In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Consolidated Case Nos. 22-1422, 22-1503

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITIONERS' OPENING BRIEF

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SUMMARY OF THE CASE AND ORAL ARGUMENT REQUEST

This case concerns an arbitrary and capricious U.S. Environmental Protection Agency ("EPA" or "Agency") rule effectively banning the insecticide chlorpyrifos, a crop protection tool growers have relied on for decades. Petitioners challenge EPA's denial of objections to the rule and the rule itself as contrary to the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Agency's own scientific findings. *See* AR 1[1], Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"); Add. 1[2]; Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("Denial Order"); Add. 23.

Petitioners respectfully request oral argument in this case due to the novel and important issues raised, and in light of the ramifications of EPA's Final Rule and Denial Order on Petitioners and the agricultural community. Petitioners respectfully request 20 minutes to present their case.

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[1] "AR" refers to EPA's Certified Index to the Administrative Record. Case No. 22-1422, Doc ID: 5146142 (under seal).

[2] "Add." refers to the Addendum filed with this Brief.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure Petitioners submit the following corporate disclosure statement:

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International, Inc**. states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

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JURISDICTIONAL STATEMENT

I. THIS COURT HAS JURISDICTION OVER PETITIONERS' CLAIMS

This Court has jurisdiction to review Petitioners' challenge to the EPA's Denial Order and to the Final Rule under FFDCA § 408(h)(1). 21 U.S.C. § 346a(h)(1) ("any person . . . adversely affected by" an order on objections to a final rule revoking tolerances "may obtain judicial review . . . in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business"). This action properly lies in this circuit because most of the Petitioners reside within the Eighth Circuit. Eleven of the nineteen Grower Petitioners[3] are all based in States located within the Eighth Circuit. *See id.* An additional five Petitioners[4] have members located within the Eighth Circuit. The aggregate value of the eleven crops adversely affected by

[3] These eleven Petitioners are Red River Valley Sugarbeet Growers Association, Minn-Dak Farmers Cooperative, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, and North Dakota Soybean Growers Association.

[4] These five Petitioners are U.S. Beet Sugar Association, American Sugarbeet Growers Association, American Farm Bureau Federation, National Association of Wheat Growers, and National Cotton Council.

the revocation of chlorpyrifos tolerances to the U.S. economy is more than $59 billion annually.[5] A large share of those crops are grown within the Eighth Circuit.

II. PETITIONERS HAVE STANDING TO BRING THIS CASE

Petitioners have standing to seek review of EPA's Final Rule and Denial Order. To satisfy Article III's standing requirements, a petition must show: (1) a "concrete and particularized" and "actual or imminent" "injury in fact"; (2) that is "fairly traceable" to the conduct complained of; and (3) that will be "redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citations omitted). An association has standing to sue on its members' behalf "when its members would otherwise have standing, . . . the interests at stake are germane to the organization's purpose," and the claim and requested relief do not require the individual members' participation in the lawsuit. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

[5] USDA, National Agricultural Statistics Service, www.nass.usda.gov.

"[W]here one plaintiff establishes standing to sue, the standing of other plaintiffs is immaterial to jurisdiction." *Jones v. Gale*, 470 F.3d 1261, 1265 (8th Cir. 2006); *Nat'l Wildlife Fed'n v. Agric. Stabilization & Conservation Serv.*, 955 F.2d 1199, 1203 (8th Cir. 1992) (internal quotation marks omitted). "[A] regulated party generally has standing to challenge an agency action regulating its behavior." *Ameren Servs. Co. v. FERC*, 893 F.3d 786, 792 (D.C. Cir. 2018).

The Grower Petitioners, on their own behalf or on behalf of their members, demonstrate a "concrete and particularized" and "actual or imminent" injury in fact because EPA's unlawful revocation action has deprived them of a pest control tool that is critical for their crops, including sugarbeets, cherries, and soybeans. *See, e.g.*, Pet. App. 1374[6] ¶ 8; Pet. App. 1384–85 ¶ 10; Pet. App. 1394 ¶ 9; Pet. App. 1405 ¶ 9; Pet. App. 1418–19 ¶¶ 13–14; Pet. App. 1427–28 ¶ 12; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1455–56 ¶ 9; Pet. App. 1463–64, 1466–74 ¶¶ 4, 9–22; Pet. App. 1479–81 ¶¶ 10–15; Pet. App. 1486–93 ¶¶ 6–19; Pet. App. 1499–501 ¶¶ 11–14; Pet. App. 1508–09 ¶¶ 12–16; Pet. App. 1516–18 ¶¶ 12–18; Pet. App. 1525–26 ¶¶ 11–14; Pet. App. 1535 ¶¶ 12–14;

[6] "Pet. App." refers to the Petitioners' Appendix.

Pet. App. 1543–44 ¶¶ 11–15; Pet. App. 1560–63 ¶¶ 4–16; Pet. App. 1568–69 ¶ 8; Pet. App. 1579–80 ¶¶ 10–14; Pet. App. 1586–87 ¶¶ 12–14; *see also Lujan*, 504 U.S. at 560; *Ameren Servs.*, 893 F.3d at 791.

As a result of EPA's revocation of tolerances, any commodity treated with chlorpyrifos as of the rule's February 28, 2022, effective date is deemed "adulterated," 21 U.S.C. §§ 342(a), 346a(a)(1), and subject to seizure, *id.* § 334(a)(1), and any grower who applies chlorpyrifos to commodities in interstate commerce is subject to criminal sanctions, *see id.* §§ 331, 333. The inability to lawfully apply chlorpyrifos will likely cause the growers represented by Grower Petitioners financial harm from reduced crop yields due to an increase in pest pressure, *see, e.g.*, Pet. App. 1378 ¶ 21; Pet. App. 1396 ¶ 14; Pet. App. 1405, 1407 ¶¶ 10, 16; Pet. App. 1419 ¶ 14; Pet. Ap. 1431–32 ¶ 22; Pet. App. 1437, 1439–49 ¶¶ 4, 9–26; Pet. App. 1386–87 ¶¶ 10–15; Pet. App. 1458 ¶ 14; Pet. App. 1471–72 ¶ 18, as well reputational harm, *see, e.g.*, Pet. App. 1397–98, 1399 ¶¶ 21, 25; Pet. App. 1472–73 ¶ 20; Pet. App. 1492 ¶ 17. This harm would be remedied for the 2023 growing season and beyond by a favorable decision from this Court.

Petitioner Gharda also has standing as the chlorpyrifos registrant and primary supplier of chlorpyrifos for agricultural use in the United States. *See Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 870 (8th Cir. 2013) (injury based on members' interest in Clean Water Act permits); *Coteau Props. Co. v. Dep't of Interior*, 53 F.3d 1466, 1472 (8th Cir. 1995) (applicant for surface mining permit had standing). Gharda similarly has a "concrete and particularized" interest in the tolerances and the harm to that interest is "actual or imminent," *Lujan*, 504 U.S. at 560, because EPA's Final Rule has denied Gharda the necessary authorizations for Gharda to manufacture and sell chlorpyrifos for use on food, 7 U.S.C. § 136(bb). These concrete injuries are directly caused by EPA's revocation of tolerances and would be remedied by a decision from this Court vacating the Final Rule and Denial Order with respect to those uses. *See Lujan*, 504 U.S. at 560–61.

STATEMENT OF ISSUES

Whether EPA's Final Rule and Denial Order revoking all food tolerances for chlorpyrifos are arbitrary and capricious, an abuse of discretion, and otherwise contrary to law in light of:

1. EPA's disregard of its own scientific evidence supporting the retention of eleven uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in specifically designated regions the Agency unequivocally found safe (the "Safe Uses").

2. The plain text and intent of the FFDCA, which require a forward-looking, individual review of tolerances, based on the latest scientific developments.

3. EPA's failure to coordinate its actions under the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as the statutes require and consistent with prior Agency practice.

4. EPA's failure to offer a reasoned explanation justifying its departure from its own scientific findings.

Apposite statutory provisions and cases for issue 1: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State*

Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *Chlorine Chemistry Council v. E.P.A.*, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000).

Apposite statutory provisions and cases for issue 2: 21 U.S.C. §§ 346a(b)(1), 346a(b)(2)(A); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 3: 21 U.S.C. § 346a(l)(1); 7 U.S.C. § 136(bb); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29.

Apposite statutory provisions and cases for issue 4: *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

STATEMENT OF THE CASE

III. EPA'S REGULATION OF FOOD USE PESTICIDES UNDER TWO INTERRELATED STATUTES: THE FFDCA AND FIFRA

Pesticides are among the most heavily regulated substances in the United States. EPA regulates pesticides used on food under a comprehensive, science-based regime arising primarily under two separate but interrelated federal statutes: the FFDCA, 21 U.S.C. § 346a, and FIFRA, 7 U.S.C. §§ 136–136y. Congress made clear that it intends for EPA to coordinate its actions under the two laws. H.R. Rep. No. 104-669(II), 104th Cong. at 51 (1996) ("The Committee expects EPA to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties.").

A. The FFDCA

The FFDCA requires EPA to set food safety "tolerances," which are maximum levels of pesticide residues allowed in or on food. 21 U.S.C. § 346a. EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* § 346a(b)(2)(A)(i). Food containing pesticide residues that exceed an established tolerance level is deemed "adulterated" under the FFDCA and may not be moved in interstate commerce. *Id.* §§ 331, 342. In considering whether to establish, modify, or revoke a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." *Id.* § 346a(b)(2)(D)(i).

In 1996, Congress amended the FFDCA with the passage of the Food Quality Protection Act ("FQPA") which, among other things, established a new safety standard for pesticide tolerances covering pesticide residues in or on raw agricultural commodities. A tolerance is deemed "safe" under the FFDCA if "there is a reasonable certainty that

no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). This includes exposure from food, drinking water, and in residential settings, but does not include occupational exposure. In assessing reasonable certainty of no harm, EPA is to apply an additional tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" but EPA has discretion to apply a different margin of safety if there is "reliable data" to support that determination.[7] *Id.* § 346a(b)(2)(C)(ii).

While application of "reasonable certainty of no harm" to tolerances for raw agricultural commodities was new to EPA when the

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[7] The FFDCA does not define "reliability" or "reliable data." In a February 2002 guidance document, EPA counseled that "the data and information" relied upon to inform a safety factor determination "must be *sufficiently sound* such that [EPA's Office of Pesticide Programs] could routinely rely on such information in taking regulatory action." AR 9, *EPA, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance* (Feb. 28, 2002) at A-6; Pet. App. 536 (emphasis added). Data that are not replicable are not reliable. AR 24, *EPA, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (Dec. 28, 2016) at 30; Pet. App. 1055 ("[R]eliability general[ly] refers to the ability to reproduce results. . . .").

FQPA was passed, EPA and the Food and Drug Administration ("FDA") had used the same standard for decades when establishing tolerances for processed foods under FFDCA § 409. And the FDA used the same standard in approving food additives under FFDCA § 409.[8]

B. FIFRA

EPA also regulates pesticides under FIFRA. Under FIFRA, all pesticides must be registered by EPA before they can be marketed, distributed, or sold in the United States. 7 U.S.C. § 136a(a). FIFRA registrations operate as "product-specific license[s]" and confer on registrants legally protectable property rights. *See Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 36 (D.D.C. 2011); Add. 79–80, *Ctr. for Biological Diversity v. E.P.A.*, No. 11-cv-00293-JCS, 2013 WL 1729573, at *6–7 (N.D. Cal. Apr. 22, 2013) ("[O]wners of the pesticide

[8] In the 1958 amendments to the FFDCA, Congress made clear that a safety determination under the "reasonable certainty of no harm" standard does not require absolute proof of safety: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rep. No. 85-2422, 85th Cong., reprinted in 1958 U.S.C.C.A.N. 5300, 5305; *see also* H.R. Rep. No. 83-2284, 83rd Cong (1958).

registrations . . . have property and financial interests in the registrations.").

As originally enacted, "FIFRA was primarily a licensing and labeling statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). Through a series of amendments to the law in the 1970s, Congress transformed FIFRA into a "comprehensive regulatory statute" under which EPA exercises broad authority. H.R. Rep. No. 92-511, 92d Cong., at 1 (1971).

To approve a pesticide registration, EPA must determine, based on a review of extensive scientific data, that use of the product in accordance with its label will not pose "unreasonable adverse effects" on humans or the environment. 7 U.S.C. § 136a(c)(5)(D). The product label establishes the scope of the FIFRA registration, and is submitted to and approved by EPA as a core element of every registration. *See, e.g., id.* § 136a(c)(1)(C). Every registered product is required to display an EPA-approved label that identifies the approved crop uses, applications, and directions for use. Use of a pesticide in a manner inconsistent with that label is unlawful. *Id.* § 136j(a)(2)(G).

FIFRA also requires EPA to conduct comprehensive reevaluations of all registered pesticides every fifteen years, a process known as registration review. This process ensures that all pesticides and their approved uses continue to satisfy FIFRA's safety standard as scientific capabilities improve and agricultural practices change over time. *Id.* § 136a(g)(1)(A)(iii)–(iv); 40 C.F.R. § 155.40(a). During registration review, EPA reviews available data and information and conducts a number of risk assessments. EPA makes these assessments available for public comment, conducts further scientific analyses, and revises its assessments, as necessary.

C. Congress's Intended and Purposeful Harmonization of the FFDCA and FIFRA

FIFRA and FFDCA cross-reference one another and are intended to be carried out in harmony. For pesticides used on food, FIFRA's "unreasonable adverse effects" registration standard expressly incorporates FFDCA's "reasonable certainty of no harm" safety standard. 7 U.S.C. § 136(bb). Thus, when EPA registers a pesticide for use on food, it must determine that doing so will not cause higher amounts of pesticide residue on food commodities than the approved tolerances allow. Moreover, through the FQPA, Congress amended

FIFRA to adopt the fifteen-year registration review process: part of the purpose of this update to the law was to ensure that existing tolerances are consistent with current science. *See* 142 Cong. Rec. H8127-02, 104th Cong. (1996), at H8147 (contemplating that tolerance assessments would "take advantage of the latest scientific advances"); *see also* Add. 99, EPA Testimony on Pesticide Regulations Before the H.R. Subcomm. on Health & Env't and Comm. on Com., 1995 WL 347288 (June 7, 1995) (fifteen-year registration review process will "ensure that tolerances keep pace with advances in scientific knowledge").

Additionally, the FFDCA mandates that when revoking a tolerance EPA "shall coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(l)(1). For example, EPA may modify or cancel the pesticide's registration and enter an "existing stocks" order to "permit the continued sale and use of existing stocks" of a pesticide whose registration is being cancelled. 7 U.S.C. § 136d(a), (b).

IV. CHLORPYRIFOS AND ITS IMPORTANCE TO U.S. AGRICULTURE

A. Chlorpyrifos Has Benefited U.S. Farmers and Contributed to a Safe and Affordable Food Supply for Decades

Chlorpyrifos is an organophosphate insecticide that has been approved for use in the United States since 1965. Chlorpyrifos is a vitally important agricultural tool that protects valuable U.S. food crops from destruction due to insect pests. *See* AR 62 (EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos, EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits")); Pet. App. 299. Growers rely on chlorpyrifos due to its broad-spectrum efficacy against multiple pests, low cost, and minimal impact on beneficial insects. It is the leading active ingredient to control a wide variety of difficult-to-control insect pests and is often relied on as the first line of defense against new or unknown insect pests. For some growers represented by Grower Petitioners, chlorpyrifos is the only effective crop protection tool available. *See* Pet. App. 1373–74 ¶ 7; Pet. App. 1385–86 ¶ 10; Pet. App. 1393–94 ¶ 8; Pet. App. 1405 ¶ 9; Pet. App. 1417 ¶ 8; Pet. App. 1427–28 ¶ 12; Pet. App. 1440–41 ¶ 11; Pet. App. 1455–56 ¶ 9; Pet. App. 1466–67

¶ 10; Pet. App. 1568–69 ¶ 8; Pet. App. 1586 ¶ 10; *see also* AR 62 at 2; Pet. App. 301.

The eleven crops adversely affected by the revocation of chlorpyrifos tolerances contribute more than $59 billion to the U.S. economy annually. Access to chlorpyrifos as a crop protection tool protects growers' crops and income and benefits consumers who enjoy affordable, healthy, and high quality produce throughout the year.

B. EPA's Revocation Decision Threatens the Viability of Essential U.S. Food Crops

EPA's revocation decision will have a significant, negative impact on the agricultural economy. Without chlorpyrifos, some crops will be left without viable alternatives, putting those crops and their growers' livelihoods at risk. Lack of access to chlorpyrifos will significantly diminish the production capabilities of many growers, causing crippling economic losses. *See* Pet. App. 1500–01 ¶ 13; Pet. App. 1489–90 ¶ 13; Pet. App. 1386, 1387 ¶¶ 11, 14; Pet. App. 1455–56 ¶ 9; Pet. App. 1444–46 ¶¶ 20–21; Pet. App. 1431–32 ¶ 22; Pet. App. 1471–72 ¶ 18. In particular, loss of chlorpyrifos threatens the continued viability of sugarbeet production in the United States. *See* Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc ID 5132688 (Mar. 3, 2022) at 4–5.

These economic impacts will ultimately be felt by U.S. consumers, who are already experiencing staggering inflation and supply chain disruptions.

V. EPA'S SHIFTING REGULATORY OVERSIGHT OF CHLORPYRIFOS LEADING UP TO THE 2020 PID

A. EPA Reaffirms Chlorpyrifos's Safety In a 2006 Reregistration Action

EPA has long evaluated the safety of chlorpyrifos based on its potential to inhibit acetylcholinesterase ("AChE"), an enzyme necessary for proper nervous system function in target pests and other organisms, as well as in humans. AChE inhibition can be measured at very low levels in the blood, enabling EPA to determine safe levels of exposure to humans, in accordance with its safety standard under FIFRA and the FFDCA. EPA has concluded that exposure to chlorpyrifos below levels that cause 10% red blood cell AChE ("RBC AChE") inhibition does not adversely affect human health. This conclusion is supported by decades of scientific review and an extensive and complete database of toxicology studies. AR 1 at 48,323; Add. 9.

Since it was first registered in 1965, EPA has reviewed chlorpyrifos several times to ensure that it continues to meet FIFRA and FFDCA safety standards. In 2006, EPA completed "reregistration"

of chlorpyrifos, a review of older pesticides required by FIFRA, which included a reassessment of existing tolerances. In a final decision, EPA reauthorized all existing agricultural uses and determined that all chlorpyrifos food tolerances are "safe," meaning there is "a reasonable certainty that no harm will result from aggregate exposure" to chlorpyrifos. AR 33, EPA, Reregistration Eligibility Decision for Chlorpyrifos (2006); Pet. App. 546–48; 21 U.S.C. § 346a(b)(2)(A)(ii). That decision remained undisturbed until the Final Rule.

B. A 2007 Administrative Petition Spurs Inconsistent Regulatory Action

In 2007, a group of nongovernmental organizations that oppose pesticide use petitioned EPA to revoke all chlorpyrifos tolerances. The petition was based principally on an epidemiology study claiming associations between trace levels of chlorpyrifos (below those that cause 10% RBC AChE) in umbilical cord blood and neurodevelopmental effects in children later in life.

In response to the administrative petition, EPA accelerated registration review of chlorpyrifos. As part of that process, EPA conducted multiple risk assessments and sought public comment on those assessments. EPA also convened several sessions of its FIFRA

Scientific Advisory Panel ("SAP"), an independent advisory committee of scientific experts, *see* 7 U.S.C. § 136w(d)(1), to evaluate several scientific issues relating to chlorpyrifos, including the epidemiology study. The SAP looked closely at the epidemiology data and concluded that they contained numerous deficiencies and were insufficient to support a new regulatory standard.[9]

From 2007 to 2015, EPA gave every indication that it intended to deny the administrative petition. In March 2015, in litigation challenging EPA's response to the administrative petition, EPA informed the Ninth Circuit that it planned to deny the petition, having determined based on its 2014 Revised Human Health Risk Assessment that the petition's claims did not provide a basis to revoke tolerances. *See* Status Rep. at 2, *In Re Pesticide Action Network North America*, No.

[9] *See, e.g.*, AR 27 at 19; Pet. App. 914 (2012 SAP concurring with EPA that the epidemiology data "are not adequate enough to obtain a point of departure (POD) for the purposes of quantitative risk assessment."); AR 41 at 46; Pet. App. 853 (2008 SAP stating that "the Panel agreed with the Agency that there were limitations in the . . . epidemiological studies that precluded them from being used to directly derive the [point of departure] or the uncertainty factor"). "Point of departure" refers to the maximum level of pesticide exposure for which there are no observable adverse effects. It is the "starting point" for EPA's risk calculations. *See* AR 1 at 48,322; Add. 8.

14-72794 (9th Cir. Mar. 31, 2015), ECF No. 14. EPA also informed the court that the scientific evidence was "insufficient" to depart from the 10% RBC AChE inhibition regulatory standard upon which its 2006 safety determination was based. *Id.*, Attach. 1 at 3.

Later in 2015, EPA changed course, not due to any newfound concern related to the administrative petition, but instead based on drinking water issues the Agency was in the process of studying. In response to a court deadline, EPA issued a Proposed Rule to revoke tolerances, published on November 6, 2015. Pet. App. 994, Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080 (Nov. 6, 2015) (the "Proposed Rule").[10] EPA made clear that the Proposed Rule was based on a preliminary drinking water assessment it was working to refine, not food or other exposures, which EPA said in the Proposed Rule "*are safe*." *Id.* at 996, 1021 (emphasis added). EPA reiterated that "AChE inhibition remains the most robust quantitative dose response

[10] Some regulatory materials referenced in Petitioners' Statement of the Case are not included in EPA's AR. While these materials do not bear directly on the issues before the Court, they are cited here as background and context for Petitioners' arguments. If the Court would like copies of any of these documents, Petitioners will be pleased to provide them.

data for chlorpyrifos and thus continues to be the critical effect for the quantitative risk assessment." *Id.* at 1002. EPA acknowledged that its drinking water assessment was ongoing and stated that it "may update this action with new or modified analyses as EPA completes additional work." *Id.* at 999.

In April 2016, EPA took a radical regulatory detour, convening an SAP to review an unprecedented proposal that would base a new regulatory standard for chlorpyrifos directly on cord blood concentrations reported in the epidemiology study. EPA, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies (Mar. 11, 2016). The SAP rejected EPA's proposal: "[T]he majority of the Panel considers the Agency's use of the results from a single longitudinal study to make a decision with immense ramifications based on the use of cord blood measures of chlorpyrifos as a [point of departure] for risk assessment as premature and possibly inappropriate." AR 28 at 25, EPA, Scientific Advisory Panel for Chlorpyrifos; Analysis of Biomonitoring Data (Apr. 19–21, 2016).

Ignoring the SAP's admonition, in November 2016 EPA proposed and sought comment on yet another new regulatory standard, also

based solely on the same epidemiology study previously rejected.[11] *See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049 (Nov. 17, 2016). The proposal was severely criticized in public comments, including by the Obama Administration U.S. Department of Agriculture. *See* Pet. App. 1078, USDA Comments on the Risk Assessment Underlying the Reopened Proposed Rule "Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment" (EPA-HQ-OPP-2015-0653-0648), Jan. 17, 2017 (expressing "grave concerns that ambiguous response data from a single, inconclusive study are being combined with a mere *guess* as to dose levels . . . to underpin a regulatory decision about a pesticide chemical that is vital to U.S. agriculture, and whose removal from market would have a major economic impact on growers and consumers").

[11] Rather than accept the weaknesses the SAP identified with the cord blood data, EPA's new 2016 proposal doubled down and used a dose reconstruction approach to develop a new point of departure. Under this approach, EPA interviewed New York City pesticide applicators in 2016 to estimate the amounts of chlorpyrifos the study subjects might have been exposed to 15–20 years earlier.

In April 2017, EPA retreated from pursuing novel regulatory approaches based on unreliable, previously rejected epidemiology data. EPA denied the administrative petition, finding the epidemiology data urged in support of the petition were not sufficiently valid, complete, or reliable. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Pet. to Revoke Tolerances, 82 Fed. Reg. 16,581 (Apr. 5, 2017). The NGO petitioners filed objections and simultaneously challenged EPA's petition denial order in the Ninth Circuit. *League of United Latin American Citizens v. Wheeler*, Case No. 17-71636 (9th Cir.) ("*LULAC I*"). An *en banc* panel of the Ninth Circuit found that it had no jurisdiction to review EPA's petition denial but ordered EPA to act on the objections by July 18, 2019. *LULAC I*, 922 F.3d 443 (9th Cir. 2019). EPA then denied the objections to its petition denial order, again finding concerns about neurotoxicity of chlorpyrifos at levels below 10% RBC AChE inhibition unsupported by valid, complete, and reliable data. *See* Chlorpyrifos; Final Order Denying Objs. to Mar. 2017 Pet. Denial Ord., 84 Fed. Reg. 35,555, 35,563 (July 24, 2019). The NGO petitioners challenged the objection denial order in the Ninth Circuit. *LULAC v. Wheeler*, Case No. 19-71979 (9th Cir.) ("*LULAC II*").

VI. EPA FINDS ELEVEN CROP USES SAFE AND BEGINS NEGOTIATIONS WITH THE REGISTRANT TO MODIFY LABEL USES ACCORDINGLY

A. EPA's 2020 Proposed Interim Decision ("PID") Finds Eleven Critical Crop Uses Safe

On December 7, 2020, as part of its ongoing registration review of chlorpyrifos,[12] EPA published its PID. Pesticide Registration Review; PID for Chlorpyrifos; Notice of Availability, 85 Fed. Reg. 78,849 (Dec. 7, 2020); AR 40, PID for Chlorpyrifos; Pet. App. 366. The PID is supported by a number of underlying risk and benefits assessments, including: EPA's September 21, 2020, Third Revised Human Health Risk Assessment (the "2020 RHHRA"), AR 2; Pet. App. 157, which in turn relied on EPA's September 15, 2020, Updated Chlorpyrifos Refined Drinking Water Assessment (the "2020 DWA"), AR 38; Pet. App. 1. EPA's PID and the risk assessments on which it relies reflect a fulsome, measured, and well-reasoned evaluation by EPA's expert scientists of potential human health and drinking water risks of chlorpyrifos. In these assessments, EPA reaffirmed its reliance on its long-standing 10%

[12] Registration review for chlorpyrifos is scheduled to be completed by October 2022.

RBC AChE endpoint as the appropriate standard for assessing human health risks. AR 2 at 5; Pet. App. 161.

The PID was also based on EPA's 2020 DWA, which updated and refined the Agency's 2016 drinking water assessment (the "2016 DWA"). The 2020 DWA is one of the most sophisticated drinking water analyses EPA has conducted and relied on EPA's most highly refined methods for assessing drinking water risks. *See* Pet. App. 1774–75 ¶¶ 9–11. EPA subjected the 2020 DWA to peer review by nine EPA expert scientists, an unprecedented level of peer review for an assessment of its kind. *Id.* ¶ 12. In the 2020 DWA, EPA considered eleven crop uses identified as high-benefit, critical uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) (the Safe Uses). AR 38 at 9, 17, 19–21; Pet. App. 10, 18, 20–22. The 2020 DWA conducted an analysis of these crops in select regions of the country where estimated drinking water concentrations are below the drinking water level of concern. AR 38 at 27–28; Pet. App. 28–29.

In the 2020 RHHRA and PID, EPA assessed potential risk to human health from aggregate exposure to chlorpyrifos residues. EPA determined that there were *no* potential risks of concern from exposure

to chlorpyrifos in food or residential uses alone. AR 2 at 12; Pet. App. 168; AR 40 at 14, 18; Pet. App. 379, 383. With respect to drinking water, EPA determined that risks exceeded safe levels taking into account all registered uses. But, relying on its 2020 DWA, EPA found that risks were *below* the drinking water level of concern benchmark when anticipating use only on the Safe Uses. AR 40 at 18; Pet. App. 383.

In its 2020 RHHRA and PID, EPA presented two approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to the Safe Uses, or (ii) application of a 1X FQPA safety factor, which would allow for the retention of *all* currently registered uses. Regarding the first approach, EPA was unequivocal that it had found the Safe Uses safe: "[the Safe Uses] are the high-benefit agricultural uses that ***the agency has determined*** *will not pose potential risks of concerns with an FQPA safety factor of 10X*." AR 40 at 40 (emphasis added); Pet. App. 405. EPA acknowledged that it was "currently in discussions with the registrants regarding the proposed/considered mitigation measures." AR 40 at 40; Pet. App. 405. EPA stated that it would "consider registrant and stakeholder input on

the subset of crops and regions from the public comment period and may conduct further analysis to determine *if any other limited uses may be retained*." AR 40 at 40; Pet. App. 405 (emphasis added). In other words, the Safe Uses were the minimum subset of uses that EPA said it would retain, which EPA would consider expanding through review of public comment and further analysis.

B. EPA Negotiates with Petitioner Gharda a Voluntary Narrowing of Chlorpyrifos Uses Consistent With Its Safety Finding

In early April 2021, EPA approached Gharda about a possible agreement to voluntarily cancel some uses of chlorpyrifos. Pet. App. 1611–12 ¶ 21. In these initial discussions, EPA urged Gharda to accept a voluntary phase-out of all uses other than the Safe Uses. *Id*.

On April 29, 2021, the Ninth Circuit issued a decision in *LULAC II*. The Ninth Circuit held that EPA's denial of objections to its 2017 denial of the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition. *LULAC II*, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit gave weight to EPA's proposals in 2015 and 2016 in which EPA suggested that existing tolerances were

not sufficiently health protective, *see id.* at 677—proposals that were based on drinking water analyses the Agency later refined and on epidemiology data it ultimately deemed insufficient. Crediting these proposed findings by the Agency, the Ninth Circuit ordered EPA "*either* to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "*or* to revoke all chlorpyrifos tolerances." *Id.* at 678 (emphasis added).

In making this ruling, the court acknowledged that EPA's scientific analyses were ongoing and expressly recognized the importance of the PID. The court observed that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." *Id.* at 703. The court also acknowledged the need to harmonize EPA's proposed tolerance action with action under FIFRA, ordering EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." *Id.* at 678.

After the Ninth Circuit decision in *LULAC II*, EPA continued discussions with Gharda about a voluntary narrowing of chlorpyrifos uses. Pet. App. 1613–14 ¶ 23. The PID continued to provide the backdrop for these discussions, as they culminated in Gharda's *written commitment* to EPA to voluntarily cancel all uses of chlorpyrifos except the Safe Uses. *Id.* 1614–15 ¶ 24. As part of these discussions, Gharda and EPA actively discussed and exchanged written proposals for the orderly phase-out of existing stocks of all *other* uses. *Id.* 1613–22 ¶¶ 23–33. As the parties neared an agreement, EPA informed Gharda that it would likely need a written voluntary cancellation letter to reference quickly in the Final Rule and thanked Gharda for its "continued patience and engagement." *Id.* 1621–23 ¶¶ 33–35. Gharda was standing by awaiting guidance from EPA on when to submit the voluntary cancellation letter when EPA abruptly terminated the discussions, without explanation. *Id.* 1622–25 ¶¶ 34–40.

VII. EPA DOES A REGULATORY TURNABOUT AND INEXPLICABLY ISSUES A FINAL RULE REVOKING CHLORPYRIFOS TOLERANCES FOR *ALL* CROP USES

To the shock of growers and registrants, EPA then did a regulatory 180-degree turn and, in August 2021, announced the Final

Rule revoking *all* chlorpyrifos tolerances. AR 1 at 48,315; Add. 1. EPA stated that, "taking into consideration the *currently registered uses* for chlorpyrifos," it is unable to make ***any*** safety finding under the FFDCA. AR 1 at 48,315, 48,317; Add. 1, 3 (emphasis added).

In reaching this conclusion, EPA did not rely on any new data or scientific analyses, nor did it attempt to walk back in any way its scientific conclusions in the PID. In fact, the scientific analysis in the Final Rule is largely consistent with that outlined in the PID. For example, EPA's Final Rule reaffirmed its long-standing 10% RBC AChE standard as the appropriate regulatory endpoint for assessing human health risks. AR 1 at 48,325; Add. 11 ("EPA has determined that the most appropriate toxicological endpoint for deriving points of departure for assessing risks of chlorpyrifos is 10% RBC AChE inhibition."). And as in the PID, EPA stated that it "remains unable to make a causal linkage between chlorpyrifos exposure and the [neurodevelopmental] outcomes reported" in epidemiology data. AR 1 at 48,324; Add. 10.

As to the aggregate exposure assessment, EPA confirmed in the Final Rule, as it had found in the PID, that "exposures from food and non-occupational exposures individually or together do not exceed

EPA's levels of concern." AR 1 at 48,333; Add. 19. EPA agreed that it is only drinking water exposures, when combined with food and non-occupational (residential) exposures, that create risks of concern. AR 1 at 48,333; Add. 19. As to drinking water, the Final Rule acknowledged EPA's findings in the PID that drinking water exposures do not exceed levels of concern when assuming use on only the Safe Uses. AR 1 at48,333; Add. 19.

Nevertheless, and despite admitting that it had found eleven uses safe, EPA claimed that because it is required to assess aggregate exposure taking into account all "currently registered uses," and based on the 2016 DWA, it could not find that aggregate exposures to chlorpyrifos are safe. AR 1 at 48,333; Add. 19. The Agency stated, without explanation or any reference to Gharda's commitment to drop all but the Safe Uses, that it lacked "effective mitigation upon which to base a reduced aggregate exposure calculation." AR 1 at 48,333; Add. 19. The Final Rule stated that the tolerances would expire six months later, on February 28, 2022.[13] AR 1 at 48,334; Add. 20.

[13] EPA's press release announcing the Final Rule made statements that are not supported by the Final Rule or its scientific findings, including that tolerance revocation would ensure

Petitioners timely submitted objections to the Final Rule, pursuant to Section 408(g) of the FFDCA. 21 U.S.C. § 346a(g)(2)(A). In light of the irreparable harm revocation of tolerances would cause, several Petitioners also sought an administrative stay of the Final Rule pending EPA's review of the objections. *See, e.g.*, AR 44–47, 49, 51, 54–56, 58–59, 67, 69, 71–72, 75–78, 80–84; Pet. App. 1085–284.

VIII. EPA'S INACTION ON PETITIONERS' OBJECTIONS AND STAY REQUESTS LEADS TO LITIGATION

EPA refused to act on the objections and stay requests for months, despite Petitioners' claims of irreparable harm and the approaching effective date of the Final Rule. Accordingly, on February 9, 2022, Petitioners petitioned this Court for review of the Final Rule and EPA's constructive denial of the objections and stay requests. *Red River Valley Sugarbeet Growers Ass'n v. Regan* (No. 22-1294), Doc. ID 5126162 (the "First Petition"). Petitioners also filed a motion for partial stay of the Final Rule on February 10, 2022, Doc. ID 5126280. On

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"farmworkers . . . are protected from the potentially dangerous consequences of this pesticide" and that EPA was "follow[ing] the science." AR 63, Press Release, EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health (Aug. 18, 2021) https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.

February 18, 2022, EPA filed a motion to dismiss the First Petition, contending that this Court had no jurisdiction because EPA had not yet made a "final" decision on the objections and stay requests. *See* Pet. App. 1285–306; Resp't Opp. to Pet'rs' Mot. to Stay Pending Review, Doc. ID 5129078 at 7, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 18, 2022).

The following business day, EPA released its 193-page Denial Order, denying all of Petitioners' objections and requests for an administrative stay. *See* Resp'ts Rule 28(j) Notice of Issuance of Final Order, Doc. ID 5130160 at 1, *Red River Valley Sugarbeet Growers Ass'n* (No. 22-1294) (Feb. 24, 2022). The Denial Order was published in the Federal Register on February 28, 2022, the same day the Final Rule took effect. Add. 23. EPA's Denial Order, like the Final Rule, did not retreat from any scientific findings in the PID. *Id.* at 42 ("EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [*i.e.*, the Safe Uses]."). EPA's Denial Order instead repeated the rationale for revocation outlined in the Final Rule: that EPA is required to assess

aggregate exposure under the FFDCA based on "currently registered uses," which it acknowledged as a "legal matter." *Id.*

On the same day the Final Rule was published, Petitioners filed a second Petition for Review in this Court, incorporating all issues raised in the First Petition as well as a challenge to EPA's Denial Order. Pet. App. 1355–67 (the "Second Petition"). Petitioners also renewed their motion to stay the Final Rule ("Renewed Motion to Stay"). Pet'rs' Renewed Mot. for a Partial Stay Pending Review, Doc. ID 5132688. In the midst of the briefing, EPA asserted a novel, unprecedented argument that the Court lacked jurisdiction to hear the Second Petition because it was filed fewer than fourteen days after publication of the Denial Order in the Federal Register. Pet. App. 1343. For avoidance of doubt, on March 14, 2022, Petitioners filed a third petition for review, Pet. App. 1816–913, incorporating the Second Petition and its attachments in their entirety, as well as the Renewed Motion to Stay.

On March 15, 2022, the Court entered an order stating that it is exercising jurisdiction in this matter and denying Petitioners' Motion for a Partial Stay Pending Review. Thereafter, the parties submitted

and the Court granted a stipulation consolidating the Second and Third Petitions and setting a briefing schedule. Pet. App. 1914–15.

SUMMARY OF THE ARGUMENT

This action challenges EPA's arbitrary and capricious decision to revoke all tolerances for chlorpyrifos, effectively banning an agricultural tool farmers in the Midwest and around the country depend on to protect their crops and investment from destructive insect pests. Without adequate protection, an infestation of insect pests can cripple crop production and threaten farmers' livelihoods. This reality is especially stark for some of the growers represented by Petitioners here, for whose crops there exist no effective alternatives. *Supra* § IV.

The Final Rule was an abrupt and unexpected change in position not only because chlorpyrifos has been safely used for over fifty years but because just months earlier, EPA completed a rigorous scientific human health assessment that unequivocally found that use of chlorpyrifos on eleven high-benefit crops in select regions is safe. This assessment was based on a highly sophisticated Agency drinking water assessment that had undergone unprecedented peer review. After completing this assessment, EPA then spent months negotiating with

Petitioner Gharda to modify the approved uses on the label consistent with its safety finding. And Gharda committed to do just that.

Then, EPA abruptly ceased those discussions and pulled the rug out from under the regulated community by revoking *all* tolerances. EPA did so at a time when growers and consumers already face severe supply chain shortages and record-high inflation.

In revoking all tolerances, EPA did not back away from the scientific findings supporting its safety finding as to the eleven uses. Rather, in a flawed and unheard-of interpretation of the law, EPA claimed that it is required to assess safety by considering exposure from all currently approved uses, and that it is powerless to order changes to the product labels consistent with the science.

EPA's refusal to act on its own scientific evidence is arbitrary and capricious, an abuse of discretion, and contrary to law. EPA has a statutory mandate to review tolerance safety based on current science. This is reflected in the FFDCA's forward-looking text, which compels EPA to review tolerances on an individual basis, considering "anticipated" exposures based on the "reliable information" at its disposal. It is confirmed in the legislative history in which Congress

explicitly directed EPA to periodically review tolerance safety "based on the latest advancements in the science." EPA's position that it is confined to review only currently approved uses reads EPA's authority to "modify" tolerances out of the statute, and disregards EPA's obligation to coordinate its tolerance actions with registration actions under FIFRA. It is also at odds with the Agency's consistent historical practice of using tolerance modification and corresponding FIFRA action as a risk mitigation tool.

None of the reasons EPA offers to justify its revocation decision are defensible. EPA claims that a court order mandated this result, but that court in fact recognized EPA's ongoing scientific assessment and directed EPA to "act based on the evidence." While it ordered EPA to revoke or modify tolerances in sixty days, it gave EPA flexibility to modify related FIFRA registrations in a "timely fashion." EPA's attempt to diminish its scientific findings as "proposals" also fails. Scientific evidence confirmed by numerous expert Agency scientists is not entitled to less weight because it is summarized in a document labeled a proposal. The record also reflects that EPA believed its

scientific findings were final and actionable, and that EPA relied on them to negotiate corresponding label changes with the registrant.

The Agency's revocation decision was not driven by science or any reasonable reading of the statute. It therefore appears to be a pretext for an unexplained policy change. The law is clear that EPA must provide a reasoned, science-based explanation for its change in position, especially given the harms its revocation decision have caused and will continue to cause the growers, registrants, and consumers. For reasons outlined more fully below, this Court should vacate EPA's arbitrary and capricious Final Rule and Denial Order.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews EPA's Final Rule and Denial Order for compliance with the FFDCA under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Under the APA, the court shall hold unlawful and set aside an agency action found to be "in excess of statutory jurisdiction, authority, or limitation. . ." or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A), (C).

An agency decision is arbitrary and capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *accord Nebraska v. E.P.A.*, 812 F.3d 662, 666 (8th Cir. 2016). When an agency changes course, it must "supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42. A reviewing court "'may not supply a reasoned basis for the agency's action that the agency itself has not given.'" *Id.* at 43 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

II. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT DISREGARDS THE AGENCY'S OWN SCIENTIFIC EVIDENCE

EPA's scientific review of chlorpyrifos over the past fifteen years has examined a number of different issues, and not always in a consistent manner. But the current scientific record before the Agency is not the subject of dispute.

EPA previously (in 2015 and 2016) explored proposals to address claims of neurodevelopmental effects below the current regulatory

standard. EPA has since consistently concluded (under prior and current leadership) that the data urged in support of those claims are insufficient. EPA has accordingly maintained its longstanding 10% RBC AChE regulatory standard, and it has chosen to address potential neurodevelopmental risks by application of an FQPA Safety Factor of 10X. EPA's Final Rule and Denial Order unequivocally reaffirmed those scientific conclusions. AR 1 at 48,317; Add. 3, 23.

EPA does not dispute that the sole dietary exposure source of concern—and therefore the focal point of the Agency's latest human health risk assessment of chlorpyrifos—is drinking water, and only in certain parts of the country. While EPA years ago issued a Proposed Rule to revoke all tolerances for chlorpyrifos based on drinking water concerns, it did so in response to a court mandamus deadline and in reliance on its incomplete drinking water assessment. Pet. App. 995, 999. EPA has since updated, refined, and completed that assessment—a process that culminated in the 2020 DWA.

The 2020 DWA is EPA's most cutting edge, sophisticated drinking water assessment yet, that reflects the most advanced, updated tools and methodologies for assessing drinking water exposures and risks.

AR 38 at 9–11; Pet. App. 10–11, 1774 ¶ 9. It has undergone an unprecedented level of peer review by nine expert Agency scientists. Pet. App. 1774 ¶ 9. In the 2020 DWA, EPA analyzed risks from exposures from eleven high-benefit agricultural uses in select regions where estimated drinking water concentrations of chlorpyrifos are below EPA's benchmark level of concern (the Safe Uses). EPA's PID relied on the 2020 DWA and unequivocally found those uses *safe*:

> To mitigate potential dietary exposure to chlorpyrifos, the agency is proposing to limit application to select uses in certain regions where the [estimated drinking water concentrations] are lower than the [drinking water benchmarks of concern]. . . . [T]he agency has determined that [those uses] ***will not pose potential risks of concerns*** with an FQPA safety factor of 10X . . .

AR 40 at 40; Pet. App. 405 (emphasis added). The PID and the 2020 DWA on which it relied reflect a careful, conservative, and well-reasoned scientific assessment.

EPA nevertheless cast these assessments aside in the Final Rule and Denial Order and refused to apply their findings. EPA's refusal to act on its scientific evidence is arbitrary and capricious. *See, e.g.*, *Chlorine Chemistry Council*, 206 F.3d at 1290–91 (D.C. Cir. 2000) (vacating EPA rule that "openly overrode" its own science); *Dow*

AgroSciences LLC v. Nat'l Marine Fisheries Serv., 707 F.3d 462, 472–73 (4th Cir. 2013) (finding arbitrary and capricious agency reliance on older data that was not "representative of current and future pesticide uses and conditions" and failure to adequately explain its decision "despite the existence of new data and the potential drawbacks of using the older data") (internal quotations omitted); *Sierra Club v. E.P.A.*, 671 F.3d 955, 966–68 (9th Cir. 2012) (EPA action was arbitrary and capricious for not utilizing a more recent model); *Am. Wildlands v. Norton*, 193, F. Supp. 2d 244, 257 (D.D.C. 2002) (finding agency action arbitrary and capricious where agency "ignored scientific data and existing models"); *cf. Sugule v. Frazier,* 639 F.3d 406, 412 (8th Cir. 2011) (rejecting agency action where weight of evidence went against agency decision).

EPA's refusal to follow its scientific evidence was not due to any error in the science—the Final Rule and Denial Order do not attempt to walk back the PID or 2020 DWA's scientific findings. *See* Add. 42 (EPA admitting that it "does not dispute its own scientific conclusions and findings in the 2020 PID" regarding the Safe Uses, and ultimately the issue is "whether EPA properly interpreted its obligation under the

FFDCA in assessing aggregate exposure to chlorpyrifos," which is "a question of law and not one of fact"). Rather, EPA's sole basis for revoking all tolerances and effectively banning an agricultural tool growers have depended on for decades is that EPA could not conclude that tolerances are safe taking into account all "currently registered uses" of chlorpyrifos. *Id.* at 47–48. None of the arguments EPA has put forward in support of this newly fashioned rationale hold water.

As outlined below, EPA has abused its discretion, and its Final Rule and Denial Order are arbitrary and capricious and otherwise contrary to law, because they disregard the text and intent of the FFDCA and FIFRA, are contrary to the record, and are contrary to the Agency's own past practice.

III. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS AND CONTRARY TO LAW BECAUSE IT IGNORES THE TEXT AND INTENT OF THE FFDCA AND FIFRA

A. The FFDCA Compels a Forward-looking, Individual Tolerance Approach That Is Driven by Science

EPA's rationale that it must assess safety by considering only currently registered uses is contrary to the FFDCA's plain language and Congress's expressed intent that tolerance actions be driven by science.

EPA's construction defies Congress's forward-looking mandate that EPA find "there is a reasonable certainty that no harm *will result* from aggregate exposure" to the pesticide residue from "all *anticipated* dietary exposures and all other exposures for which there is *reliable information*." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). If Congress intended for EPA to assess safety of existing exposures only, based on tolerances previously approved, it would have referred to existing exposures rather than using the word "anticipated." *United States ex rel. Harlan v. Bacon*, 21 F.3d 209, 210 (8th Cir. 1994) ("When construing a statute, we are obliged to look first to the plain meaning of the words employed by the legislature," and the court "must give effect to the unambiguously expressed intent of Congress") (internal quotations omitted).

EPA's position is also at odds with FFDCA's mandate that the Agency reassess tolerance safety by employing a tolerance-by-tolerance approach. In drafting the FFDCA, Congress specified that EPA "may establish or leave in effect *a tolerance* . . . if the Administrator determines that *the tolerance* is safe . . . [and] shall modify or revoke *a tolerance* if the Administrator determines *it* is not safe." 21 U.S.C. §

346a(b)(2)(A)(i) (emphasis added); *accord id.* § 346a(b)(2)(C). Congress reiterated in setting forth the standard for the safety determination that it is to be made "with respect to *a tolerance* for a pesticide chemical residue. . . ." *Id.* § 346a(b)(2)(A)(ii) (emphasis added). The FFDCA's use of "*a* tolerance" rather than "*the* tolerances" shows Congress intended for EPA to make safety determinations for each tolerance on an individual basis—not based on "the universe of currently registered chlorpyrifos uses" as EPA urges. Add. 45; *see Life Techs. Corp. v. Promega Corp.*, 137 S. Ct. 734, 742 (2017) (courts must give meaning to the particular words Congress chose in drafting a statute, including its choice between the singular and plural form).

An approach focused on currently registered uses is also inconsistent with Congress's directive that tolerance assessments be driven by advancements in science. Indeed, the legislative history underlying the FQPA makes Congress's intent abundantly clear: the "reasonable certainty of no harm" standard was intended to promote "the efficient, science-based administration of FIFRA and the [FFDCA]" by ensuring that tolerance assessments are based on "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8147. EPA is to

assess safety based on the latest, reliable scientific evidence at its disposal and then leave in effect, modify, or revoke in accordance with that evidence.

Congress's decision to provide for modifying a tolerance if it is found not safe further supports an individual tolerance, science-based approach. The FFDCA encourages EPA to "modify *or* revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). The statute clarifies that "the term 'modify' shall not mean expanding the tolerance to cover additional foods," and therefore to "modify" can only mean to *narrow* permissible uses. *Id.* § 346a(b)(1) (emphasis added). Thus, EPA has authority to modify a tolerance to narrow uses if EPA finds based on the scientific evidence that the current tolerance is not safe.

EPA's position that all of the tolerances must rise or fall together and that it is required to assess currently registered uses effectively reads modification out of the statute. If accepted, it would lead to the absurd result that EPA would never be able to narrow uses based on new or updated scientific data. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("interpretations of a statute which would

produce absurd results are to be avoided"). By EPA's logic, any time it found currently registered uses cumulatively unsafe, it would have to revoke *all* tolerances. But that is not what the law says: EPA plainly has authority to modify tolerances by narrowing the uses.

EPA's own practice also undermines its contention that it must consider only registered uses, and not anticipated uses as the statute says, in making its safety determination. For example, EPA increased the tolerance for residues of benzobicyclon in or on rice grain without changing the tolerances for other uses. Benzobicyclon; Pesticide Tolerances, 86 Fed. Reg. 60,368 (Nov. 2, 2021). There, EPA explained that it could make a "determination on aggregate exposure for benzobicyclon, including exposure resulting from the tolerance established by this action," *id.* at 60,369, and considered "cumulative exposures . . . (based on proposed and registered pesticidal uses at the time the assessment was conducted)," *id.* at 60,370.

Relatedly, EPA has also previously amended individual tolerances, showing that tolerances do not have to rise or fall together. For instance, on May 18, 2022, EPA established in a final rule a new tolerance for the insecticide flonicamid in or on small fruit vine, and

amended the existing tolerance for flonicamid in or on alfalfa (hay) by increasing it from 1.0 ppm to 7.0 ppm. Flonicamid; Pesticide Tolerances, 87 Fed. Reg. 30,425 (May 19, 2022). According to EPA, the establishment of these new tolerances for flonicamid were based upon EPA's authority under section 408 of the FFDCA and the Agency's review of "available scientific data and other relevant information." *Id.* at 30,426. EPA also established tolerances of tebuconazole "in or on multiple commodities" while modifying other tebuconazole tolerances. Tebuconazole; Pesticide Tolerances, 84 Fed. Reg. 60,932 (Nov. 12, 2019).

In short, EPA's position that it could not consider its scientific evidence because it is required to assess currently registered uses finds no support in the FFDCA's text or underlying legislative history. It is also contrary to the Agency's prior practice.

B. EPA Failed to Coordinate Its Action Under the FFDCA with FIFRA, as the Statutes Require

EPA's Final Rule and Denial Order are also contrary to law because EPA failed to harmonize its safety determinations under the FFDCA with FIFRA, as the statutes require. *Supra* § III.

FIFRA's registration standard expressly incorporates the FFDCA "reasonable certainty of no harm" standard. 7 U.S.C. § 136(bb). The

approved food uses identified on a pesticide label must conform to EPA's safety determinations under the FFDCA. The FFDCA, for its part, mandates that once EPA has made a safety determination with respect to individual tolerances, it is required to modify or cancel the FIFRA registrations accordingly. 21 U.S.C. § 346a(l)(1) ("[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]."). This is also consistent with the forward-looking approach specified in the FFDCA: the "anticipated exposures" considered as part of EPA's safety determination, *id.* § 346a(b)(2)(A)(ii), are the future uses that will be in effect based on EPA's coordinated action under FIFRA, *id.* § 346a(l)(1).

Congress's directive that EPA coordinate its actions under the two laws to reflect the latest science could not have been more clear. And yet, EPA has taken the never-before-asserted position that its actions under the two statutes are "separate," *see* Add. 45, and that, short of action by the registrant, it is powerless to modify the FIFRA registrations to conform to its safety findings, *see id.* at 47. EPA's rationale is untenable and cannot be squared with the law or the Agency's prior conduct.

1. *EPA's Denial Order Is Internally Inconsistent Regarding FIFRA*

EPA's Denial Order is riddled with statements that cannot be reconciled with one another or with the statutory directives. EPA claims that it has discretion to determine the proper order of its actions under FFDCA and FIFRA, and challenges the notion that the Agency cannot lawfully revoke tolerances unless it "has first cancelled—or simultaneously cancels—associated pesticide registrations under FIFRA." *Id.*

EPA's argument actually supports Petitioners' reasoning. EPA's revocation decision must be reviewed based on the adequacy of its rationale—and EPA's sole explanation for not following the science is that it could *not* legally retain a subset of uses found safe without conforming FIFRA registrations in place. EPA cannot have it both ways—it cannot claim that it has discretion to revoke tolerances in disregard of FIFRA but that it must assess retention of tolerances found safe only through the lens of currently registered uses. EPA cannot claim that the FIFRA and FFDCA actions are separate, and then state that it "could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations [in the

2020 DWA and PID], *unless all other uses were canceled*." *Id.* at 57 (emphasis added).

2. *EPA's Claim That Harmonization Was "Not Practicable" Fails*

EPA next claims that it did attempt to harmonize its tolerance actions under the FFDCA with cancellation actions under FIFRA but that coordination ultimately was "not practicable." *Id.* at 48–50 (citing 21 U.S.C. § 346a(l)(1)). First, EPA claims that the Ninth Circuit did not give it sufficient time to coordinate its FIFRA and FFDCA actions. *Id.* This argument is unavailing. While the Ninth Circuit gave EPA sixty days to either modify or revoke tolerances, it imposed no time limit on EPA's corresponding action under FIFRA—ordering only that EPA modify or cancel related FIFRA registrations "in a timely fashion." *LULAC II*, 996 F.3d at 678. The Ninth Circuit thus expressly recognized EPA's authority to modify tolerances and then update the FIFRA registrations accordingly. The Ninth Circuit further acknowledged that FIFRA actions would take more time and follow EPA's tolerance action.

Second, EPA claims that it did not have a "reasonable basis" to believe registrations would be amended consistent with its safety

finding because it did not have voluntary cancellation requests. Add. 47. This argument ignores law and reality. Congress conferred on EPA broad authority to regulate the safe use of pesticides on food under two comprehensive federal statutes, and directed that the Agency administer those statutes in an "efficient, science-based" manner that reflects "the latest scientific advancements." 142 Cong. Rec. H8127-02 at H8145-46. This includes the authority to initiate cancellation actions to conform FIFRA registrations to the Agency's safety determinations, with or without the registrant's cooperation. 7 U.S.C. § 136d(b), (f); *see also* 40 C.F.R. § 155.58(d) (EPA "may take appropriate action under FIFRA" if a registrant fails to comply with a registration review decision). EPA's assertion that it is incapable of acting on its scientific evidence without some affirmative action by a regulated party strains credulity. EPA is not only empowered to conform its FIFRA registrations to its scientific findings but compelled to do so by law.

Indeed, EPA admits registrant negotiations are largely irrelevant to the validity of its actions under the FFDCA: "Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the

tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question." Add. 49. This is precisely Petitioners' point: EPA made a scientific finding that the Safe Uses are safe. AR 40 at 40; Pet. App. 405. EPA did not back away from that safety finding either in its Final Rule or Denial Order. EPA was thus required to follow that scientific determination and modify the tolerances and registrations accordingly.[14]

In any event, EPA downplays that it *had* a voluntary cancellation commitment from Petitioner Gharda, the primary supplier of chlorpyrifos for agricultural use in the United States. Pet. App. 1611–21 ¶¶ 21–32. EPA and Gharda had spent months negotiating voluntary cancellation terms, and Gharda had submitted to EPA a written commitment to conform its registration to EPA's safety finding. *Id.*

[14] EPA states in the Denial Order that cancellation proceedings under FIFRA require a number of time-consuming procedural steps. EPA cannot claim that it did not have time to complete these steps because the Ninth Circuit required only that it take action under FIFRA "in a timely fashion." 996 F.3d at 678. More importantly, aggregate exposures would not have exceeded those analyzed and found safe in the PID during the pendency of any cancellation proceeding because the tolerance revocation and modification consistent with the PID would have ensured as much. 21 U.S.C. § 346a(a)(1).

1626–27 ¶ 43. Gharda was standing by awaiting word from EPA on when to submit a formal voluntary cancellation request reflecting the agreed terms when EPA abruptly ceased discussions. *Id.* 1622–23 ¶¶ 34–35. Weeks later, EPA took a 180-degree turn and revoked all tolerances. *Id.* 1623 ¶ 37.

3. *EPA Has Consistently Coordinated Its Tolerance Actions With FIFRA In the Past*

Where, as here, EPA has conducted a tolerance assessment based on thorough and detailed scientific analyses and found, based on that scientific evidence, that a subset of uses are safe, it must leave in effect the uses found safe, and modify or revoke tolerances to narrow the scope of permissible uses as the science dictates. It is then empowered to modify or cancel the FIFRA registrations in accordance with that science. This is how EPA has consistently applied the law in the past. *See Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) ("existing practice" evidence of agency interpretation).

EPA routinely mitigates risks identified in its tolerance assessments by taking corresponding action to modify or cancel FIFRA registrations. For example, EPA modified some, but not all, tolerances for dicloran and later modified the FIFRA registrations for dicloran.

See Acephate, Cacodylic, Dicamba, Dicloran, et al.; Tolerance Actions, 75 Fed. Reg. 60,232 (Sept. 29, 2010); Dicloran; Cancellation Order for Amendment to Terminate Use on Potatoes, 76 Fed. Reg. 71,022 (Nov. 16, 2011); Dicloran and Formetanate; Tolerance Actions, 77 Fed. Reg. 40,812 (July 11, 2012); Dicloran (DCNA); Amendments To Terminate Uses for Certain Pesticide Registrations, 83 Fed. Reg. 4,651 (Feb. 1, 2018). EPA's action with respect to chlorpyrifos is not consistent with this prior practice. Such "inconsistent treatment" by the Agency "is the hallmark of arbitrary agency action." *Clean Wisconsin v. E.P.A.*, 964 F.3d 1145, 1163 (D.C. Cir. 2020).

IV. EPA'S REVOCATION DECISION IS ARBITRARY AND CAPRICIOUS BECAUSE IT OFFERS NO REASONED EXPLANATION LET ALONE ONE THAT ADEQUATELY ADDRESSES THE RELEVANT FACTORS AND EVIDENCE

It is a foundational principle of administrative law that agencies must provide a reasoned explanation for departing from prior conclusions. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Northport Health Services of Arkansas, LLC v. HHS*, 14 F.4th 856, 873 (8th Cir. 2021). "Reasoned decision-making requires that when departing from precedents or practices, an agency must 'offer a reason to distinguish them or explain its apparent rejection of their

approach.'" *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020) (quoting Sw. *Airlines Co. v. FERC*, 926 F.3d 851, 856 (D.C. Cir. 2019); *see also Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978) (greater scrutiny applies to agency actions departing from prior norms and "it is at least incumbent upon the agency carefully to spell out the bases of its decision when departing from prior norms"). An agency may not "gloss[] over or swerve[] from prior precedents without discussion." *Sw. Airlines Co.*, 926 F.3d at 856 (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970).

EPA admits that its revocation decision disregards the Agency's safety finding in the PID. EPA's primary reason for revoking all tolerances is that EPA claims it was required to consider all currently registered uses because EPA had no reason to believe that the registrations would be amended. As outlined above, that reasoning is plainly contrary to the statute and the Agency's prior course of dealing. *Supra* §§ III.A–B. EPA's additional arguments for departing from the scientific evidence are not defensible.

A. EPA Cannot Escape from the Scientific Evidence by Disguising It as A "Proposal"

EPA does not attempt to argue that the scientific findings as to the Safe Uses are wrong. Instead, EPA tries to assert that the PID was simply a "proposal," and thus, EPA was not required to consider it. Add. 45–48. EPA is wrong.

The Ninth Circuit in *LULAC II* expressly recognized that EPA issued the PID proposing to modify tolerances while that proceeding was pending, such that the PID was not part of the record before the Ninth Circuit when it issued its decision. The Ninth Circuit nevertheless acknowledged the PID in ordering EPA to act, stating that "[i]f, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them." 996 F.3d at 703. The Court made clear that "*EPA must act based upon the evidence*." *Id.* (emphasis added). The PID was *evidence* before the Agency that EPA was required to act on or, at a minimum, offer a reasoned explanation before departing from it.

EPA cannot disregard the scientific evidence before it simply because it may later be revised. In *Chlorine Chemistry Council*, 206

F.3d at 1291, the D.C. Circuit vacated an EPA rule that blatantly disregarded the Agency's own scientific evidence. In doing so, the court rejected EPA's characterization of its scientific findings as not representing the Agency's "ultimate conclusions" as "semantic summersaults." *Id.* The court observed that "[a]ll scientific conclusions are subject to some doubt," and "however desirable it may be for EPA to consult [a Scientific Advisory Board] and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime." *Id.* at 1290–91.

Moreover, EPA's claim that it was permitted to simply ignore the scientific findings in the PID because it was merely a "proposal" is at odds with the record. The PID may have been labeled a "proposed" interim decision, but that is because EPA still needed to complete two additional assessments: (1) the Endangered Species Act analysis and (2) the endocrine screening for the chlorpyrifos registration review. *See* EPA Registration Review Process, https://www.epa.gov/pesticide-reevaluation/registration-review-process (last visited May 16, 2022) (explaining that during Registration Review "EPA may issue a proposed interim decision *when the Agency needs to conduct additional*

assessments such as an endangered species assessment or endocrine screening") (emphasis added). Neither of those issues is relevant to the safety determination for purposes of establishing or leaving in effect tolerances under the FFDCA. 21 U.S.C. § 346a(b)(2).[15]

As to the safety findings in the PID, EPA made clear that further analyses and review of public comment on its tolerance assessments would only *expand* the scope of permissible uses, not contract them. AR 40 at 40; Pet. App. 405 ("[T]he agency will consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if *any other limited uses may be retained*.") (emphasis added). EPA went on to state in the PID that it could issue a final decision for chlorpyrifos without issuing an interim decision. AR 40 at 62; Pet. App. 427; *see also* https://www.epa.gov/pesticide-reevaluation/registration-review-process (explaining that interim decisions may be issued to, among

[15] That EPA's scientific findings are reflected in Agency proposals does not diminish their weight. The Ninth Circuit credited scientific findings in EPA proposals in ordering EPA to "act based on the evidence" and issue a final order revoking or modifying tolerances. *See LULAC II*, 996 F.3d at 703. It recognized that EPA could act on the PID. *Id.*

other things, explain changes to or respond to comments on a proposed interim decision). EPA thus unquestionably believed that its scientific findings concerning tolerances were final and actionable. Indeed, there is no logical reason EPA would have devoted enormous resources to developing a sophisticated drinking water assessment based on a limited subset of uses, and then a proposed interim decision based on that assessment, if it did not believe that decision could support corresponding regulatory action.

EPA's actions treating the PID as final are not an anomaly. EPA regularly takes action to amend uses in response to a proposed interim registration review decision. For instance, a registrant agreed to make certain changes to uses for the fungicide famoxadone based on EPA's proposed interim registration review decision for that product. Corteva Agriscience, Response Comments to: Famoxadone: Proposed Interim Registration Review Decision (Dec. 17, 2021), https://downloads.regulations.gov/EPA-HQ-OPP-2015-0094-0067/attachment_1.pdf (last visited May 15, 2022).

B. EPA Treated Its Scientific Findings In the PID As Final

Even more, EPA has treated the scientific findings in the PID as its final decision on the safety of chlorpyrifos under the FFDCA. *Cf. FWS v. Sierra Club*, ___ U.S. ___, 141 S. Ct. 777, 786 (2021) (decision is final where agency treats it as such). EPA relied on the PID when attempting to reach an agreement with Gharda on a voluntary narrowing of uses consistent with the PID.

For months, EPA and Gharda actively exchanged proposals for the retention of uses, for which the PID was the backdrop. At all times, Gharda understood that the Safe Uses would be retained. Pet. App. 1611–18 ¶¶ 21–29. For example, during these discussions EPA rejected a proposal by Gharda to retain chlorpyrifos for use on cotton in Texas, saying that "[t]he PID indicated that if cotton were maintained, it could be used in AL, FL, GA, NC, SC, and VA," but "Texas would not be an option." *Id.* 1746; *see Am. Maritime Ass'n v. Blumenthal*, 458 F. Supp. 849, 858 (D.D.C. 1977) (agency action is final where it "represents the final, crystallized agency position on the matter"). EPA never backed away from the scientific findings in the PID or hinted that they were not final and subject to change. Ultimately, Gharda put forward a

written commitment to modify its label consistent with the safety finding in the PID. Pet. App. 1743–44, 1756–58.

EPA could not have entertained these proposals, and all of these months of negotiations would have been pointless, unless EPA believed that its PID could support a coordinated modification of registered uses under FIFRA. Thus, in treating and relying on the PID as a final Agency action, and in causing regulated parties to rely on the PID accordingly, EPA has cemented the finality of the PID with respect to the Safe Uses. *See Dep't of Homeland Sec. v. Regents of the Univ. of California,* 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)) ("When an agency changes course, . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'"). EPA has given no reasoned explanation for ignoring this final safety determination and so its decision is arbitrary and capricious. *Supra* § IV.

CONCLUSION

For all of the foregoing reasons, Petitioners respectfully request that EPA vacate the Denial Order and Final Rule.

May 24, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief compiles with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,170 words. I further certify that Petitioners' Brief complies with the typeface and type style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (a)(6), as it was prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Pursuant to Eighth Circuit Rule 28A(h)(2), I certify that the electronic version of this Brief has been scanned for viruses and is virus-free.

/s/ Nash E. Long
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 24, 2022, a true and accurate copy of the foregoing Petitioners' Opening Brief was electronically filed with the United States Court of Appeals for the Eight Circuit. Within five (5) days of receipt of notice that the Brief has been filed and accepted, Petitioners will serve each party separately represented with a paper copy of the Brief.

I further certify that ten (10) paper copies of the foregoing Brief will be provided to the Court within five (5) days after receipt of notice that the foregoing has been filed and accepted pursuant to Rule 28A(d).

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