October 31, 2015, either a proposed or final revocation rule or a full and final response to the 2007 Petition to Revoke. *Id*. at 811, 815. EPA published a rule proposing to revoke all tolerances. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (Nov. 6, 2015), Pet'rs' App. at 995. EPA's proposed revocation was based on a determination that drinking water concentrations of chlorpyrifos in some watersheds would exceed exposure levels that EPA considered "safe." *Id*. at 69083, Pet'rs' App. at 998.

The Ninth Circuit then ordered EPA to take final action on the proposed revocation rule by December 30, 2016. *In re Pesticide Action Network N. Am.*, 808 F.3d 402 (9th Cir. 2015). In 2016, EPA developed a revised Human Health Risk Assessment, which it released for public comment as additional support for the 2015 proposal.[3] To incorporate those additional comments, EPA sought a six-

[3] 2015 Proposed Rule. Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81049 (Nov. 17, 2016).

month extension of the December 30, 2016 deadline to issue a final response to the 2007 Petition to Revoke. *In re Pesticide Action Network N. Am.*, 840 F.3d 1014 (9th Cir. 2016). The court characterized EPA's request as "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action' that has been repeated for the past nine years." *Id.* at 1015 (quoting *In re Pesticide Action Network*, 798 F.3d at 811). The court ordered EPA to take final action by March 31, 2017. *Id*. Instead of finalizing the 2015 proposal, EPA subsequently denied the 2007 Petition to Revoke on the ground that the science concerning adverse neurodevelopmental effects remained uncertain and EPA would address those issues as part of its FIFRA registration review process. Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16581, 16583 (April 5, 2017).

Several states and organizations filed objections to this denial pursuant to FFDCA § 408(g), 21 U.S.C. § 346a(g), Resp'ts' Add. at 11-12. Many of them also sought relief in the Ninth Circuit without awaiting EPA's decision on their objections. *League of United Latin Am. Citizens v. Wheeler,* 899 F.3d 814 (9th Cir. 2018). A Ninth Circuit panel ordered EPA to revoke all chlorpyrifos tolerances. *Id*. at 829. On rehearing, the court vacated the panel's opinion and ordered EPA to issue a final order responding to the objections. *League of United Latin Am. Citizens v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc). EPA

denied all objections in July 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555 (July 24, 2019). Petitions were filed challenging this denial order, which were referred to the same panel. *League of United Latin Am. Citizens v. Wheeler*, 940 F.3d 1126, 1127 (9th Cir. 2019).

2. EPA's 2020 Proposed Interim Registration Review Decision for Chlorpyrifos

Concurrent with its consideration of the petition under the FFDCA, EPA continued its FIFRA registration review. In December 2020, EPA released the Proposed Interim Registration Review Decision ("PID") for Chlorpyrifos pursuant to FIFRA. *See* AR 40, Pet'rs' App. at 366. The PID proposed to conclude that aggregate exposure (including exposures in food, drinking water, and residential settings) from all currently-registered uses of chlorpyrifos was unsafe. *Id.* at 19, Pet'rs' App. at 384. To reduce aggregate exposures to safe levels, under the FQPA's 10X safety factor, EPA proposed that uses of chlorpyrifos be limited to applications for eleven "high-benefit" uses in limited geographic areas: alfalfa, apple, asparagus, cherry (tart), citrus, cotton, peach, soybean, strawberry, sugar beet, wheat (spring and winter).[4] *Id.* at 40–41, Pet'rs' App. at 405–06. The proposal for retention of those uses also relied on application rate reductions

[4] These specific uses were identified as critical by a registrant or as high-benefit to growers by EPA. 87 Fed. Reg. at 11255, Pet'rs' Add. at 56.

consistent with rates that were assessed in EPA's 2020 drinking water assessment. *Id*. at 55-59, Pet'rs' App. at 420–24. In other words, EPA proposed that *if* use on those 11 crops was amended as indicated in the PID *and* all other uses were cancelled—both FIFRA actions—EPA could determine that the aggregate exposure to chlorpyrifos was safe and thus tolerances associated with those 11 specific uses could be left in place under the FFDCA.

As required under EPA's regulations, EPA solicited public comment on the PID. 40 C.F.R. § 155.58(a); AR 40 at 62, Pet'rs' App. at 427. Multiple groups submitted comments disagreeing with the subset of 11 uses EPA identified. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. Some commenters, including cranberry and banana growers, argued that their crops should also be retained; others, including advocacy and environmental groups, argued that a safety determination supporting even those limited 11 uses would contravene the available science. *Id.* at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not issued an interim or final registration review decision.

At the time of the issuance of the Final Rule, no chlorpyrifos registrant had submitted voluntary cancellation requests or applications for label amendments consistent with the proposed mitigation measures in the PID.

3. The Ninth Circuit's decision vacating EPA's denial of the petition

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the 2007 Petition and EPA's order denying related objections and concluded that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01 (listing six EPA and Scientific Advisory Panel assessments and notices from 2012 to 2016 that indicated that there is not a reasonable certainty of no harm under the FFDCA). Indeed, the Ninth Circuit found that since 2006, EPA had "consistently concluded that the available data support a conclusion of increased sensitivity of the young to the neurotoxic effects of chlorpyrifos and for the susceptibility of the developing brain to chlorpyrifos." *Id.* at 697. The Ninth Circuit chided EPA for taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition," which was an "egregious delay [that] exposed a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 703. According to the Court, that EPA was in the midst of registration review under FIFRA did not justify the "total abdication of the EPA's statutory duty under the FFDCA," as registration review was "separate from [EPA's] continuous obligation to ensure safety under the FFDCA." *Id.* at 678, 691. The Ninth Circuit made clear that it was not remanding for further factfinding, as "further delay would make a

mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." *Id.* at 702.

The Ninth Circuit instructed EPA to publish a final response to the 2007 Petition within 60 days after the issuance of its mandate, without notice and comment, "that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703 ("EPA's time is now up."). Regarding modification, the Ninth Circuit stated that "[i]f, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it *may* modify chlorpyrifos registrations rather than cancelling them." *Id.* (emphasis added). The Ninth Circuit also directed EPA to modify or cancel related FIFRA registrations "in a timely fashion." *Id.* at 704.

4. EPA's attempt to negotiate voluntary cancellations with Petitioner Gharda and other registrants

Shortly after the issuance of the Ninth Circuit's decision in *LULAC II*, EPA entered into good-faith negotiations with each of the technical registrants, including Gharda, regarding the voluntary cancellation of chlorpyrifos

registrations.[5] None of the technical registrants, however, ultimately submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. Indeed, instead of proceeding quickly given the Ninth Circuit's 60-day deadline, Gharda repeatedly sought unreasonable cancellation terms:

- On May 12, 2021, Gharda stated that it was "willing to negotiate and execute an agreement with EPA" that contained nine separate terms, including allowing continued uses on several crops not listed in the PID; phasing out the production, sale, and distribution of chlorpyrifos products for certain uses through 2026; and retaining all import tolerances. Redacted Decl. of Ram Seethapathi, Ex. B, at 1–2, (Doc. ID 5133345 at 28-29), Pet'rs' App. at 1739-40.
- On June 7, 2021, Gharda committed to voluntarily cancel all currently approved agricultural uses except the subset of 11 uses identified in the PID if EPA agreed to nine other terms, including allowing: (1) use of chlorpyrifos on cotton in Texas (which was not proposed in the PID); (2) Gharda to import all finished technical product from Gharda's foreign warehouse for processing and sale in the United

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

States for all currently registered uses; and (3) Gharda to process and sell product in its possession for all currently registered uses. *Id.,* Ex. C at 1–2, Pet'rs' App. at 1743–44. Gharda also stated that it would reserve the right to withdraw from voluntarily cancelling uses in the event that the U.S. Supreme Court granted certiorari in *LULAC II*. *Id.* at 2.[6]

- On June 25, 2021, Gharda proposed new terms, including retention of nine of the 11 uses outlined in the PID; the formulation, distribution and sale of end-use products until December 31, 2022; the use of existing stocks until December 31, 2023; the use of aerial application through December 31, 2023; and retention of all import tolerances. Seethapathi Ex. G, at 1–2 (Doc. ID 513345 at 45–46), Pet'rs' App. at 1756–57. Gharda noted that "[t]erms will be set forth in a separate, written agreement" and that the company "reserves the right to withdraw from the written agreement in the event that the U.S. Supreme Court grants certiorari in the *LULAC II* case." *Id.* at 2, Pet'rs' App. at 1757.
- On July 6, 2021, Gharda stated that it was "willing to accept" the voluntary cancellation of certain uses, such as strawberry, asparagus,

[6] No petition for certiorari was ultimately filed for *LULAC II*.

cherry (tart) and cotton, that had been proposed for retention in the PID, if, "in return," EPA agreed to allow the formulation and distribution for all current uses through June 2022 and the use of existing stocks through June 2023, instead of EPA's proposals of February and August 2022. *Id.,* Ex. H, at 2 (Doc. ID 513345 at 51), Pet'rs' App. at 1762.

EPA did not agree to these conditions since they would not have adequately addressed the FFDCA requirement not to leave in place tolerances that are unsafe and due to concerns that such an extended existing stocks period would have been inconsistent with *LULAC II*. 87 Fed. Reg. at 11248, Pet'rs' Add. at 48. Ultimately, neither Gharda nor any of the other chlorpyrifos registrants submitted voluntary cancellation requests or applications for label amendments prior to the issuance of the Final Rule or the Denial Order. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

5. EPA's revocation rule

On August 30, 2021, EPA published a Final Rule revoking all tolerances for chlorpyrifos. AR 1, Pet'rs' Add. 1. Given the immediate deadline from the Ninth Circuit, and lack of an agreement on any new label terms or use deletions, EPA relied on its previously conducted aggregate assessments of chlorpyrifos, which

covered all registered uses and included extensive information about the potential impacts of chlorpyrifos.

More specifically, chlorpyrifos inhibits acetylcholinesterase ("AChE"), an enzyme necessary for the proper functioning of the nervous system. 87 Fed. Reg. at 11231, Pet'rs' Add. at 32. Thus, exposure to chlorpyrifos can lead to neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. *Id.* There is also an extensive body of information (epidemiological, mechanistic, and laboratory animal studies) studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children (including cognitive, anxiety and emotion, social interactions, and neuromotor functions), although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38.

EPA's decision relied on the effect of AChE inhibition for assessing risks from chlorpyrifos and retained the default FQPA 10X safety factor to account for scientific uncertainties around the potential for adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11237, Pet'rs' Add. at 38. Taking into account the available data and literature and the currently registered uses of chlorpyrifos, EPA determined that it could not make the safety finding to support leaving in place current tolerances. AR 1 at 48317, Pet'rs' Add. at 3. The

Agency's analysis indicated that although exposures from food alone did not exceed safe levels, EPA concluded that aggregate exposures from food, drinking water, and residential settings due to currently registered uses exceeded safe levels. 87 Fed. Reg. at 11237–38, Pet'rs' Add. at 38–39. Because EPA could not conclude that aggregate exposure to chlorpyrifos residues was safe, the Agency revoked all chlorpyrifos tolerances as required under FFDCA section 408(b)(2). *Id.* at 11238, Pet'rs' Add. at 39; *see also* AR 1 at 48334, Pet'rs' Add. at 20 ("EPA has determined that the current U.S. tolerances for chlorpyrifos are not safe and must be revoked.").

To ease the transition away from chlorpyrifos for growers and to accommodate international trade considerations, EPA allowed the tolerances to remain in place for six months following publication of the Final Rule, setting an expiration date of February 28, 2022, for the tolerances. AR 1 at 48334, Pet'rs' Add. at 20, 87 Fed. Reg. 11238, Pet'rs' Add. at 39.

On February 28, 2022, EPA published its Denial Order objecting to the Final Rule, requests for hearing on those objections, and requests to stay the Final Rule, 87 Fed. Reg. 11222, Pet'rs' Add. at 23, which reaffirmed EPA's conclusions in the Final Rule for revoking the chlorpyrifos tolerances.

6. The petition for review

On February 9, 2022, Petitioners filed a petition for review challenging the Final Rule. *Red River Valley Sugarbeet Growers Ass'n v. Regan*, No. 22-1294, Doc. ID 5126162. The next day, Petitioners moved to stay the February 28, 2022, expiration date in the Final Rule. Doc. ID 5126280. On February 18, 2022, EPA moved to dismiss that petition for lack of jurisdiction because EPA had not yet issued a final order denying objections to the Final Rule. Doc. ID 5129068, Pet'rs' App. at 1285.

On February 28, 2022, Petitioners filed a second petition for review challenging both the Final Rule and the Denial Order, and renewed their stay motion. Doc. IDs 5131400, 5132688 (No. 22-1422). On March 14, 2022, Petitioners filed a third petition for review of the Final Rule and the Denial Order. Doc. ID 5136561 (No. 22-1530), Pet'rs' App. at 1816.

On March 15, 2022, the Court denied Petitioners' stay motion and exercised jurisdiction over the second petition. Doc. ID 5136844. The following day, the Court dismissed the first petition for lack of jurisdiction. Doc. ID 5137001. The Court subsequently granted a stipulation consolidating the second and third petitions. Doc. ID 5149661, Pet'rs' App. at 1914.

7. Cancellation status of chlorpyrifos registrations under FIFRA

On April 28, 2022, EPA published in the Federal Register requests to voluntarily cancel 16 different chlorpyrifos registrations. Requests to Voluntarily Cancel Certain Pesticide Registrations, 87 Fed. Reg. 25256, 25257–58 (Apr. 28, 2022). EPA plans to initiate involuntary cancellation proceedings for every chlorpyrifos registration for which it has not received a voluntary cancellation request.

SUMMARY OF ARGUMENT

As required under the FFDCA, in determining whether chlorpyrifos tolerances could be left in place, EPA considered "aggregate exposure . . . , including *all* anticipated dietary exposures and other exposures" of chlorpyrifos based on existing registered (*i.e.,* legally permitted) uses. 21 U.S.C. §346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added). That assessment showed that the "[c]ontinued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3. Accordingly, EPA revoked all chlorpyrifos tolerances. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; AR 1 at 48316, Pet'rs' Add. at 2.

The ultimate relief sought by Petitioners in this case is the retention of *all* chlorpyrifos tolerances. But Petitioners' actual legal argument is more limited.

Specifically, they argue that EPA should not have assessed safety with respect to aggregate exposures, but was required to retain a specific geographically-limited subset of 11 uses that EPA proposed for retention in the PID and purportedly determined are safe. Petitioners' argument lacks merit for five reasons.

First, no one disputes that EPA must revoke or modify a tolerance that is not safe. Regarding chlorpyrifos, EPA concluded that exposure can lead to neurotoxicity and that there is an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. 87 Fed. Reg. at 11231, 11237, Pet'rs' Add. at 32, 38. Based on these and other findings, EPA reasonably concluded that aggregate exposure to chlorpyrifos exceeded safe levels and revoked all tolerances. *Id.* at 11270, Pet'rs' Add. at 71; AR 1 at 48317, Pet'rs' Add. at 3.

Second, contrary to Petitioners' claim, the PID was not "final." The PID was a *proposed* determination as part of registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's proposed scientific assessment that a particular subset of 11 high-benefit uses would not pose potential risks of concern, using the 10X safety factor, if certain mitigation was adopted, including geographic and application restrictions. AR 40 at 40, Pet'rs' App. at 405. The proposed nature of the PID means that EPA's safety

determination (and the subset of uses to be retained) might be adjusted or revised. EPA requested public comment on the PID, and some commenters disagreed with the retention of those 11 uses, while others advocated for a different combination of uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA could not fully consider those comments and reach a definitive conclusion in the timeframe the Ninth Circuit provided EPA to act under the FFDCA, and it has not yet issued an interim or final registration review decision.

Third, contrary to Petitioners' claim, the FFDCA does not require EPA to undertake a tolerance-by-tolerance analysis generally, nor is that analysis prudent in situations like this, where aggregate risk is not safe. EPA's consideration of all tolerances for a specific pesticide is consistent with the FFDCA's mandate (and the Ninth Circuit's edict) to assess "aggregate" exposure, as well as longstanding EPA policy. Moreover, Petitioners do not explain how, from a practical perspective, EPA could actually carry out a tolerance-by-tolerance approach in this case in a manner consistent with that mandate.

Fourth, EPA's consideration of all currently-registered uses, instead of only the 11 uses proposed in the PID, was entirely reasonable under the FFDCA's direction to consider "all anticipated dietary exposures." The FFDCA requires EPA to determine whether tolerances *are* safe. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2. It does not allow EPA to leave tolerances in place if they *might*

be safe *if* the suite of mitigation measures proposed under FIFRA might be implemented at some indeterminate time in the future. At the time of the Final Rule, no concrete steps under FIFRA had been taken by registrants that would have altered the universe of uses EPA needed to assess: EPA had received no cancellation requests or applications to amend labels to geographically limit uses or limit applications consistent with the mitigation proposed in the PID. The proposed mitigation measures in the PID are not self-executing, and without efforts to make changes to the registrations, they do not, by themselves, support an assumption that aggregate exposures would be limited to that subset of uses. Nor would the revocation of tolerances associated with uses other than the subset of 11 alone have supported a safety determination without the necessary geographic and application restrictions occurring on those 11 uses, which would need to occur under FIFRA. Thus, EPA's consideration of all existing chlorpyrifos registrations in its assessment of "anticipated" exposures was reasonable.

Fifth, EPA was not required to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. Petitioners point to the FFDCA's direction that "[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocation of tolerances with FIFRA "[t]o the

extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704. Given the length of time an involuntary cancellation proceeding can take, Petitioners' view could force EPA to leave in effect pesticide tolerances it had found unsafe long after making that finding, contrary to the FFDCA.

Ultimately, EPA reasonably considered aggregate exposure from all anticipated sources based on all currently registered uses in determining that the continued use of chlorpyrifos did not meet the FFDCA's strict safety standard, and that all tolerances therefore must be revoked.

STANDARD OF REVIEW

The APA provides the standard of review for this case. *See* 5 U.S.C. § 706. Under this standard of review, EPA's Final Rule and Denial Order can be overturned only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A)). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). That standard requires the court to "affirm the EPA's rules if the agency has considered the relevant factors

and articulated a 'rational connection between the facts found and the choice made."' *Allied Local and Reg'l Mfrs. Caucus v. EPA,* 215 F.3d 61, 68 (D.C. Cir. 2000) (quoting *Motor Vehicles Mfrs. Ass'n,* 463 U.S. at 43).

ARGUMENT

I. EPA reasonably revoked chlorpyrifos tolerances based on its determination that those tolerances were not safe.

There is no dispute that the statutory criteria for leaving a tolerance in place or revoking a tolerance is whether the residue is "safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2; *see also LULAC II*, 996 F.3d at 696 (amendments to the FFDCA "explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns."). If EPA cannot conclude that a tolerance is safe, it "shall" revoke or modify it. 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.

EPA's scientific analysis of chlorpyrifos is complicated, but its conclusion is not: "Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270, Pet'rs' Add. at 71. Because EPA concluded that aggregate exposure to chlorpyrifos residues from all registered uses was not safe, it revoked all chlorpyrifos tolerances. *Id*. As noted above, exposure to chlorpyrifos can lead to neurotoxicity through inhibition of an enzyme necessary for the proper functioning of the nervous system. *Id.* Moreover, there is also an extensive body of

information studying the potential association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children, although there was insufficient information at the time of the Final Rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes. *Id*. at 11231, 11237, Pet'rs' Add. at 32, 38. Although EPA did not identify risks of concern based on exposure to residues of chlorpyrifos in food alone, it concluded, consistent with the FFDCA, that aggregate exposure to residues of chlorpyrifos in food, drinking water, and residential settings from currently registered uses exceeded safe levels. *Id.* at 11237–38, Pet'rs' Add. at 38-39.

Petitioners' claim that "the sole dietary exposure source of concern . . . is drinking water" is a red herring. Pet'rs' Br. at 39. It does not matter what the "sole" or "primary" source of exposure is that drives risk concerns. The FFDCA directs EPA to consider "aggregate" exposure in making a safety determination. If aggregate exposure—taking all the relevant sources of exposure together—is not safe, then EPA cannot find that the tolerances are safe.

Amicus curiae State of Missouri's claim that, contrary to the statute, EPA "failed to make any finding—either that the tolerances for any food were unsafe or safe" similarly misreads the Final Rule, as well as the statute. *See* Missouri Br. at 5, 7-8. First, EPA did conclude that chlorpyrifos tolerances were not safe. AR 1 at 48317, Pet'rs' Add. at 3 ("[T]he Agency's analysis indicates that aggregate

exposures (*i.e.,* exposures from food, drinking water, and residential exposures), which stem from currently registered uses, exceed safe levels. . . "). Second, the FFDCA permits EPA to "leave in effect a tolerance for a pesticide chemical residue in or on a food *only* if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2 (emphasis added). Put differently, EPA is required to revoke or modify any tolerance for which it cannot make a safety finding. *LULAC II,* 996 F.3d at 694.

Petitioners and *amicus curiae* State of North Dakota attempt to undercut EPA's conclusions about adverse impacts to infants' and children's developing brains by arguing that, without chlorpyrifos, growers will experience "dramatic adverse reduction in its yield" and "crippling economic losses" that "will ultimately be felt by U.S. consumers." Pet'rs' Br. at 15-16; N. Dakota Br. at 19; *see also* Missouri Br. at 10 ("EPA has forced a disruptive change that endangers agricultural yields that are critical to Missouri's economy.") Those arguments conflate two *different* statutory standards, attempting to import FIFRA's "unreasonable adverse effects" standard—which considers economic and social costs and benefits—into the FFDCA's strict safety standard. The FFDCA, however, imposes "an uncompromisable limitation: the pesticide must be

determined to be safe for human beings." *LULAC II*, 996 F.3d at 678; *see* 21 U.S.C. § 346a(b)(2)(A)(i), Resp'ts' Add. at 2.[7]

Similarly without merit are Petitioners' and North Dakota's claims that the Final Rule and Denial Order failed to sufficiently account for their reliance interests in the continued use of chlorpyrifos. North Dakota purports to have "reasonably relied on" EPA's safety finding in the 2006 Reregistration Eligibility Determination for chlorpyrifos. N. Dakota Br. at 12–13; AR 33, Resp'ts' App. at 80. But the Ninth Circuit concluded in 2021 that, based on subsequent evidence before the Agency, "the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA." *LULAC II,* 996 F.3d at 700–01. And in fact, since 2006, EPA's extensive scientific analyses of chlorpyrifos provided North Dakota with ample notice that EPA's 2006 safety finding could change. Moreover, the Ninth Circuit's mandate to revoke all tolerances unless the Agency could make a safety finding supporting modification left no room for EPA to consider reliance reasons, even absent such a safety

[7] Petitioners and North Dakota rely in large part upon materials from outside of the administrative record for their economic arguments. These extra-record materials are not properly before the Court. *See Newton Cty. Wildlife Ass'n. v. Rogers,* 141 F.3d 803, 807 (8th Cir. 1998) ("APA review of agency action is normally confined to the agency's administrative record."); *CTS Corp. v. E.P.A.,* 759 F.3d 52, 64 (D.C. Cir. 2014) ("[A] reviewing court [in an APA case] should have before it neither more nor less information than did the agency when it made its decision.") (internal quotations and citations omitted).

finding. *Cf. Brachtel v. Apfel,* 132 F.3d 417, 419–20 (8th Cir. 1997) (applying law-of-the-case doctrine to administrative agencies on remand). Accordingly, North Dakota's purported reliance on the 2006 RED was unreasonable.

Petitioners' purported reliance on the 2020 PID was also unreasonable. Petitioners argue that *Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) and *Encino Motorcars, LLC v. Navarro,* 136 S. Ct. 2117, 2126 (2016) impose a more demanding requirement for justifying an action that deviates from a prior policy. Pet'rs' Br. at 61; *see also* CropLife Br. at 15–16. But both cases specifically addressed changes from "longstanding policies" that may have "engendered serious reliance interests that must be taken into account." *Encino Motorcars,* 136 S. Ct. at 2126 (quoting *F.C.C. v. Fox TV Stns., Inc.,* 129 S. Ct. 1800, 1811); *Dep't of Homeland Sec.,* 140 S. Ct. at 1913. That is not the case here. First, the PID was a *proposed* determination—not an Agency policy—signed only nine months before the Final Rule was published and heavily caveated. 40 C.F.R. § 155.58(b)(1) (the PID contained "proposed findings"); *compare* AR 40 (signed Dec. 3, 2020), Pet'rs' App. at 366, with Final Rule (published Aug. 30, 2021), Pet'rs' Add. at 1. Second, the Ninth Circuit's April 29, 2021 decision in *LULAC II* explicitly contemplated that EPA would, absent a safety finding, revoke all chlorpyrifos tolerances in response to that decision. 996 F.3d at 703.

Accordingly, any reliance by Petitioners on the PID was unreasonable, not to mention irrelevant to the Agency's safety analysis under the FFDCA.

In sum, consistent with the FFDCA's strict safety standard, EPA reasonably and properly revoked all chlorpyrifos tolerances when it found that aggregate exposure to chlorpyrifos was unsafe.

II. The PID was not final, and neither EPA nor Gharda treated it as such.

Petitioners claim that EPA "unquestionably believed that its scientific findings concerning tolerances [in the PID] were final and actionable." Pet'rs' Br. at 59. But that assertion is contradicted by the plain language of the PID itself, FIFRA regulations regarding registration review, and the APA.

The PID was a *proposed* determination as part of a registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim, a final safety finding. *See* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. The PID reflected EPA's scientific assessment that, based on the evidence available at the time, a subset of 11 high-benefit uses with geographic and application rate restrictions would not pose potential risks of concern with the 10X safety factor, *if* other uses contributing to aggregate exposures were cancelled. AR 40 at 40. Accordingly, EPA determined that those 11 uses "may be considered for retention." *Id.*

The proposed nature of the PID means that EPA's safety determination might be adjusted or revised. EPA requested public comment on the PID, and

some commenters, including cranberry and banana growers, argued that their crops should be retained as well. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. Others, including advocacy and environmental groups, argued that a safety determination supporting even those 11 uses would contravene the available science. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. EPA has not fully considered these comments and has not yet issued a final interim decision. Petitioners' contention (at 55–61) that the PID nevertheless was final disregards that the APA and FIFRA regulations require that EPA address those comments. *See* 5 U.S.C. 553(c); 40 C.F.R. § 155.58(c); *U.S. Satellite Broad. Co., Inc. v. FCC,* 740 F.2d 1177, 1188 (D.C. Cir. 1984) (Agency must respond "in a reasoned manner to significant comments received."). FIFRA regulations also contemplate that there may be changes to the mitigation measures in a proposed interim decision, which the Agency is required to explain. 40 C.F.R. § 155.58(c). As a practical matter, mitigation measures in a proposed interim decision are often modified in the final interim decision, which establishes the legally-required mitigation and label changes. For example, the Interim Registration Review Decision for oxadiazon strengthened certain mitigation measures from the proposed interim decision, including requiring thorough post-application irrigation to mitigate post-application risks of concern and designating oxadiazon as a Restricted Use Pesticide. Oxadiazon: Interim Registration Review Decision Case

Number 2485, EPA Docket No. EPA-HQ-OPP-2014-0782 (Mar. 31, 2022) at 6, Resp'ts' App. at 626.

Petitioners claim that the PID was labeled a "proposal" solely because EPA needed to complete its Endangered Species Act analysis and endocrine screening for registration review. Pet'rs' Br. at 58. Petitioners are wrong. First, EPA's regulations require EPA to publish a proposed registration review decision for every registration review case for at least 60 days of public comment. 40 C.F.R. § 155.58(a). As explained above, EPA was required to consider comments submitted on the PID, including comments on the proposed subset of 11 uses. Second, as EPA explained in the PID, the Agency still needed to consider the forthcoming 2020 FIFRA Scientific Advisory Panel's latest recommendations, which could impact the human health risk assessment and the proposed mitigation measures. AR 40 at 10, 40 ("EPA's conclusions about risk, and thus proposed mitigation measures, may be revised.").

Nor did the Ninth Circuit treat the PID as final. Recognizing EPA's proposal in the PID for modifying certain tolerances and the intervening Scientific Advisory Panel, the Ninth Circuit noted that "*[i]f*, based upon the EPA's further research the EPA *can now conclude* to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos

registrations rather than cancelling them." *LULAC II*, 996 F.3d at 703 (emphasis added).

Petitioners' claim (at 61) that "[a]t all times, Gharda understood that the Safe Uses would be retained" is contradicted by the record of negotiations between EPA and Gharda. At one point, Gharda asked EPA to retain cotton use in Texas (even though it was not proposed for retention in the PID), while later Gharda was willing to eliminate four uses—strawberry, asparagus, cherry (tart) and cotton—that had been proposed for retention in the PID. Seethapathi Ex. H, at 2; (Doc. ID 5133345 at 51), Pet'rs' App. at 1762; *see also* Ex. G, at 1; (Doc. ID 5133345 at 45), Pet'rs' App. at 1756.

Accordingly, the PID did not represent EPA's final position on which uses, if any, could be retained for chlorpyrifos. But ultimately that question is not the deciding one here. The PID's proposed continuation of a limited subset of chlorpyrifos uses was conditioned on the cancellation of all other uses under FIFRA and the implementation of new geographic and application restrictions. AR 40 at 40, 55. At the time of the Final Rule, EPA had not received a single voluntary cancellation request or label amendment from any of the chlorpyrifos registrants, and, as discussed *infra* at 54, FIFRA does not provide EPA with another way to quickly cancel or modify existing registrations. With the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision

based upon an assessment of the science and facts that actually existed. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49.

In sum, the PID was not final, and neither EPA nor Gharda treated it as such. And, even if it were final, because EPA had not received any voluntary cancellation requests or label amendments at the time of the Final Rule, it reasonably made a decision based on its scientific assessment of the registrations that actually existed.

III. EPA reasonably assessed "aggregate" exposure under the FFDCA.

Petitioners argue that the Final Rule and Final Order were arbitrary and capricious because EPA did not utilize a "tolerance-by-tolerance approach." *See* Pet'rs' Br. at 43–46. Petitioners are wrong. EPA's consideration of all tolerances together is consistent with the FFDCA's mandate to assess "aggregate" exposure, as well as longstanding EPA practice. While tolerances may be established or modified individually, the assessment of exposures required to support such actions necessarily includes exposures from all tolerances and other drinking water and residential exposures from registered uses of the pesticide, and this is especially true in the case of a decision to "leave" tolerances "in place." *See supra* at 5 (describing the aggregate exposure assessment required by the FFDCA).

A. EPA's approach is consistent with the text of the FFDCA.

Petitioners and CropLife argue that the plain text of the FFDCA commands an individual tolerance-by-tolerance approach. Pet'rs' Br. at 43–47; CropLife Br. at 15–16. As an initial matter, they have waived this statutory argument because they did not raise it in their objections to the Final Rule. *See Friends of the Norbeck v. U.S. Forest Serv.,* 661 F.3d 969, 974 (8th Cir. 2011). Petitioners and CropLife also fail to explain what, in their view, such an approach would entail. Most importantly, they ignore that the FFDCA explicitly directs EPA to assess "*aggregate* exposure to the pesticide chemical residue" based on "*all* anticipated dietary exposures and *all* other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3 (emphasis added); *see also id*. at § 346a(b)(2)(D)(vi), Resp'ts' Add. at 5 (requiring EPA to consider when leaving in effect or revoking a tolerance, "available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue*, and exposure from other non-occupational sources.") (emphasis added). Congress's use of the word "aggregate" and the plural for both "all anticipated dietary exposure***s***" and "all other exposure***s***" plainly indicates that something more than any one tolerance for a specific pesticide is to be considered at a time. For this reason, EPA's standard

practice is to assess all exposures from all tolerances for a specific pesticide chemical (as well as from drinking water and residential uses) whenever making a safety determination for any given pesticide. AR 16 at 25, Resp'ts' App. at 26.

Nowhere does the FFDCA instruct EPA to employ a tolerance-by-tolerance approach. Petitioners nevertheless argue, without explanation, that the statute's use of "*a* tolerance" instead of "*the* tolerances" mandates such an approach. *See* Pet'rs' Br. at 44; *but cf.* 1 U.S.C. § 1 ("unless the context indicates otherwise—words importing the singular include and apply to several persons, parties or things."). But the use of singular versus plural in this case is irrelevant, as the statute mandates EPA to assess aggregate exposure. *See* 21 U.S.C. §§ 346a(b)(2)(A)(ii), (D)(vi), Resp'ts' Add. at 2-3, 5. Accordingly, the safety finding for any particular tolerance would be the same as for all tolerances together—either way, EPA is required to assess the aggregate exposure caused by *all* tolerances. *See* Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59608, 59675 (Nov. 18, 2009) ("The consequence of this requirement [to consider aggregate exposures] is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels.")

Petitioners also argue that the FFDCA's provision for modifying a tolerance if it is not safe further supports their argument that the text of the FFDCA requires

an individual tolerance-by-tolerance approach. Pet'rs' Br. at 45. Specifically, they argue that because the statute provides that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," 21 U.S.C. § 346a(b)(1), Resp'ts' Add. at 2, the term "modify" can only mean "to narrow permissible uses." Pet'rs' Br. at 45. Thus, Petitioners argue, "EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe." *Id.* at 45–46. This, too, misses the mark.

Just because EPA has the authority to lower or revoke tolerances to reduce the number of approved uses for a pesticide does not mean that the FFDCA compels the Agency to do so, nor does the statute automatically provide the Agency with all of the necessary criteria or tools.[8] Instead, this record needs to be developed and evaluated by EPA in the context of each relevant action. As discussed above, at the judicially-mandated time for EPA's decision here, the Agency lacked an appropriate record basis to make such a decision. Finally, if EPA were to revoke certain tolerances and leave others in place consistent with the PID, EPA would still need to find that the tolerances left in place were safe, which EPA could not do in this case because no changes had been made to (nor had

[8] The term "modify" can also mean to lower a tolerance level. *See, e.g.,* MCPA; Pesticide Tolerances, 86 Fed. Reg. 71152 (Dec. 15, 2021) (reducing MCPA tolerances for clover commodities).

applications been submitted for) the underlying registrations to incorporate the PID's geographic, rate and application restrictions at the time of the Final Rule.

Petitioners do not explain, from a practical perspective, how EPA could conduct, for a pesticide with multiple tolerances, a tolerance-by-tolerance analysis in a manner consistent with the FFDCA's requirement to assess aggregate exposure. With regard to chlorpyrifos, the PID proposed a subset of uses that could fit within the "risk cup,"[9] subject to geographic, rate and application method restrictions, as part of the FIFRA registration review process. But there were likely other possible combinations of uses and restrictions that could have resulted in safe levels of aggregate exposure. 87 Fed. Reg. at 11245, Pet'rs' Add. at 46. EPA specifically noted in its 2020 Drinking Water Assessment that the analysis focused solely on the limited subset of 11 crops to assess whether there were any areas where the estimated drinking water concentrations would not exceed EPA's safe levels of exposures; it did not evaluate every possible combination of uses and restrictions to assess whether a different subset could also result in safe aggregate exposures. *Id.* EPA's 2016 Refined Drinking Water Assessment had already shown that estimated concentrations of chlorpyrifos in drinking water from all uses

[9] The "risk cup" is the total exposure allowed for a pesticide considering its toxicity and required safety factors and is equal to the maximum safe exposure for the duration and population being considered. 87 Fed. Reg. at 11222, Pet'rs' Add. at 23.

would exceed levels of concern, *see* AR 37 at 124, Resp'ts' App. at 464; therefore, EPA's 2020 Drinking Water Assessment focused on whether aggregate exposures might be safe if only some uses were retained. Given the large number of registered chlorpyrifos uses, EPA focused its registration review resources on a subset of potentially higher-benefit uses. AR 38 at 8, Resp'ts' App. at 473.

Even if EPA had adopted the proposed subset of 11 uses from the PID in its tolerance action under the FFDCA, as Petitioners advocate, it is not clear that all stakeholders would agree that EPA had selected the appropriate combination of chlorpyrifos tolerances. For example, some commenters on the PID advocated that bananas and cranberry be included in the list of continued uses. 87 Fed. Reg. at 11246, 11249, Pet'rs' Add. at 47, 50. And in its negotiations with EPA, Gharda proposed the retention of uses for corn, mint, and grapes. Seethapathi Ex. B at 2. (Doc. ID 5133345 at 29), Pet'rs' App. at 1740. Critically, the FFDCA, which does not permit the consideration of benefits in determining whether to leave a tolerance in place, provides no basis for EPA to unilaterally choose one tolerance over another where aggregate exposures for tolerances overall are unsafe.

FIFRA and the FFDCA are complementary but different statutes with separate requirements. As it did under FIFRA, EPA may propose in the PID (and specify in the Interim Decision) label modifications and product or use cancellations that are necessary in order for the product to meet FIFRA's

unreasonable adverse effects standard. 40 C.F.R. § 155.56. Consistent with FIFRA, the proposed measures consider the benefits of those uses. AR 40 at 41–42. When registrants comply with EPA's requirements in an interim decision to voluntarily cancel registrations or amend pesticide product labels, then the pesticide, as assessed, is one step closer to meeting the FIFRA registration standard because the aspects found to cause unreasonable adverse effects no longer exist. *See*, *e.g.*, Oxadiazon: Interim Registration Review Decision Case Number 2485 (Mar. 31, 2022) at 70, Resp'ts' App. at 690 (finding that oxadiazon does not meet the FIFRA registration standard without the specified changes to the affected registrations and their labeling).

By contrast, in assessing the safety of a tolerance under the FFDCA, EPA is required to consider whether aggregate exposures from all anticipated dietary exposures and all other exposures *are* safe. *See* 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. When EPA finds that tolerances are not safe, EPA's sole option under the FFDCA is to modify or revoke tolerances; EPA cannot modify the underlying registrations. Any changes to underlying registrations to reduce aggregate exposures to safe levels occur under FIFRA, not under the FFDCA. *See* 40 C.F.R. § 152.44. Since that is not what happened here, *see supra* at 18, EPA could not base its FFDCA safety analysis on a potentially more limited universe of uses that did not actually exist yet in the real world. In sum, because the sole

consideration under the FFDCA is safety, and safety requires consideration of aggregate exposures, the statute does not provide EPA with any basis upon which to choose which uses to retain. As the Ninth Circuit explained in *LULAC II*, although FIFRA review includes a safety assessment under the FFDCA, it also requires EPA to assess a pesticide's economic, social, and environmental costs and benefits, including impacts on agricultural production and food prices. 996 F.3d at 692–93. But "Congress's decision to give the EPA discretion to set FIFRA priorities does not translate to the FFDCA." *Id.* at 693. Thus, while EPA might be able to conclude that some uses contribute lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment, consideration of those relative benefits is not permitted under the FFDCA in determining whether a tolerance is safe.

B. EPA's approach in the Final Rule and Denial Order is consistent with Agency practice for assessing aggregate exposures when determining whether tolerances are safe.

Contrary to Petitioners' and CropLife's claims (at 44–45, 47 and 16–17), it has not been EPA's practice to conduct a tolerance-by-tolerance analysis along the lines suggested by Petitioners, particularly where the aggregate exposure level is unsafe. To the contrary, as EPA has previously explained, the FFDCA "does not compel EPA to determine the appropriate subset [of tolerances] that would meet

the safety standard." Carbofuran Order, 74 Fed. Reg. at 59675[10]; *see also* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 Fed. Reg. 3421, 3423 (Jan. 19, 2011) (proposing to grant request to stay promulgation of sulfuryl fluoride tolerances because aggregate exposure was unsafe). Indeed, EPA's general practice when the Agency has determined that aggregate exposures are unsafe (making tolerances overall not safe) is not to independently select a subset of uses that meets the safety standard, but instead to engage in a public process that allows registrants and the public to indicate which of the various subsets of tolerances are of sufficient importance to warrant retention. 74 Fed. Reg. at 59675; *see also* 87 Fed. Reg. at 11246, Pet'rs' Add. at 47. EPA attempted to work in this way with Gharda and other chlorpyrifos registrants here, but ultimately was unable to reach an agreement with any registrant regarding voluntary cancellations and label amendments before the Ninth Circuit's 60-day deadline. *See supra* at 15–18.

[10] The U.S. Court of Appeals for the D.C. Circuit denied the portion of a petition for review that challenged EPA's revocation of domestic carbofuran tolerances, but granted the portion challenging EPA's revocation of import tolerances for carbofuran. *Nat'l Corn Growers Ass'n v. EPA,* 613 F.3d 266 (D.C. Cir. 2010). There, EPA had concluded that carbofuran exposure from import tolerances alone would be safe. *Id.* at 275. EPA has made no such conclusion with regard to import tolerances for chlorpyrifos nor has EPA determined that the subset of 11 uses would be safe in the absence of changes to the registrations under FIFRA.

Despite EPA's consistency in addressing tolerances for which aggregate exposures are unsafe, Petitioners and CropLife claim that EPA's tolerance actions on flonicamid, tebuconazole, fludioxonil, and ethalfluralin show that "tolerances do not have to rise or fall together." *See* Pet'rs' Br. at 46-47; CropLife Br. at 11–12. Petitioners and CropLife's examples miss the point, as the individual tolerances to which Petitioners and CropLife refer were not assessed in a vacuum; instead, EPA assessed all tolerances together as part of an aggregate exposure analysis in response to petitions requesting new tolerances. In EPA's tolerance actions for those pesticides, the Agency was able to increase or decrease existing tolerances and/or establish new tolerances because aggregate exposure levels—*i.e.,* exposures from the newly requested tolerance plus all existing tolerances and uses contributing to aggregate exposure—fit within the "risk cup."[11] Put differently, EPA could establish tolerances requested by those petitioners because aggregate exposure levels were safe. By contrast, EPA determined that aggregate exposure to chlorpyrifos was unsafe. Therefore, none of these examples contradicts EPA's position of not independently selecting the subset of uses that meets the safety standard, when, as is the case with chlorpyrifos, aggregate exposure levels are

[11] Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30425 (May 19, 2022); Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60932 (Nov. 12, 2019); Fludioxonil; Pesticide Tolerances, 85 Fed. Reg. 51354 (Aug. 20, 2020); Ethalfluralin; Pesticide Tolerances, 85 Fed. Reg. 45336 (July 28, 2020).

unsafe. If anything, they support the general principle that EPA considers aggregate exposures when assessing whether tolerances are safe. *See* 21 U.S.C. § 346a(b)(2), Resp'ts' Add. at 2-3.

CropLife argues that "with the EPA's new policy of revoking all tolerances whenever the risk cup overflows—even though modification of tolerances would achieve a safe risk cup—registrants and other stakeholders would have no basis to rely on EPA's ability to negotiate and work with them to determine what specific subsets of uses warrant retention." CropLife Br. at 19. CropLife's characterization of EPA's course of action with regard to chlorpyrifos as a "new policy" is incorrect.

First, EPA had a tight timeframe to revoke or modify tolerances as a result of the Ninth Circuit's order, much of which Gharda spent repeatedly seeking unreasonable terms for cancellations and label amendments under FIFRA. Second, as explained above, EPA's actions regarding chlorpyrifos are fully consistent with longstanding Agency policy. Third, where changes to registrations need to occur under FIFRA for remaining tolerances to be found safe by a date certain, EPA cannot leave those tolerances in place when it has no reason to believe that those changes are imminent. Finally, EPA does attempt to work with registrants to cancel or modify registrations and labels in order to lower aggregate exposure where aggregate exposure exceeds the risk cup. For example, in the case of

bifenthrin, registrants cancelled certain registrations and amended others to address residential application risks identified during registration review. *See* Bifenthrin; Pesticide Tolerances, 86 Fed. Reg. 68150, 68154 (Dec. 1, 2021); Product Cancellation Order for Certain Pesticide Registrations, 86 Fed. Reg. 38339 (July 20, 2021). These actions created sufficient room in the risk cup for EPA to establish tolerances for certain food uses. *See* 86 Fed. Reg. at 68151, 68154. The tolerance actions for bifenthrin also contradict Petitioners', CropLife's, and Missouri's claims that EPA's approach effectively reads the term "modify" out of the FFDCA. Pet'r's Br. at 46; CropLife Br. at 12-13, Missouri Br. at 9.

In sum, EPA's process for considering aggregate exposure was consistent with the FFDCA and past policy and practice and, therefore, reasonable.

IV. When assessing all "anticipated" exposures, EPA reasonably considered all currently registered uses of chlorpyrifos.

Petitioners argue (at 43) that by evaluating exposure from all registered chlorpyrifos uses, EPA essentially replaced the statute's use of the word "anticipated" with the word "existing." This argument misinterprets the FFDCA's mandate to assess *all anticipated exposures* in making EPA's safety determination. 21 U.S.C. § 346a(b)(2)(A)(ii), Resp'ts' Add. at 2-3. In guidance developed after the FQPA amendments to the FFDCA, EPA established that "[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure

assessment is the universe of *proposed* and *approved* uses for the pesticide,"[12] which are determined by use patterns on labels of the proposed and registered products. AR 16 at 44–45, Resp'ts' App. at 45-46 (emphasis added); *see, e.g.,* Fluoxastrobin; Pesticide Tolerances, 84 Fed. Reg. 38138, 38140 (Aug. 6, 2019) (considering petitioned-for tolerances and existing tolerances). Accordingly, EPA's consideration of all registered chlorpyrifos uses when determining which exposures are "anticipated" was consistent with the ordinary reading of the statute and long-standing Agency guidance and practice.

Citing EPA's tolerance action on benzobicyclon, Petitioners assert that EPA's consideration of registered uses for chlorpyrifos was not a consideration of "anticipated uses." *See* Pet'rs' Br. at 46–47 (citing Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60368 (Nov. 2, 2021)). Petitioners again misunderstand how EPA assesses tolerances and implements the aggregate exposure directive of the FFDCA. For benzobicyclon, EPA received a petition to increase one tolerance. In response, the Agency considered the "anticipated" aggregate exposures, which included exposures from uses already registered as well as what was anticipated from the new use if it was approved. 86 Fed. Reg. at 60370–71. This example is

[12] The term "approved uses" refers to uses that have already been approved or registered by EPA, *see* 40 C.F.R. § 152.112; "proposed uses" refers to new uses for which an application has been submitted for registration. *See* 40 C.F.R. § 152.3 (definition of "new use" referring to "proposed use pattern").

consistent with EPA's chlorpyrifos action. The "anticipated exposures" for chlorpyrifos reasonably included exposures from registered uses because no registrant had submitted any label amendment applications to align uses with the Agency's proposal in the PID to potentially retain certain tolerances.

Critically, EPA cannot require changes to registered pesticides under the FFDCA. Changes such as application rate restrictions or geographical limitations can only be accomplished through amendments to the label approved under FIFRA, which EPA cannot do unilaterally. *See infra* at 54, n.13. When a tolerance for residues of a pesticide on a particular food is revoked, that pesticide may no longer be registered for use on that food. *See* 21 U.S.C. § 346a(a), Resp'ts' Add. at 1; 7 U.S.C. § 136(bb). However, for chlorpyrifos, it would not be as simple as revoking all but the 11 uses proposed for retention in the PID. Aside from the fact that it was not a final determination, EPA's proposal to find the 11 uses safe was also contingent on restrictions being made to the underlying labels under FIFRA, *i.e.*, restricting applications to specific geographic areas and ensuring that application rates reflected the usage rates assessed in EPA's 2020 Drinking Water Assessment. Without those labeling changes, the 11 uses EPA identified would not be consistent with the proposal in the PID. *See* 87 Fed. Reg. 11246, Pet'rs' Add. at 47 (explaining that tolerances are broadly applicable rules without geographic limitations, and in order to limit geographic use, associated

FIFRA labels would need to be amended). Put differently, EPA could not modify tolerances under the FFDCA in a way that would render those 11 proposed uses safe, because additional changes to associated labeling would still need to occur under FIFRA, and at the time of the Final Rule no applications for label revisions had been submitted or approved under FIFRA. Until the universe of chlorpyrifos uses reflected the subset proposed in the PID—or at least until EPA had a reasonable basis to believe that would happen—the Agency could not conclude that the subset of 11 geographically restricted uses proposed in the PID comprised the "anticipated" exposures under the FFDCA. *Id.*

Gharda's argument to the contrary portrays its negotiations with EPA as final and complete because it "had submitted to EPA a written commitment to conform its registration to EPA's safety finding." *See* Pet'rs' Br. at 52. Typically, a formal request for voluntary cancellation of registered uses includes a letter requesting cancellation of product or uses along with applications to amend relevant labels. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. EPA received neither from Gharda. *Id.* Even Gharda's final proposal to EPA stated only that it was "willing to accept" certain voluntary cancellations if, "in return," EPA agreed to extended terms for formulation, sale, distribution, and use of existing stocks. Seethapathi Decl. Ex. H, at 2, (Doc. ID 5133345 at 51), Pet'rs' App. at 1762.

Conditional proposals such as Gharda's do not provide EPA with a reasonable basis to conclude that uses will be cancelled and exposures reduced. 87 Fed. Reg. at 11248, Pet'rs' Add. at 49. Gharda defends its inaction by claiming that it was merely "standing by awaiting word from EPA on when to submit a formal voluntary cancellation request." Pet'rs' Br. at 53. But there was no need to wait: FIFRA permits any registrant to submit a voluntary cancellation request to EPA at any time. 7 U.S.C. § 136d(f)(1).

EPA also could not have completed involuntary cancellation proceedings prior to the Ninth Circuit's 60-day deadline. *See supra* at 8. Without cancellation and label amendment requests in hand from Gharda and the other chlorpyrifos registrants, or the ability to quickly complete involuntary cancellation proceedings, EPA lacked a reasonable basis for concluding that chlorpyrifos uses would be limited as proposed in the PID. 87 Fed. Reg. at 11246, Pet'rs' Add. at 47.

Gharda is not without a remedy. Namely, it may petition to establish new chlorpyrifos tolerances, and EPA would be required to evaluate any such request. Instead, Petitioners ask this Court to restore *all unsafe* chlorpyrifos tolerances (by vacating EPA's revocation). Restoring all chlorpyrifos tolerances would also undermine judicial comity among sister circuits and stand in considerable tension with the Ninth Circuit's explicit instruction to immediately revoke or modify all tolerances.

Finally, Gharda's suggestion (at 28–29) that EPA did not permit it to meaningfully participate in the revocation process rings hollow. Since the petition to revoke chlorpyrifos tolerances was filed nearly 15 years ago, EPA has solicited comments on revocation multiple times. After years of administrative process in response to the 2007 Petition to Revoke, in which registrants were afforded numerous opportunities to participate, and in light of the extensive scientific record EPA developed indicating chlorpyrifos is unsafe at current exposures, the Ninth Circuit said enough is enough and directed EPA to modify or revoke the chlorpyrifos tolerances "immediately" and without notice and comment. *LULAC II*, 996 F.3d at 702–03. No additional notice of its decision to revoke tolerances was required. *See* 21 U.S.C. § 346a(d)(4)(A)(i), Resp'ts' Add. at 9 (authorizing EPA to issue a "final regulation" without notice and comment in response to a petition to revoke).

For these reasons, EPA's assessment of registered uses in its aggregate exposure analysis was reasonable.

V. The FFDCA does not require EPA to cancel chlorpyrifos registrations before revoking tolerances.

Petitioners appear to argue that the FFDCA required EPA to cancel all chlorpyrifos registrations under FIFRA before revoking the corresponding tolerances under the FFDCA. *See* Pet'rs' Br. at 45-48. This argument misreads the FFDCA.

In support of their argument, Petitioners point to the FFDCA's direction that "the Administrator shall coordinate such action with any related necessary action under [FIFRA]." Pet'rs' Br. at 48 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1), Resp'ts' Add. at 15. Thus, the FFDCA does not require EPA to cancel registrations *before* revoking tolerances. *See* Carbofuran; Final Tolerance Revocations Rule, 74 Fed. Reg. 23046, 23069 (May 15, 2009) ("Nothing in this provision establishes a predetermined order for how the Agency is to proceed to resolve dietary risks.") Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use only "in a timely fashion." *LULAC II,* 996 F.3d at 704.

Petitioners accuse EPA of trying to "have it both ways" by "claim[ing] that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses." Pet'rs' Br. at 49-50. Petitioners' apparent suggestion that the FFDCA requires EPA to utilize any FIFRA-specific process or considerations prior to revoking tolerances lacks any basis under the statute. And, in these particular circumstances, where the Ninth Circuit gave EPA a 60-day deadline to act and

rejected EPA's argument that a decision on tolerances should be delayed pending completion of registration review, EPA reasonably assessed the registrations that existed at the time. *See LULAC II,* 996 F.3d at 678, 691, 702. That assessment led to the Final Rule revoking all tolerances, *see supra* at 18–20, and then, after issuing the Final Rule, EPA began the extensive process under FIFRA of conforming registrations to the Final Rule.

Similarly without merit is Petitioners' suggestion (at 50–52) that EPA may modify registrations quickly without registrants' consent, such that the Agency could have cancelled or modified all registrations before the 60-day deadline to leave in place tolerances for the proposed subset of 11 uses. To the contrary, registrants whose registrations are subject to involuntary cancellation have substantial process rights, including the right to a hearing, appeal to the Environmental Appeals Board, all *before* the registration is actually cancelled, and judicial review. *See supra* at 8.[13]

Petitioners also ignore that EPA is proceeding with the cancellation of chlorpyrifos registrations in a timely manner. Following the expiration of

[13] Relatedly, EPA lacks the authority to unilaterally modify pesticide labels. Instead, the registrant must submit an application to amend the label, which EPA may then approve. *See* 40 C.F.R. § 152.44(a). Where registrants do not submit revised labels for approval, EPA may take appropriate action under FIFRA, which may include initiating cancellation. *See* 7 U.S.C. § 136d(b); 40 C.F.R. § 155.58(d).

chlorpyrifos tolerances, EPA received several requests for voluntary cancellation of chlorpyrifos registrations and published a notice regarding 16 voluntary cancellations. 87 Fed. Reg. 25256 (Apr. 28, 2022). Moreover, EPA has consistently stated its intention to initiate involuntary cancellation proceedings for all registrations for which it does not receive a voluntary cancellation request.

Petitioners claim (at 53) that EPA's practice has been to modify or revoke tolerances to reflect analyses that a subset of uses are safe, and then modify registrations to reflect changes to those tolerances. Petitioners are wrong. For example, in the case of bifenthrin, after the registrants cancelled certain uses and amended labels to address residential application risks, there was sufficient room in the "risk cup" to establish new tolerances. *See* Bifenthrin, 86 Fed. Reg. at 68154; 86 Fed. Reg. at 38339. Petitioners cite (at 54) dicloran as a contrary example, claiming that there EPA first modified the tolerances for dicloran and later modified the registrations to reflect the tolerance modifications. But, in fact, EPA first terminated the uses of dicloran on potatoes and carrots in response to voluntary cancellation requests by the registrant. Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71022 (Nov. 16, 2011); Dicloran; Cancellation Order for Amendment to Terminate a Use of DCNA Pesticide Registrations, 75 Fed. Reg. 16105 (March 31, 2010). EPA subsequently revoked the tolerances for dicloran on potatoes and carrots. Dicloran and

Formetanate; Tolerance Actions, 77 Fed. Reg. 40812 (July 11, 2012).[14] Moreover, the dicloran tolerance actions were not taken to address safety, and instead served only to remove tolerances that were no longer necessary because of action by the registrant.

In sum, the FFDCA does not require that EPA cancel chlorpyrifos registrations before revoking tolerances.

CONCLUSION

For the foregoing reasons, EPA respectfully requests that the Court deny Petitioners' request to vacate the Final Rule and Denial Order. Petitioners' request for vacatur would leave all chlorpyrifos tolerances in place, despite the expert agency's conclusion that they are unsafe.

[14] Petitioners also cite Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4651 (Feb. 1, 2018) in support of their claim, however that order canceled uses unrelated to the cited tolerance actions.

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