No. 19-71979 and No. 19-71982
Consolidated

United States Court of Appeals for the Ninth Circuit

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

v.

ANDREW WHEELER,
Administrator, United States Environmental Protection Agency and
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review of the Order of the Administrator of the United States Environmental Protection Agency

BRIEF FOR THE STATES OF NEW YORK, CALIFORNIA, WASHINGTON, MARYLAND, VERMONT, HAWAII, OREGON, THE COMMONWEALTH OF MASSACHUSETTS, AND THE DISTRICT OF COLUMBIA

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PRELIMINARY STATEMENT

For years, the U.S. Environmental Protection Agency (EPA) has possessed compelling evidence that exposure to chlorpyrifos, a widely used agricultural pesticide, harms brain development in infants and young children. EPA has been unable to identify a safe level of exposure to this chemical. As a result, in 2015 and 2016, EPA acknowledged that it could not satisfy the requirement of the Federal Food, Drug, and Cosmetic Act (FFDCA) that chlorpyrifos "tolerances"—levels of the pesticide that may lawfully remain as residues on designated foods—may be left in place "only if" EPA "determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). "Safe" means that EPA's Administrator "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii).

At the same time, EPA has delayed in fulfilling its responsibility to revoke chlorpyrifos tolerances, a step the FFDCA required once EPA could not find the tolerances safe. Although environmental groups filed an administrative petition seeking revocation of chlorpyrifos tolerances in 2007, EPA did not take final action on the petition until 2019, after

this Court issued two writs of mandamus in response to agency delay that the Court called "egregious" back in 2015.

Then, by order dated July 18, 2019 (the Final Order), EPA denied objections to an interim ruling, including objections filed by the State petitioners and intervenors here, and finally denied the 2007 administrative petition. Yet the agency still did not—because it could not—find that chlorpyrifos tolerances were safe. Instead, EPA argued that petitioners had the burden of showing the tolerances were *unsafe*. And EPA said it would not address the tolerances' safety before it reviewed chlorpyrifos's registration as a pesticide. Registration review, however, is a separate administrative process that EPA need not complete until October 2022. By deferring review of chlorpyrifos tolerances for three more years, EPA continued its years-long record of delay.

The States of New York, California, Hawaii, Maryland, Oregon, Vermont, Washington, the Commonwealth of Massachusetts, and the District of Columbia (the States) bring this proceeding to compel EPA to comply with the law. Because EPA's Final Order leaves chlorpyrifos tolerances in effect without finding them safe, it violates the FFDCA and

must be set aside. In light of EPA's continued delay in addressing the safety of chlorpyrifos tolerances on the merits, as well as the wealth of scientific evidence establishing that those tolerances are not safe, the Court should grant mandamus relief compelling EPA to revoke them.

JURISDICTION AND TIMELINESS

This Court has jurisdiction to review EPA's Final Order under the FFDCA, 21 U.S.C. § 346a(h)(1), and the Administrative Procedure Act, 5 U.S.C. §§ 706(1), (2)(A), and (2)(C). The en banc Court accepted jurisdiction over the States' petition challenging the Final Order and the separate petition of the League of United Latin American Citizens and other environmental and labor organizations (collectively, LULAC) as "comeback cases" under Ninth Circuit General Order 3.6(b). *LULAC v. Wheeler,* 940 F.3d 1126, 1126-27 (9th Cir. 2019). The en banc Court referred both cases to this panel "for resolution on the merits." *Id.*

The States' petition was timely filed. EPA published the Final Order in the Federal Register on July 24, 2019. The States filed their petition with this Court on August 7, 2019 (*see* ECF #1-5), well within the 60-day period for challenging the order. *See* 21 U.S.C. § 346a(h)(1). The District of Columbia and the States of Oregon and Hawaii timely

moved to intervene in the States' proceeding as petitioners on September 6, 2019. (*See* ECF #13, 15, 18.) Their motions were granted on November 8, 2019. (*See* ECF #30.)

QUESTIONS PRESENTED

1. Whether EPA's Final Order violates the FFDCA, specifically 21 U.S.C. § 346a(b)(2), for any of four reasons: it leaves existing chlorpyrifos tolerances in effect without the required affirmative finding of safety; it fails to take required steps to protect infants and children from injury; it improperly attempts to impose on petitioners the burden of proving that existing chlorpyrifos tolerances are unsafe; and, without statutory authorization, it defers final action on chlorpyrifos tolerances until October 1, 2022, the separate deadline for registration review of chlorpyrifos.

2. Whether the Court should grant mandamus relief to compel EPA's Administrator to revoke existing chlorpyrifos tolerances.

STATUTORY BACKGROUND

EPA regulates the use of pesticides on food and the resulting human exposure to the residues of such pesticides. To allow a pesticide to be used on food, EPA must comply with two statutes: the FFDCA, *see*

21 U.S.C. § 346a; and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y.

A. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, food containing "any pesticide chemical residue" shall be "deemed unsafe," 21 U.S.C. § 346a(a)(1), and therefore barred from interstate commerce, *see* 21 U.S.C. §§ 342(a)(2)(B), 331(a)–(c). The FFDCA grants EPA limited authority to promulgate pesticide tolerances for both raw agricultural commodities and processed foods. 21 U.S.C. § 346a(b). A "tolerance" is the maximum residue of a pesticide permitted to remain in or on a specified food. EPA may establish, modify, or revoke a tolerance, or leave an existing tolerance in effect. 21 U.S.C. § 346a(b)(1). When a tolerance is in effect, a food containing pesticide residues within that tolerance can move in interstate commerce. *See* 21 U.S.C. § 346a(a)(4).

Since its amendment by the Food Quality Protection Act of 1996, Pub. L. No. 104-170, the FFDCA has conditioned EPA's authority to set and maintain tolerances. The agency may "establish or leave in effect" a tolerance "*only* if the [EPA] Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). A tolerance

qualifies as "safe" if the Administrator "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii).

While EPA can act on its own initiative to establish, suspend, modify, or revoke tolerances, *see* 21 U.S.C. § 346a(e)(1), the FFDCA also provides a means for the public to petition for tolerances to be reviewed. "Any person may file" with EPA a petition proposing the issuance of a regulation "establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." 21 U.S.C. §§ 346a(d)(1), (d)(1)(A). The statute further provides that EPA "shall, after giving due consideration to a petition ... and any other information available to the Administrator," issue a proposed or final regulation establishing, modifying, or revoking a tolerance, or issue an order denying the petition. 21 U.S.C. § 346a(d)(4)(A).

In establishing, modifying, leaving in effect, or revoking tolerances, EPA's Administrator "shall consider" the "available" information on the pesticide's toxic effects, human risk, dietary consumption patterns,

cumulative effects, and aggregate exposure levels. 21 U.S.C. § 346a(b)(2)(D). If EPA cannot find existing tolerances safe, it is required to revoke them, 21 U.S.C. §§ 346a(b)(2)(A)(i), and also "[t]o the extent practicable" to coordinate the revocation with "any related necessary action" under FIFRA, such as cancelling the pesticide's registration, 21 U.S.C. § 346a(*l*)(1).

Also, as amended in 1996, the FFDCA provides special protections for infants and children. The statute requires EPA to assess the risks to infants and children separately and to take appropriate action based on "available information" about (1) food consumption patterns, (2) special susceptibility of infants and children, and (3) cumulative effects on infants and children of pesticide residues and other poisonous substances having a common mechanism of toxicity. 21 U.S.C. § 346a(b)(2)(C)(i). The statute further requires EPA to apply an additional tenfold margin of safety to protect infants and children unless, based on reliable data, EPA concludes that a different margin will be safe for infants and children. 21 U.S.C. § 346a(b)(2)(C)(ii). And the statute specifically requires that EPA act to "ensure that there is a reasonable certainty that no harm will result" to infants and children. *Id.*

Thus, when "leaving in effect" a tolerance, EPA must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C)(ii). Additionally, EPA must "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." *Id.*

The 1996 amendments to the FFDCA further set a schedule for EPA to review existing tolerances to assure they met the statute's additional safety standard, requiring the completion of all such review by 2006. 21 U.S.C. § 346a(q)(1)(C).

B. The Federal Insecticide, Fungicide, and Rodenticide Act

All pesticides sold in the United States must be registered under FIFRA. 7 U.S.C. §§ 136a(a). Existing pesticide registrations must be "periodically reviewed" by EPA, and all registration reviews under applicable safety standards must be completed by the later of 15 years after the pesticide was first registered or October 1, 2022. 7 U.S.C. § 136a(g)(1)(A).

In a registration review, EPA must determine that the pesticide's use will not cause "unreasonable adverse effects on the environment." 7

U.S.C. § 136a(c)(5)(C)–(D). Such effects include, among other things, human dietary risks from pesticide residues that violate the FFDCA. 7 U.S.C. § 136(bb)(2). A pesticide's registration may be canceled if EPA finds that it causes unreasonable adverse effects. 7 U.S.C. §§ 136a(c)(5)(D), 136d(b).

STATEMENT OF THE CASE

A. Background on Chlorpyrifos

Chlorpyrifos is an organophosphate pesticide, a class of chemical poisons that includes nerve gases. (*See* LULAC's Excerpts of Record [ER] 1, 327, 873.) Chlorpyrifos and other organophosphates adversely affect the human nervous system and developing brain. (ER964, 1183.)

These pesticides disrupt the nervous system by suppressing an enzyme called acetylcholinesterase (or cholinesterase). (ER1804-1805.) Cholinesterase serves the important function of breaking down the neurotransmitter acetylcholine. (ER1, 1139.) Without that breakdown, acetylcholine accumulates, causing an over-activation of its targets (ER1139), which include muscles, sweat glands, the digestive system, and even heart and brain cells (ER1). Clinical symptoms of such over-activation include nausea, headaches, skin rashes, eye irritation,

vomiting, dizziness, seizures, and, with sufficient over-activation, death by suffocation resulting from loss of respiratory muscle control. (ER1, 1139, 1805.)

Chlorpyrifos was first registered for use as a pesticide in 1965. (ER28, 1135.) Thereafter, it became one of the most widely used pesticides in the United States. (ER28.) As of 2012, between 5 and 8 million pounds of chlorpyrifos were applied to U.S. food crops annually.[1] (ER131 & n.7.) EPA's chlorpyrifos tolerances cover numerous fruits, nuts and vegetables, *see* 40 C.F.R. § 180.342, including many fruits commonly consumed by infants and children, such as apples, bananas, berries, peaches, nectarines, and grapes (ER1728).

EPA's tolerances for chlorpyrifos were set with the assumption that the pesticide would be safe so long as chlorpyrifos residues did not inhibit the body's production of cholinesterase at a rate of 10% or more, a biological marker "that can be reliably measured" (ER1139) and was

[1] Chlorpyrifos is also used for non-agricultural purposes, such as controlling pests on golf courses, utility poles, and fences. (ER1183.) Those uses are not at issue in the States' petition.

determined to be the "precursor for adverse neurological symptoms" (ER1135).

The tolerances were based largely on EPA's understanding of cholinesterase inhibition and how adult animals respond to chlorpyrifos exposures.[2] But developing fetuses, infants, and children are far more sensitive than adults to pesticides and other toxins. (ER1802-1803.) And multiple studies have concluded that pre- and postnatal exposure to chlorpyrifos, even at levels less than those that cause 10% cholinesterase inhibition in adults, increases the risk that children will have lower intelligence, pervasive developmental disorder, attention deficit hyperactivity disorder, and behaviors typical of the autism spectrum. (ER225, 1260, 1807.) A study using magnetic resonance imaging found that even low to moderate levels of prenatal exposure to chlorpyrifos may lead to long-term, potentially irreversible changes in the structure of the developing brain. (ER1807.)

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[2] U.S. EPA, "Chlorpyrifos Preliminary Human Health Risk Assessment" at 2-3 (June 30, 2011), available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025 (last visited Dec. 4, 2019); U.S. EPA, "Revised OP (Organophosphate) Cumulative Risk Assessment at I.B p.33, and I.G p.5 (June 10, 2002), available at https://nepis.epa.gov/Exe/ZyPDF.cgi/9100BFLL.PDF?Dockey=9100BFLL.PDF (last visited Dec. 5, 2019).

Indeed, damage to children's brains was found to result from exposures to chlorpyrifos that produced no cholinesterase inhibition or less than 1% inhibition in adults—far below the 10% permitted by existing tolerances. (ER1807, 1808.) Those results underscored the inadequacy of using cholinesterase inhibition as the sole biological marker for assessing the potential for harm from chlorpyrifos exposure (*see* ER13), an inadequacy of which EPA was aware since at least 2000.[3]

Moreover, the adverse effects of chlorpyrifos are long-term and can persist into adulthood. (ER208, 785, 969, 1183.) They are documented in the extensive body of literature that includes both human and animal studies. (*See* ER208, 216, 229, 343, 432, 1183, 1260-1261, 1805.)

B. The 2006 Reregistration of Chlorpyrifos and Review of Chlorpyrifos Tolerances

In 1998, EPA initiated its first registration review of chlorpyrifos. EPA found unacceptable risks associated with residential uses of chlorpyrifos and, in 2000, reached a voluntary agreement with the

[3] U.S. EPA, "Human Health Risk Assessment–Chlorpyrifos" 16, 22 (June 8, 2000), available at https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf (last visited Dec. 5, 2019).

registrants to cancel and phase out those residential uses. (ER45, 1135.) EPA continued to allow the widespread use of chlorpyrifos on food crops, however.

In 2001, EPA issued an interim decision approving both the reregistration of chlorpyrifos for use on food crops and specified chlorpyrifos tolerances.[4] EPA determined that chlorpyrifos could be reregistered provided that, among other things, the registrants implemented "risk reduction measures." 2001 Interim Decision, *supra* n.4, at 61. EPA left most chlorpyrifos tolerances unchanged, except for lowering tolerances for apples and grapes and eliminating the tolerance for tomatoes. *Id.* at 63-68. Widespread use of chlorpyrifos on other food crops persisted. The State of New York, among others, objected

[4] U.S. Environmental Protection Agency, Interim Reregistration Eligibility Decision for Chlorpyrifos, Case No. (0100), included as an attachment in Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006), available at https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/ired_PC-059101_28-Sep-01.pdf (last visited Dec. 4, 2019).

vigorously to the continued use of chlorpyrifos on food crops. (*See* ER88-120.)

Nevertheless, by memorandum dated July 31, 2006, EPA finalized the reregistration and tolerance review for chlorpyrifos.[5] The 2006 memorandum did not alter the 2001 interim decision on chlorpyrifos. EPA simply stated that it had completed a cumulative risk assessment and the 31 pesticides listed in an attachment (which included chlorpyrifos) were "eligible for reregistration" and that the tolerances adopted for those pesticides met the safety standard under 21 U.S.C. § 346a(b)(2). Memorandum, *supra* n.5, at 1-2.

[5] U.S. Environmental Protection Agency, Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006), available at https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/ired_PC-059101_28-Sep-01.pdf (last visited Dec. 4, 2019).

C. The Administrative Petition to Revoke Tolerances and Cancel Registration for Chlorpyrifos

In September 2007, the Pesticide Action Network North America and the Natural Resources Defense Council ("PANNA/NRDC") filed an administrative petition with EPA challenging the 2006 reregistration of chlorpyrifos and seeking revocation of chlorpyrifos tolerances. (ER1-24.)

PANNA/NRDC urged that evidence from both animal and epidemiological studies linked chlorpyrifos exposure from food to long-lasting adverse neurodevelopmental effects on children, that adverse health effects occurred at exposures below the level required for 10% cholinesterase inhibition, and that existing chlorpyrifos tolerances could not be considered safe because they failed to account for those effects. (ER6-9, 11-13, 22-23.) EPA's July 31, 2006 reregistration and cumulative risk assessment had not cited or incorporated the results of the studies and reports on which PANNA/NRDC relied. (ER13.)

PANNA/NRDC contended that "no safe level of early-life exposure to chlorpyrifos can be supported." (ER5.) In support, PANNA/NRDC cited numerous studies that postdated EPA's 2001 interim safety finding, including an epidemiological study from Columbia University (ER6-7) and multiple animal studies (ER12).

D. The Scientific Consensus on Chlorpyrifos's Harm to Human Development

Over the next 10 years, EPA issued a series of analyses and proposed rules concerning chlorpyrifos's safety. As shown below, in those releases the agency expressed with increasing confidence its conclusions that chlorpyrifos harms children's developing brains, existing tolerances fail to take those harms into account, and the harms occur at levels of exposure far below those permitted by existing tolerances.

1. August 2008: EPA's Science Issue Paper

In August 2008, EPA's Health Effects Division released a paper that analyzed the risks associated with chlorpyrifos exposure and updated EPA's review of scientific developments since the 2006 reregistration. Discussing those developments, EPA recognized the "growing body of literature on the effects of chlorpyrifos in the developing brain which indicate that gestational and early postnatal exposure can lead to neurochemical and behavioral alterations into adulthood," and that these changes are observed long after the body has recovered from any cholinesterase inhibition. (ER754.) EPA further noted that some authors had reported finding no or only marginal cholinesterase

inhibition at the doses that caused these effects. (ER754.) And EPA noted various animal studies supporting these findings. (ER729, 760.)

EPA also discussed three independent studies documenting adverse neurodevelopmental effects in children resulting from gestational and postnatal exposure to chlorpyrifos. (ER760-766.) The studies were undertaken independently by Columbia University, the University of California-Berkeley, and Mt. Sinai Medical Center, extended over years, and provided "complementary information" (ER761): all three found "delays in mental development" associated with chlorpyrifos exposure (ER763). EPA "preliminarily concluded that chlorpyrifos likely played a role" in the adverse health outcomes reported in children. (ER766.)

2. September 2008: Scientific Advisory Panel Report

In 2008, EPA convened the FIFRA Scientific Advisory Panel to address the recent developments in understanding the adverse health effects of chlorpyrifos exposure, particularly in children. Established under the Federal Advisory Committee Act, 5 U.S.C. App. 2 §§ 1–16, and FIFRA, 7 U.S.C. § 136w(d), the Panel acts as the primary scientific peer-

review mechanism for EPA's pesticide decisions. It has included biologists, toxicologists, pharmacologists, and other experts.[6]

The Panel agreed with EPA's conclusion that laboratory studies of animals show "gestational or early postnatal exposures [to chlorpyrifos] can lead to neurochemical and behavioral alterations that persist into adulthood," including "long-term neurobehavioral changes in motor and cognitive behaviors." (ER785-786.) The Panel also agreed with EPA that sensitivity to chlorpyrifos's toxic effects is greater in the young. (ER784.) And considering the animal data along with the human epidemiological studies, the Panel concluded that "chlorpyrifos is likely associated with adverse neurodevelopmental outcomes." (ER817.)

3. 2010-2012: Further Scientific Review by EPA

EPA thereafter continued to collect, analyze, evaluate, and interpret scientific evidence showing that chlorpyrifos exposure was associated with adverse health effects in the young.

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[6] *See* U.S. EPA, "FIFRA Scientific Advisory Panel Members," available at https://www.epa.gov/sap/fifra-scientific-advisory-panel-members (last visited December 4, 2019). (*See also* ER1179-1181.)

In 2011, EPA issued a Preliminary Human Health Risk Assessment that maintained its focus on the cholinesterase-inhibiting potential of chlorpyrifos; discussed the three epidemiological studies; and recounted the Scientific Advisory Panel's conclusion that the results of those studies, "in concert with the animal studies indicate that 'maternal chlorpyrifos exposure would likely be associated with adverse neurodevelopmental outcomes in humans.'"[7] EPA then asked the Scientific Advisory Panel to peer-review that analysis. (*See* ER964.)

In its 2012 response, the Panel recommended further inquiry, but also noted that "multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels lower than those associated with [cholinesterase] inhibition"—i.e., levels lower than those permitted by existing tolerances. (ER973.) The Panel concluded that "the overall evidence across these studies is persuasive in indicating that there are

[7] U.S. EPA, "Chlorpyrifos Preliminary Human Health Risk Assessment" at 33 (June 30, 2011), available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025 (last visited Dec. 4, 2019).

enduring effects on the Central Nervous System" from developmental exposure to relatively low doses of chlorpyrifos. (ER969; *accord* ER989.)

4. December 2014: EPA's Revised Human Health Risk Assessment

Using a new framework developed in 2010 for evaluating multiple lines of scientific evidence,[8] EPA in December 2014 issued a Revised Human Health Risk Assessment for chlorpyrifos. (ER184-714.) In the revised assessment, EPA concluded that, when taken together, the available evidence showed "chlorpyrifos likely played a role" in the harms the Columbia researchers observed to children's brain function (ER189, 232), even at doses lower than 10% cholinesterase inhibition (ER230), the threshold used to establish the current tolerances. Remarking on the consistency among the various studies, EPA wrote: "Given the differences across laboratory animal and epidemiology studies, the qualitative similarity in research findings is striking." (ER229.)

[8] *See* U.S. EPA, "Framework for Incorporating Human Epidemiologic and Incident Data in Risk Assessments for Pesticides" at 3-4 (2010, updated 2016), available at https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf (last visited Dec. 4, 2019).

The revised assessment incorporated new information that had become available since the 2011 risk assessment. (ER188.) Among other things, EPA cited the "considerable and growing body of literature" showing that early exposure of rats and mice to chlorpyrifos could cause "persistent behavioral effects into adulthood." (ER208; *accord* ER343.)

EPA also expanded and updated its review of the three independent human epidemiological studies, all of which remained ongoing and now provided additional data. (ER216.) The agency noted that all three studies found "positive associations between *in utero* chlorpyrifos exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years)." (ER216.) These adverse effects included delayed mental development in infants, attention problems and pervasive developmental disorder in early childhood, and reduced intelligence in school-aged children. (ER225.) EPA regarded all three human epidemiological studies as "strong studies which support a conclusion that chlorpyrifos likely played a role in these outcomes." (ER216.)

5. October 2015: EPA Proposes to Revoke Tolerances for Chlorpyrifos

In October 2015, EPA issued a notice of proposed rulemaking to revoke all tolerances for chlorpyrifos. (ER1132-1163.) EPA stated that it was "unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard" of the FFDCA, 21 U.S.C. §346a(b)(2). (ER1133; *accord* ER1159.)

After reviewing "the available scientific data and other relevant information" (ER1139), EPA concluded that exposure to chlorpyrifos results in adverse neurodevelopmental outcomes in humans, even at levels of exposure lower than those authorized by EPA's tolerances. (ER1146-1147, 1148.)

Examining the animal studies, EPA observed that "[a] considerable and still-growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals" showed gestational or postnatal exposure to chlorpyrifos could "cause persistent behavioral effects into adulthood." (ER1143.) Despite differences in method among the animal studies, "the consistency of finding neurological effects" from early chlorpyrifos exposure was "striking." (ER1143.)

Human cohort studies generally are viewed as the "gold standard" for observational research.[9] The three such studies considered by EPA tracked mother-infant pairs to ascertain the effect of prenatal exposure to chlorpyrifos or other organophosphate pesticides on children from birth to age 7. (ER1144.) The studies covered different types of exposed groups, "which strengthen[ed] the weight of the evidence." (ER1144.) All three studies found "positive associations between *in utero* [organophosphate pesticide] exposure and adverse neurodevelopmental effects." (ER1144.) Recognizing "the strengths and limitations" of the studies, EPA nonetheless concluded that "these are strong studies which support a conclusion that [organophosphate pesticides] likely played a role" in the adverse outcomes for children. (ER1144.)

EPA therefore proposed to revoke all chlorpyrifos tolerances effective 180 days after publication of a final rule. (ER1159.)

[9] Matthew S. Thiese, "Observational and Interventional Study Design Types; An Overview," 24(2) Biochemia Medica 199-210 (June 15, 2014), available at http://dx.doi.org/10.11613/BM.2014.022 (last visited Dec. 4, 2019).

6. April 2016: SAP Peer-Reviews the 2014 Revised Human Health Risk Assessment

EPA had meanwhile convened the Scientific Advisory Panel to peer-review the agency's 2014 Revised Human Health Risk Assessment, including its analysis of the human cohort studies. In an April 2016 report, the Panel agreed with EPA's overall assessment that "both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% [cholinesterase] inhibition," that is, "toxicity at lower doses" than EPA's tolerances presently permit. (ER1191; *accord* ER1198, 1225-1226.)

Nonetheless, the Panel cautioned EPA not to use the Columbia study's measurements of chlorpyrifos levels in umbilical cord blood after delivery to estimate an infant's risk within the assessment. (ER1191-1192, 1198.) Instead, the Panel advised EPA to continue relying on a model developed by the registrant (*see* ER2a-3a, 1808) called the physiologically-based pharmacokinetic (PBPK) model to estimate those levels. (ER1192, 1221.)

7. November 3, 2016: EPA Again Revises its Human Health Risk Assessment

To address the recommendations in the Scientific Advisory Panel's April 2016 report, EPA revised its Human Health Risk Assessment again on November 3, 2016. (ER1249-1289.) EPA's revised assessment specifically incorporated the use of the industry-developed PBPK model (ER1252, 1262), which the Panel had supported (ER1258) and suggested as a "path forward" (ER1252).

Using the PBPK model, EPA concluded that chlorpyrifos tolerances based on 10% cholinesterase inhibition "may not provide a sufficiently protective human health risk assessment." (ER1261.)

The agency acknowledged the "breadth of information available on the potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos." (ER1256.) EPA pointed to the consensus of studies linking chlorpyrifos exposure to delayed mental development, attention problems, autism spectrum disorder, and reduced intelligence. (ER1260.) EPA reported that the adverse effects of chlorpyrifos had been documented with "strong measures of statistical association across several of these evaluations." (ER1260.)

EPA further found that chlorpyrifos exposure from food residues for all groups ranged from 62 to 140 times acceptable levels. (ER1271.) Children 1-2 years old were exposed to chlorpyrifos residues on food at 14,000% of the acceptable exposure level. (ER1254, 1271.) EPA also found chlorpyrifos exposure to be 93 times above acceptable levels for infants under 1 year; 110 times above acceptable levels for youths ages 6-12; and 62 times above acceptable levels for females in their child-bearing years, ages 13-49. (ER1271.) EPA stated that it did not need to include drinking water exposure in its analysis because the risks from food alone exceeded acceptable levels. (ER1272.)

EPA found the human cohort studies of "high quality" (ER1259) and stated that they provided "the most robust available epidemiological evidence" of neurodevelopmental effects (ER1260). The results were consistent with multiple animal studies, which documented "long-lasting neurodevelopmental disorders in rats and mice following gestational exposure" to organophosphate pesticides. (ER1259.)

Although researchers did not fully understand the specific biological processes by which even very low exposures to chlorpyrifos cause neurological damage, EPA noted that such uncertainties did not

undermine its conclusion that such low exposures in fact cause that damage. (ER1260.)

8. November 16, 2016: EPA Again Proposes to Revoke Chlorpyrifos Tolerances

Two weeks later, on November 16, 2016, EPA issued a new notice stating the agency's view that the analysis supporting EPA's existing tolerances, based on 10% cholinesterase inhibition, is "not sufficiently health protective." (ER1291.)

The 2016 Revised Human Health Risk Assessment "d[id] not result in a change" to EPA's 2015 conclusion that the tolerances should be revoked. (ER1291.) Even after the agency modified its methods and risk assessment "in accordance with the advice" of the Scientific Advisory Panel, "[t]he revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard" of the FFDCA. (ER1291.)

Indeed, EPA was unable to "identif[y] a set of currently registered uses [for chlorpyrifos] that meets the FFDCA safety standard." (ER1291.)

E. Litigation over EPA's Delay in Addressing the Harms Caused by Chlorpyrifos

Notwithstanding EPA's ever-increasing confidence regarding its findings of harm from chlorpyrifos exposure at levels far below those authorized by existing tolerances, EPA left those tolerances in place. As detailed below, the agency first delayed for years acting on the 2007 administrative petition to revoke those tolerances. Then, when finally faced with writs of mandamus from this Court ordering it to act by dates certain, EPA denied the administrative petition and the administrative objections filed in response to that denial, while deferring a decision on the safety of chlorpyrifos tolerances until 2022, the deadline for the pesticide's reregistration under FIFRA.

More particularly, although the PANNA/NRDC petition to revoke chlorpyrifos tolerances was filed in 2007, EPA still had not responded to the petition by 2012. PANNA/NRDC accordingly petitioned this Court for a writ of mandamus to compel agency action. *See PANNA v. EPA*, No. 12-71125. The Court dismissed that petition without prejudice based in part on EPA's representation that it had a "concrete timeline for final agency action that would resolve the 2007 Petition by February 2014." *PANNA v. EPA*, 532 F. App'x 649, 651 (9th Cir. 2013).

After EPA missed the February 2014 deadline, PANNA/NRDC renewed the mandamus request. In June 2015, EPA represented to the Court that it intended to grant the 2007 PANNA/NRDC administrative petition in part by proposing a rule to revoke all chlorpyrifos tolerances. *See PANNA v. EPA*, No. 14-72794, ECF #20 at 1-2 (9th Cir. June 30, 2015).

In August 2015, with no action yet taken on PANNA/NRDC's now eight-year-old administrative petition, this Court found EPA's delay "egregious." *PANNA v. EPA,* 798 F.3d 809, 811 (9th Cir. 2015). Pointing to EPA's "litany of partial status reports, missed deadlines, and vague promises of future action," this Court granted a writ of mandamus and ordered the agency "to issue either a proposed or final revocation rule or a full and final response to the administrative petition by October 31, 2015." *Id.* at 811, 815. "In view of EPA's own assessment of the dangers to human health posed by this pesticide," the Court wrote, "we have little difficulty concluding it should be compelled to act quickly to resolve the administrative petition." *Id.* at 814.

By December 2015, EPA had neither proposed a final rule nor acted on PANNA/NRDC's petition. On December 10, 2015, this Court ordered

EPA "to take final action by December 30, 2016 on its proposed revocation rule and its final response" to PANNA/NRDC's 2007 administrative petition. *PANNA v. EPA*, 808 F.3d 402, 402-03 (9th Cir. 2015).

In June 2016, EPA told the Court that taking final action on the PANNA/NRDC petition by the December 30 deadline would be "impracticable." *PANNA v. EPA,* No. 14-72794, ECF #39-1 at 2 (9th Cir. June 29, 2016). Citing new analyses of drinking-water risks and available epidemiological data, *id.* at 2-3, EPA informed the Court that its proposed rule "had likely *underestimated* the neurodevelopmental risks" posed by chlorpyrifos. *Id.* at 3 (emphasis added). Further, although the Scientific Advisory Panel had just issued a report in April 2016 reviewing EPA's 2014 risk assessment, EPA explained that it had just submitted these new analyses to the Panel, which had not yet rendered a written report. *Id.* at 4. EPA wrote that it "gives considerable weight to the Panel's expertise and recommendations." *Id.* at 5.

The Court took a dim view of EPA's request for additional time. "EPA's nine-year delay in taking action was 'objectively extreme' when we received PANNA's petition for mandamus," the Court wrote, adding that "nothing has changed that would justify EPA's continued failure to

respond to the pressing health concerns presented by chlorpyrifos." *PANNA v. EPA,* 840 F.3d 1014, 1015 (9th Cir. 2016). The Court therefore directed EPA to take final action by March 31, 2017, and said it would grant no further extensions. *Id.*

F. EPA's Initial Order Denying the Administrative Petition and the Administrative Objections to That Order

Despite EPA's unequivocal conclusion after a decade of administrative review and ever-mounting evidence that chlorpyrifos tolerances cannot be found safe and must be revoked, the agency reversed course in early 2017. Just before this Court's March 31, 2017 deadline, newly appointed EPA Administrator Scott Pruitt issued an order (the Initial Order) denying the 2007 PANNA/NRDC petition and leaving chlorpyrifos tolerances in effect. (ER25-36.)

The Initial Order contained neither of the affirmative safety findings required by the FFDCA to support leaving tolerances in effect. Nor did it refute EPA's findings in the 2016 Risk Assessment and elsewhere regarding the adverse effects to infants and children from low-level chlorpyrifos exposure. Instead, EPA said it would not revoke the

chlorpyrifos tolerances because "the science addressing neurodevelopmental effects remains unresolved." (ER27.)

And although the review of tolerances under the FFDCA is a separate process from pesticide reregistration under FIFRA, EPA said it would address the issues raised by the PANNA/NRDC petition regarding brain damage to children "as part of the registration review of chlorpyrifos." (ER34.) EPA claimed to have "discretion to determine the schedule" for reviewing chlorpyrifos tolerances under the FFDCA, so long as it completed the separate FIFRA registration review by October 1, 2022. (ER34.)

On June 5, 2017, the States (ER166-183) and LULAC (ER121-164) filed timely administrative objections to the Initial Order. The objections raised legal challenges to EPA's authority to leave chlorpyrifos tolerances in effect without the safety findings required by the FFDCA. (ER149-163, 173-174.) Because the objections were legal in nature, no evidentiary hearing was sought. (ER128, 176.) Citing the FFDCA's requirement that the Administrator issue a final decision on the objections "[a]s soon as practicable," 21 U.S.C. § 346a(g)(2)(C), the States (ER176) and LULAC (ER149, 163) asked EPA to respond to the objections within 60 days.

G. *LULAC I*

In addition to filing administrative objections, LULAC challenged the Initial Order directly in this Court. (*LULAC I* ECF #1.) The Court allowed the States to intervene as petitioners. (*LULAC I* ECF #31, 68.) After briefing and argument, a panel of the Court ruled in favor of LULAC and the States, vacated EPA's Initial Order, and ordered EPA to revoke chlorpyrifos tolerances. *LULAC v. Wheeler,* 899 F.3d 814 (9th Cir. 2018). On EPA's petition for rehearing or rehearing en banc (*LULAC I* ECF #115), however, the Court granted en banc review. *LULAC v. Wheeler,* 914 F.3d 1189 (9th Cir. 2019).

By the time of the en banc argument (March 26, 2019), almost two years had passed since the administrative objections had been filed. Yet EPA still had not acted on them. The en banc Court unanimously construed LULAC's opening brief to include a request for mandamus relief, granted mandamus, and ordered EPA to issue "a full and final decision" on LULAC's and the States' objections within 90 days of its April 19, 2019 decision. *LULAC v. Wheeler,* 922 F.3d 443, 445 (9th Cir. 2019).

H. EPA's Final Order and the Underlying Petition for Judicial Review

On this Court's ordered deadline, EPA issued the Final Order denying the States' and LULAC's objections (ER1a-14a).

Like the Initial Order, EPA's Final Order left chlorpyrifos tolerances in place without making the required affirmative findings of safety. Instead, EPA relied on its safety finding from the 2006 reregistration and tolerance review. (*See* ER12a.)

Although the FFDCA nowhere imposes such a burden on petitioners, EPA "construe[d] the FFDCA and the Agency's implementing regulations to require petitioners seeking withdrawal of a tolerance to support this request with valid, complete and reliable data that set forth why the tolerances are *unsafe*." (ER8a [emphasis added].) Applying that newly fashioned requirement, EPA ruled that PANNA/NRDC "have not met that burden" because they purportedly "fail[ed] to provide evidence of neurodevelopmental effects that is sufficiently valid, complete, and reliable at this time to meet the burden petitioners for revocation bear in presenting a case that tolerances are *unsafe*." (ER8a [emphasis added].)

As for the many analyses and assessments that EPA has conducted in the interim, EPA acknowledged that, based on "multiple[] lines of

evidence," including animal studies and human epidemiological studies, "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." (ER9a.) Notwithstanding that conclusion, however, EPA criticized the existing data for "lack of robustness" on three counts: (1) "the absence of a clear mechanism of action for chlorpyrifos in the developing brain"; (2) a "dosing regimen" in animal studies that supposedly differs from "internationally accepted protocols"; and (3) the unavailability of "raw data" from the epidemiological studies. (ER9a.) And EPA expressly disavowed its conclusions in 2015 and 2016 that chlorpyrifos tolerances could not be found safe, stating that those conclusions were contained in "proposals" that "do not bind" the agency. (ER12a.)

Most significantly, EPA once again left chlorpyrifos tolerances in effect without finding them safe. Instead, EPA argued that the objectors' concerns about adverse neurodevelopmental effects on children "relate to issues EPA is evaluating in its current registration review of chlorpyrifos." (ER8a.) The agency noted that it is studying the neurodevelopmental data on chlorpyrifos "in conjunction with the

statutorily prescribed FIFRA re-registration process" (ER11a), and characterized the administrative objections as "focused on EPA's ongoing work in FIFRA registration review to evaluate more recent information addressing the risk of adverse neurodevelopmental effects" (ER8a).

Therefore, EPA opted to "deny the petition to allow EPA to complete its assessment of the potential for adverse neurodevelopmental outcomes in connection with the ongoing chlorpyrifos FIFRA registration review." (ER8a.) Although EPA expressed its intent to provide "updates" by the summer of 2020 (ER 12a), the agency did not provide a date for ruling on chlorpyrifos's safety, except to say it "expects" to complete the chlorpyrifos registration review "in advance of" October 1, 2022, and "will make a determination" regarding the safety of chlorpyrifos "at that time" (ER12a).

As authorized by the FFDCA, 21 U.S.C. § 346a(h)(1), the States timely commenced the instant proceeding for judicial review of the Final Order on August 7, 2019. (*See* ECF #1-5.) Timely motions to intervene by the District of Columbia and the States of Oregon and Hawaii (ECF #13, 15, 18) were granted on November 8, 2019 (ECF #30). LULAC likewise filed a timely petition challenging the Final Order. *See LULAC v.*

Wheeler, No. 19-71979. On the States' motion, the en banc Court consolidated these proceedings (*see* ECF #21) and referred them to the panel.

STANDARD OF REVIEW

This Court's review of the Final Order is governed by section 706 of the Administrative Procedure Act (APA), 5 U.S.C. § 706. *Northwest Coalition for Alts. to Pesticides v. EPA,* 544 F.3d 1043, 1047 (9th Cir. 2008). The Court may "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Among other things, agency action is arbitrary and capricious when the agency has "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

When Congress has directly spoken to a question, or where a statute's meaning can be discerned through traditional techniques of statutory interpretation, the judiciary is the final authority on statutory construction and must reject administrative constructions that are contrary to the statute's plain language or Congress's clear intent.

Arizona Cattle Growers' Ass'n v. U.S. Fish & Wildlife Serv., 273 F.3d 1229, 1237 (9th Cir. 2001).

SUMMARY OF ARGUMENT

EPA's Final Order violates two provisions of the FFDCA. First, EPA left chlorpyrifos tolerances in effect without affirmatively finding that those tolerances are "safe," *i.e.,* that aggregate exposures are reasonably certain to cause no harm. *See* 21 U.S.C. §§ 346a(b)(2)(A)(i)–(ii). Second, EPA failed to make the separate safety finding required to protect infants and children. *See* 21 U.S.C. §§ 346a(b)(2)(B)(vi), 346a(b)(2)(C)(ii)(I)–(II).

The Final Order also improperly reversed the statutory burden of proof. Instead of determining whether the chlorpyrifos tolerances are "safe" as the FFDCA mandates, EPA required that petitioners prove the chlorpyrifos tolerances *unsafe.* Further, EPA's reliance on its findings of safety from 2006 was arbitrary and capricious. Outdated safety findings cannot overcome the subsequent scientific consensus on chlorpyrifos's toxicity to infants and children at low levels, as well as EPA's repeated admission that it cannot find the existing tolerances "safe" as the FFDCA

requires. The Final Order's flawed critiques of newer studies do not equate to a safety finding.

EPA cannot evade judicial review by deferring a decision on chlorpyrifos's safety to October 2022, the agency's deadline for deciding whether to reregister the pesticide under FIFRA. Nothing in the FFDCA authorizes EPA, as its final response to an administrative petition filed more than a decade ago, to continue tolerances in effect until the reregistration deadline without making the required findings of safety.

Finally, the Court should not simply vacate the Final Order. Instead, given EPA's decade-long delay, the Court should take the additional step requested in the States' petition and grant a writ of mandamus compelling EPA to revoke the chlorpyrifos tolerances.

ARGUMENT

POINT I

EPA'S FINAL ORDER VIOLATES THE FFDCA BY LEAVING CHLORPYRIFOS TOLERANCES IN EFFECT WITHOUT MAKING THE REQUIRED SAFETY FINDINGS

A. The Final Order violates two separate provisions of the FFDCA.

The Final Order must be set aside because it violates two provisions of the FFDCA that protect the public from dangerous pesticides.

First, the Final Order violates the FFDCA's provision requiring EPA to leave tolerances in effect only if it affirmatively finds them safe. In responding to a petition to revoke tolerances, EPA's Administrator may "establish *or leave in effect* a tolerance for a pesticide chemical residue in or on a food *only if* the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). "Safe" means "the Administrator has determined that there is a *reasonable certainty that no harm will result* from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added).

The Final Order defies this plain command. It leaves chlorpyrifos tolerances in effect, possibly until October 2022. Yet it contains no finding by the Administrator that "there is a reasonable certainty that no harm will result" from aggregate exposure. The Final Order therefore violates the FFDCA.

Second, the Final Order violates the separate FFDCA provision requiring EPA to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C)(ii)(I). EPA's determination of safety for infants and children cannot be implicit. EPA must "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." 21 U.S.C. § 346a(b)(2)(C)(ii)(II).

Although the Final Order leaves chlorpyrifos tolerances in effect, it contains no current finding that "there is a reasonable certainty that no harm will result to infants and children from aggregate exposure." Consequently, EPA's Final Order violates this requirement of the FFDCA as well.

B. EPA cannot avoid the FFDCA's requirements by shifting the burden of proof and requiring that petitioners prove chlorpyrifos unsafe.

EPA cannot avoid its obligation to make the safety findings required to leave tolerances in effect by placing on petitioners the burden of "provid[ing] evidence of neurodevelopmental effects that is sufficiently valid, complete, and reliable" to prove "that tolerances are *unsafe*." (ER8a [emphasis added].) In that regard, EPA's Final Order ignores the statute's express allocation of burden.

Under the FFDCA, EPA's Administrator has the burden of finding that tolerances are safe. The FFDCA states that EPA may leave a pesticide tolerance in effect "only if *the Administrator* determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). "Safe" means that "*the Administrator* has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). In deciding a petition to revoke a tolerance, the Administrator must give "due consideration" to the petition itself "*and any other information available to the Administrator*." 21 U.S.C. § 346a(d)(4)(A) (emphasis added).

Requiring that EPA find tolerances safe before leaving them in effect in response to an administrative petition comports with Congress's overarching intent to protect children. When Congress amended the FFDCA in 1996, a principal objective of the legislation was to "establish[] strong protections for infants and children."[10] As Dr. Lynn Goldman, then EPA's Assistant Administrator in charge of pesticide regulation, advised the Senate Committee on Agriculture, Nutrition, and Forestry, "[a]ny legislation that intends to ensure safe food for all Americans must include strong provisions to protect the health of children, our most vulnerable population."[11]

The intent, as described by Senator Richard G. Lugar, Chair of the Senate Committee on Agriculture, Nutrition, and Forestry, was to "require[] EPA, when setting pesticide tolerances, to develop procedures

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[10] Remarks of Rep. Thomas J. Bliley Jr., Chair of the House Committee on Commerce, 142 Cong. Rec. at H8142 (July 23, 1996); *accord S. 1166—Food Quality Protection Act: Hearing before the Senate Committee on Agriculture, Nutrition, and Forestry*, 104th Cong. 2 (1996) (statement of Sen. Richard G. Lugar, Chair).

[11] *S. 1166—Food Quality Protection Act: Hearing before the Senate Committee on Agriculture, Nutrition, and Forestry*, 104th Cong. 15 (1996) (statement of Lynn M. Goldman, M.D., Assistant Administrator, EPA Office of Prevention, Pesticides, and Toxic Substances).

to ensure that pesticide tolerances adequately safeguard the health of infants and children."[12] As remedial legislation, the FFDCA must be "given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States v. An Article of Drug (Bacto-Unidisk),* 394 U.S. 784, 798 (1969); *accord United States v. Kaplan,* 836 F.3d 1199, 1208 (9th Cir. 2016).

Thus, the Final Order misconstrued the question before the agency. The issue was not whether petitioners had proved existing tolerances *unsafe*. It was whether EPA could support those tolerances with current safety findings. *See* 21 U.S.C. § 346a(b)(2)(A) (general safety finding); 21 U.S.C. §§ 346a(b)(2)(C)(ii) (specific safety finding for infants and children).

Attempting to support its improper burden-shifting, EPA cited four statutory or regulatory provisions and a lone district court decision. (*See* ER8a.) None of those citations supports EPA's determination to leave tolerances in effect without the requisite safety findings.

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[12] *S. 1166—Food Quality Protection Act: Hearing before the Senate Committee on Agriculture, Nutrition, and Forestry*, 104th Cong. 22 (1996).

First, EPA gains no support from the FFDCA's requirement that, in revoking a tolerance, "the Administrator shall consider" various "relevant factors," including "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." *See* 21 U.S.C. § 346a(b)(2)(D)(i) (cited at ER8a). On its face, that mandate places a burden on EPA's Administrator, not on petitioners. Moreover, the mandate that EPA's Administrator consider relevant factors does not diminish the agency's responsibility to leave tolerances in effect only upon finding them safe. "EPA may not construe [a] statute in a way that completely nullifies textually applicable provisions meant to limit its discretion." *Whitman v. Am. Trucking Ass'ns,* 531 U.S. 457, 485 (2001); *see also Patagonia Corp. v. Bd. of Governors of Fed. Reserve Syst.,* 517 F.2d 803, 813 (9th Cir. 1975) (administrative interpretations that nullify statutory provisions are disfavored).

Second, EPA's burden-shifting is not supported by the agency's regulation providing that petitions seeking revocation of a tolerance based on "new data" present such data "in the form specified" by 40 C.F.R. § 180.7(b). (*See* ER8a.) Section 180.7(b), which governs petitions

proposing tolerances, extends to petitions to revoke them only "as applicable." 40 C.F.R. § 180.32(c). EPA's Final Order does not identify which, if any, of section 180.7(b)'s sixteen subsections would apply to the petition at issue here. And no subsection of 40 C.F.R. § 180.7(b) authorizes EPA to leave tolerances in effect without finding them safe.

Nor could the regulation be interpreted to do so. A valid statute "always prevails over a conflicting regulation," and a regulation can never override the plain meaning of a statute. *Texas v. EPA,* 726 F.3d 180, 195 (D.C. Cir. 2013) (citation and internal quotation marks omitted); *accord United States v. Doe,* 701 F.2d 819, 823 (9th Cir. 1983). An agency's construction of its regulation "must be reviewed in relation to the governing statutes." *Pacific Coast Med. Enters. v. Harris,* 633 F.2d 123, 131 (9th Cir. 1980). "Agency regulations must be consistent with and in furtherance of the purposes and policies embodied in the congressional statutes which authorize them." *Id.* If an agency's regulatory interpretations would "impede or inhibit congressional will, either on their face or as applied, they must be struck down." *Id.*

Third, EPA's regulatory requirement that a petition to revoke tolerances "furnish reasonable grounds for the action sought," *see* 40

C.F.R. § 180.32(b) (cited at ER8a) cannot transform Congress's requirement that EPA find safety into a requirement that petitioners prove lack of safety. Indeed, EPA's regulations define "[r]easonable grounds" as including "an *assertion* of facts (supported by data if available) showing that … new data are available as to toxicity of the chemical." 40 C.F.R. § 180.32(b) (emphasis added). Thus, by its terms, the regulation requires only that petitioners "assert[]" or "show[]" that "new data are available." *Id.* The underlying administrative petition satisfied that requirement by citing the relevant articles from peer-reviewed scientific journals. (*See* ER5-13 and footnotes.)

Fourth, EPA gains no ground by citing its regulatory requirement that "[t]he party whose request for an evidentiary hearing was granted has the burden of going forward in the hearing with evidence." *See* 40 C.F.R. § 179.91(a) (cited at ER8a.) That regulation governs formal evidentiary hearings, which the underlying administrative petition did not request (*see* ER23) and EPA appropriately did not hold. Indeed, in their administrative objections to EPA's Initial Order, the States (ER176)

and LULAC (ER128) specifically argued that an evidentiary hearing was unnecessary because their objections raised purely legal questions.[13]

That same regulation on evidentiary hearings also provides that a party claiming a tolerance *satisfies* the FFDCA's safety standard "has the burden of persuasion in the hearing on that issue." 40 C.F.R. § 179.91(b). PANNA/NRDC made no such claim; section 179.91(b) thus provided no basis for EPA to impose a burden of persuasion on PANNA/NRDC. Indeed, PANNA/NRDC made the opposite claim, namely, that existing chlorpyrifos tolerances *did not* satisfy the FFDCA's safety standard. Thus, to the extent the regulation governed PANNA/NRDC's petition at all, the regulation placed the burden of persuasion on EPA when the agency opted to keep the outdated tolerances in effect.

Finally, the district court decision on which EPA relied, *Ellis v. Housenger,* 252 F. Supp. 3d 800 (N.D. Cal. 2017), is inapposite. *Ellis* involved an application for emergency relief under a specialized section of FIFRA that authorizes immediate suspension of a pesticide's

[13] EPA's citation (*see* ER8a) to the regulation governing evidentiary hearings on pesticide registration issues under FIFRA, 40 C.F.R. § 164.80(a), is even further afield and lacks force for the same reasons.

registration "to prevent an imminent hazard"—essentially a mandatory preliminary injunction. *See* 7 U.S.C. §136d(c)(1). In those circumstances, the district court reasonably imposed on the litigant seeking that emergency relief "the initial burden of making an 'affirmative case' for such relief," a burden the litigant did not meet. *See Ellis,* 252 F. Supp. 3d at 809-10.

No request for emergency relief is involved here. PANNA/NRDC simply filed an administrative petition to revoke chlorpyifos tolerances. In such circumstances, the FFDCA places on EPA, when deciding whether to "leave in effect a tolerance," the burden of "determin[ing] that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). Further, far from "referenc[ing] no evidence," *see Ellis,* 252 F. Supp. 3d at 809, the PANNA/NRDC petition discussed the existing scientific evidence in detail and cited multiple publications where it could be found. (ER5-13.)

C. EPA cannot rely on the 2006 reregistration.

EPA cannot supply the requisite safety findings by relying on its 2006 decision to reregister chlorpyrifos and finalize its tolerance review for chlorpyrifos tolerances, a decision that EPA describes as "the only regulatory finding currently in effect." (ER12a.) The 2006 decision

adopted without change the findings of the 2001 interim order. 2006 Reregistration, *supra* n.5, at 1-2. It therefore fails to account for the extensive scientific evidence developed since then. The FFDCA does not permit EPA to turn the scientific clock back in this manner. To the contrary, the FFDCA requires EPA to assess the risks of pesticide chemical residues based on the information "available" at the time of its review. *See* 21 U.S.C. §§ 346a(b)(2)(C)(i), (b)(2)(D).

1. The FFDCA gave EPA only three options, and leaving tolerances in effect without the required findings of safety was not among them.

Tolerances are set by regulation. *See* 21 U.S.C. § 346a(b)(1). "Any person" may petition EPA's Administrator for a regulation that establishes, modifies, or (as here) revokes a tolerance. *See* 21 U.S.C. § 346a(d)(1)(A). When a party files such a petition, EPA has three choices. It may issue a final regulation establishing, modifying, or revoking the tolerance, 21 U.S.C. § 346a(d)(4)(A)(i); issue a proposed regulation "and thereafter issue a final regulation," 21 U.S.C. § 346a(d)(4)(A)(ii); or issue an order denying the petition, 21 U.S.C. § 346a(d)(4)(A)(iii).

When, as here, EPA issues an order denying a petition to revoke tolerances, the agency leaves the tolerances in effect. To issue such an

order, EPA must make the safety findings required by the FFDCA. The Administrator may "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) (emphasis added); *see also* 21 U.S.C. § 346a(b)(2)(C)(ii) (requiring separate safety finding for infants and children).

Here, EPA began taking the second path by issuing proposed rules in 2015 and 2016, but then abandoned that path and attempted to take the third path. In doing so, however, EPA improperly left chlorpyrifos tolerances in effect without finding them safe, *i.e.,* without finding "a reasonable certainty that no harm will result from aggregate exposure," 21 U.S.C. § 346a(b)(2)(A)(ii), and without making the required finding of safety for infants and children, 21 U.S.C. § 346a(b)(2)(C)(ii). While EPA apparently wishes to review data for three more years and take no action on those tolerances until it completes its chlorpyrifos reregistration due in October 2022 (ER11a), the FFDCA does not permit the agency to pursue such a course. EPA's action must be set aside because it exceeded the agency's statutory authority, *see* 5 U.S.C. § 706(2)(C), and was not in accordance with law, *see* 5 U.S.C. § 706(2)(A).

EPA complains that the structure devised by Congress is burdensome because it would require "a new safety determination in response to every petition to revoke." (ER8a.) Any such complaint should be addressed to Congress. And EPA exaggerates the supposed burden. If EPA concludes that the science behind a previously approved tolerance remains valid and is not cast into doubt by additional evidence, the agency may simply adopt its previous finding and continue the tolerance in effect. Thus, if EPA establishes tolerances and environmental groups simultaneously challenge them without new or overlooked scientific data, EPA need only refer to its current finding.

Here, however, PANNA/NRDC supported the petition with multiple studies that EPA's 2006 reregistration had overlooked. (*See* ER5-13 and footnotes.) And thereafter, while EPA delayed action on that petition for over a decade, the scientific evidence—and EPA's own assessments of that evidence—showed with ever-increasing confidence that exposure to chlorpyrifos at levels permitted by existing tolerances caused serious, long-term harms to children's developing brains. Indeed, EPA has twice recognized that these scientific developments made it impossible to find chlorpyrifos safe. (ER1133, 1291.)

2. EPA's continued reliance on its 2006 safety finding is arbitrary, capricious, and an abuse of discretion.

In light of the significant scientific developments that have since occurred, as well as EPA's own recognition that it could no longer find chlorpyrifos tolerances safe, the agency's continued reliance on safety findings reflected in the 2001 interim order, as adopted in the 2006 reregistration, is arbitrary, capricious, and an abuse of discretion.

Even the 2001 interim order recognized that "recent data" suggested "adverse effects on brain development" might occur at lower levels than measured by EPA's criterion then in use. 2001 Interim Order, *supra* n.4, at 12.

Subsequent scientific studies have clarified and augmented that "recent data." In 2008, EPA and its Scientific Advisory Panel noted the "growing body of literature" showing that prenatal and infant exposure to chlorpyrifos "can lead to neurochemical and behavioral alterations into adulthood" (ER754), an effect not accounted for in previous tolerances. In 2011, EPA's Preliminary Human Health Risk Assessment observed that human and animal studies both established that exposing women of child-bearing age to chlorpyrifos would likely cause "adverse

neurodevelopmental outcomes" in their children. *See supra* at 19 & n.7. The Revised Human Health Risk Assessment in 2014 described the body of animal studies showing harms of early chlorpyrifos exposure as "considerable and growing" (ER208) and found the consensus between animal and epidemiological results to be "striking." (ER229.)

In 2015, after reviewing "the available scientific data and other relevant information" (ER1139), EPA could not find chlorpyrifos to be "safe" as the FFDCA required (ER1133). Instead, the agency concluded that "exposure to chlorpyrifos results in adverse neurodevelopmental outcomes in humans." (ER1148.) The Scientific Advisory Panel agreed in 2016 that the evidence showed adverse health outcomes associated with chlorpyrifos exposures below the permitted level of 10% cholinesterase inhibition. (R1191.) After revising portions of its analysis and using the industry-developed PBPK model, EPA in December 2016 still could not find chlorpyrifos tolerances safe. (ER1291.)

The FFDCA requires EPA to assess the risk of pesticide chemical residues based on "available information." 21 U.S.C. § 346a(b)(2)(C)(i); *accord* 21 U.S.C. § 346a(b)(2)(D). Here, the scientific consensus on chlorpyrifos did not change between December 2016 and July 2019, when

EPA issued its Final Order. Nor did EPA offer any report from its Scientific Advisory Panel departing from the Panel's conclusions in 2012 and 2016. And EPA did not prepare a new Human Health Risk Assessment to replace the one from November 2016 that found children are being exposed to chlorpyrifos at up to 14,000% of acceptable levels (*see* ER1271).

Indeed, EPA acknowledged in the Final Order that the agency has "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," a conclusion that rested upon "an evaluation across multiple lines of evidence including mechanistic studies and newer *in vivo* laboratory animal studies," as well as "the available epidemiology reports along with feedback from the 2012 and 2016 [Scientific Advisory Panel] meetings." (ER9a.)

As EPA observes (ER12a), a proposed regulation need not be adopted. But that proposition is irrelevant here. The FFDCA requires that EPA's decision to leave tolerances in place be justified with specific findings, including that "there is a reasonable certainty that no harm will

result from aggregate exposure." 21 U.S.C. § 346a(b)(2)(A)(ii). Explaining why it proposed to revoke chlorpyrifos tolerances, EPA stated that it could not find those tolerances safe. (ER1133, 1291.) That was not a proposal; it was a statement of fact. And in its Final Order, EPA did not make the requisite safety findings. Because neither the proposed rule nor the Final Order contained a finding that chlorpyrifos is safe, and specifically that it is safe for infants and children, both documents support revoking the chlorpyrifos tolerances.

3. EPA's criticism of newer studies does not substitute for the requisite safety findings.

EPA seeks to avoid making the safety findings required by the FFDCA by citing three ways in which the available scientific data purportedly lack "robustness": (1) the absence of a "clear mechanism of action" showing why chlorpyrifos is harmful to developing brains; (2) the "dosing regimen" in animal studies that supposedly differs from internationally accepted protocols; and (3) "the lack of any meaningful raw data from the epidemiologic data." (ER9a.) At most, those criticisms suggest some uncertainty in the academic field. They cannot override the FFDCA's legal requirement that EPA find pesticide residue tolerances safe, including for infants and children, when leaving tolerances in effect.

EPA did not make such findings and, indeed, cannot do so in light of the evidence before it.

Even assuming any imperfection in the scientific studies to date, EPA still must find tolerances safe to leave them in effect. The FFDCA requires that EPA "shall assess the risk" of pesticide chemical residues based on "available information"—not perfect information. *See* 21 U.S.C. § 346a(b)(2)(C)(i). That is a wise policy choice. Because science continues to evolve, the law does not require "ironclad and absolute" evidence before EPA must act to protect infants and children from toxic pesticides. *Cf. Alaska Oil & Gas Ass'n v. Pritzker*, 840 F.3d 671, 680 (9th Cir. 2016) (construing Endangered Species Act's requirement that decisions be based on "the best scientific and commercial data available"), *cert. denied,* 138 S. Ct. 924 (2018). "[T]he 'best scientific … data available,' does not mean 'the best scientific data possible.'" *San Luis & Delta-Mendota Water Auth. v. Jewell,* 747 F.3d 581, 602 (9th Cir. 2014) (internal quotation marks and citation omitted; ellipsis in original).

EPA cannot ignore the mounting scientific evidence documented from 2008 to 2016 in its own risk assessments and the reports of its own Scientific Advisory Panel. To do so is arbitrary and capricious because it

"runs counter to the evidence before the agency." *Motor Vehicle Mfrs.,* 463 U.S. at 43. EPA also cannot legally refuse to act "because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will *always* be present." *Chlorine Chemistry Council v. EPA,* 206 F.3d 1286, 1290-91 (D.C. Cir. 2000).

Moreover, none of EPA's three criticisms of the scientific evidence on chlorpyrifos withstands analysis.

The absence of a "clear mechanism for action" showing how chlorpyrifos exposure harms developing brains (ER9a) simply means that scientists have not yet identified the specific chemical pathway or pathways by which chlorpyrifos causes that harm. There is no such lack of clarity on the critical point that chlorpyrifos *in fact* causes that harm. Based on a wide array of animal and epidemiological studies all reaching that same conclusion, EPA recognized that fact with increasing confidence from 2008 through 2016. (*See* ER1259-1260.) Indeed, EPA observed in November 2016 that uncertainties over chlorpyrifos's precise mechanism or pathway of toxicity "do not undermine or reduce the confidence in the findings of the epidemiology studies." (ER1260.) *See also Am. Trucking Ass'ns v. EPA,*175 F.3d 1027, 1055 (D.C. Cir.) (in

regulating air pollution, EPA was not required to prove "how particles actually interact with cells and organs to cause sickness and death"), *modified on other grounds,* 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part and rev'd in part on other grounds,* 531 U.S. 457 (2001).

As for EPA's criticism regarding the dosing in animal studies, EPA does not identify which animal studies purportedly differ from "internationally accepted protocols"; the extent to which they purportedly differ; or which protocols EPA is discussing in the first place, instead leaving the parties and the Court to guess. EPA's dosing criticism is arbitrary and capricious because it does not "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs.,* 463 U.S. at 43 (internal quotation marks and citation omitted).

To the extent EPA's critique refers to the "five new laboratory animal studies" relied upon by California in recently designating chlorpyrifos as a toxic air contaminant (ER12a), the Final Order concedes that those studies were "not previously reviewed by EPA" (ER12a). Consequently, those studies cannot have formed part of the materials

EPA relied upon in 2015 and 2016 when it concluded that it could not find chlorpyrifos safe. (*See* ER1133, 1291).

Further, as EPA previously recognized, the "substantial differences" in the experimental design of the various animal studies reflect a "wide array of testing." (ER1143.) Despite the different methodologies, however, when EPA analyzed the animal studies as a group, it found "striking" how consistent they were in finding neurological harms. (ER1143.) And those findings were strikingly consistent with the results of the human epidemiological studies, as well. (ER229.)

Finally, EPA's criticism over lack of access to "raw data" from the human epidemiological studies (ER9a-11a) is a red herring. The only raw data that has ever been at issue is the raw data underlying Columbia's human cohort study. (ER567.) That issue was resolved when EPA specifically abandoned its request for raw data. (ER567.) After a full-day meeting with Columbia's researchers in April 2013, EPA stated that "[a]s a result of new information gathered through an on-site meeting and other sources, EPA is no longer pursuing the request for the original

analytic data file from [the Columbia] researchers." (ER567.)[14] In an appendix to the 2014 revised human health risk assessment, EPA explained in detail why the Columbia study's raw data was not necessary for the agency's analysis. (*See* ER567-574.)

In contrast, the Final Order fails to explain how any such raw data would have been material to the agency's determination. EPA had relied in part on the Columbia study's data from chlorpyrifos levels in umbilical cord blood when it estimated in the 2014 Revised Human Health Risk Assessment that chlorpyrifos exposure injures the developing brains of infants and children even at exposure levels far below those authorized by existing tolerances. (ER228-229.) When the Scientific Advisory Panel disagreed with that approach in April 2016 (*see, e.g.,* ER1191-1192, 1198, 1211, 1234), EPA responded by adopting a new approach in its 2016

[14] While EPA apparently renewed its request for raw data at some later point, the record contains no explanation of how, when, or why EPA did so. Since then, EPA and Columbia have made significant progress toward allowing review. EPA and Columbia both recognized the need to protect the privacy of study participants and agreed to conduct future follow-up on that topic. (*See* ER1928.) On July 31, 2018, Columbia suggested that the EPA could review the raw data in a secure data center. (ER1927.)

Revised Health Risk Assessment that did not rely on the Columbia study's umbilical cord blood data (*see* ER1252, 1258, 1261-1262). That 2016 assessment showed even higher risks at low doses than were indicated in 2014. (*Compare* ER258 and ER1150 *with* ER1271.)

More generally, EPA did not, and does not, require provision of the raw data from independent, peer-reviewed studies. The contrary is true: EPA proposed a rule requiring the provision of raw data for the first time in April 2018. *See* 83 Fed. Reg. 18768 (Apr. 30, 2018). And EPA's proposal expressly acknowledges that it is "designed to *change* agency culture and practices regarding data access." *Id.* at 18770 (emphasis added). The proposed rule has encountered an "onslaught of criticism" and, as of the date of this brief, has not been adopted.[15] Meanwhile, EPA guidelines allow reliance on epidemiological studies in assessing pesticide safety.[16]

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[15] Sean Reilly, "EPA's controversial 'secret science' plan still lacks key details, advisers say," Science (Aug. 28, 2019), available at https://www.sciencemag.org/news/2019/08/epa-s-controversial-secret-science-plan-still-lacks-key-details-advisers-say (last visited Dec. 5, 2019).

[16] U.S. EPA, Office of Pesticide Programs, Procedures for Reviewing Relevant Effects Data Published in the Open Literature for Use in OPP's Human Health Risk Assessments at 10-11 (Aug. 28, 2012), available at https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf (last visited Dec. 5, 2019).

D. EPA cannot evade judicial review on the merits by deferring analysis of the chlorpyrifos tolerances to the FIFRA registration review.

After over a decade of delay, EPA now says it "will make a determination" regarding the safety of chlorpyrifos by the FIFRA reregistration deadline of October 1, 2022. (ER12a.) This Court should reject the agency's attempt to grant itself yet another extension and thereby evade substantive judicial review. EPA cannot use the 15-year timeframe for registration reviews under FIFRA to delay its review of a petition to revoke tolerances under the FFDCA.

The FFDCA and FIFRA are separate statutes. The FFDCA, not FIFRA, empowers EPA to establish, modify, and revoke tolerances. *See* 21 U.S.C. §346a(b)(1). The FFDCA, not FIFRA, mandates that EPA's Administrator "leave in effect a tolerance for pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe," meaning that "the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(i)-(ii). The FFDCA, not FIFRA, allows "[a]ny person" to petition for regulations

"establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." *See* 21 U.S.C. § 346a(d)(1)(A).

The FFDCA's framework enables EPA to revoke tolerances swiftly when available scientific evidence no longer permits the agency to find the tolerances safe, particularly as to infants and children. That is why the FFDCA contains a petitioning mechanism to revoke tolerances by presenting relevant scientific information for EPA to consider. *See* 21 U.S.C. § 346a(d)(1)(A). Under the FFDCA, persons seeking to revoke a tolerance need not wait 15 years for the next registration review. *Compare* 21 U.S.C. § 346a(d)(1) (FFDCA) *with* 7 U.S.C. § 136a(g)(1)(A)(iii)–(iv) (FIFRA).

EPA's position is especially unreasonable in light of the agency's history of delaying review of the petition's merits. It is only because EPA delayed for over a decade a determination on the administrative petition that the reregistration deadline for chlorpyrifos is now just three years away. EPA should not be permitted to postpone judicial review in this manner.

Indeed, a contrary holding could enable EPA to avoid judicial review altogether. In *New York v. EPA,* 350 F. Supp. 2d 429 (S.D.N.Y.

2004), *aff'd sub nom. NRDC v. Johnson*, 461 F.3d 164 (2d Cir. 2006), the district court suggested that litigants seeking to challenge the registration under FIFRA of a pesticide used on foods must first exhaust the administrative petition process provided in the FFDCA.

The litigants in *New York v. EPA* sought to challenge in federal district court EPA's reassessment of the safety of various pesticide residues on foods under the FFDCA. The court dismissed the challenge for lack of jurisdiction, finding that the FFDCA vests review of any regulation or order to which it applies exclusively in the Courts of Appeals and forecloses such review prior to exhaustion of the administrative remedies it provides. 350 F. Supp. 2d at 438 (citing 21 U.S.C. §§ 346a(g), (h)(1)). But the court further explained that, even if cast as a challenge to the reregistration of the subject pesticides under FIFRA, the registration-based claim existed "only through [plaintiffs'] challenge to the tolerances set under the [FFDCA]." *Id.* at 446. Because review of tolerances "is or was obtainable" under the FFDCA, a separate FIFRA challenge in district court was precluded. *Id.* at 446-47 (quoting 21 U.S.C. § 136a(h)(5)).

Yet now, when LULAC and the States seek judicial review under the FFDCA in the Court of Appeals after having exhausted their administrative remedies, EPA asserts that a substantive review of chlorpyrifos's safety should be deferred to the FIFRA process. That attempted regulatory whipsaw frustrates Congress's intent to protect infants and children from unsafe foods.

To be sure, the FFDCA directs EPA "[t]o the extent practicable" to coordinate tolerance revocations under the FFDCA with "any related necessary action" under FIFRA. 21 U.S.C. § 346a(*l*)(1). That provision does not, however, support EPA's Final Order. The "related" action under FIFRA that is "necessary" when tolerances are revoked would be, for example, making conforming changes to the uses for which the pesticides were registered.

More fundamentally, the coordination provision nowhere authorizes EPA to leave tolerances in effect without current findings of safety. As EPA's Dr. Lynn Goldman testified to the Senate Committee on Agriculture, Nutrition, and Forestry during hearings on what became the 1996 amendments to the FFDCA and FIFRA, the coordination provision should not "be read to have the practical effect of negating all of the

FFDCA standards including those aimed at protecting children."[17] Instead, "it should be made clear that any provision for timing regulatory actions under the two statutes does not affect the substantive provisions of FFDCA." *Id.*

Like other agencies, EPA may act only in accordance with the specific statutory authority granted by Congress. *Clean Air Council v. Pruitt,* 862 F.3d 1, 9 (D.C. Cir. 2017); *accord NRDC v. Abraham,* 355 F.3d 179, 202 (2d. Cir. 2004). Because the FFDCA does not authorize EPA to continue tolerances in effect until 2022 without making current safety findings, the Final Order must be set aside.

[17] *Hearing before the Subcommittee on Department Operations, Nutrition, and Foreign Agriculture of the Committee on Agriculture, House of Representatives, on H.R. 1627*, 104th Cong. 14 (1995) (statement of Lynn Goldman, Assistant Administrator, EPA Office of Prevention, Pesticides, and Toxic Substances).

POINT II

THE COURT SHOULD GRANT A WRIT OF MANDAMUS COMPELLING EPA TO REVOKE THE CHLORPYRIFOS TOLERANCES

Setting aside the Final Order would not afford complete relief. Without the Final Order, chlorpyrifos tolerances would remain in effect. Because the FFDCA requires EPA to revoke chlorpyrifos tolerances if it cannot find them safe, because EPA has not done so, and because the administrative record precludes EPA from doing so, this Court should also grant mandamus relief compelling the agency to revoke existing chlorpyrifos tolerances.

Federal law empowers the Court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1); *see also* 28 U.S.C. § 1651(a) (All Writs Act). Such relief is appropriate when the agency has "failed to take a discrete agency action that it is required to take." *Norton v. S. Utah Wilderness Alliance,* 542 U.S. 55, 64 (2004).

Here, the FFDCA clearly directs that EPA may "leave in effect a tolerance" for pesticide residues on food "only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). Where, as here, EPA cannot find a tolerance safe, it may not "leave in effect" that tolerance. Yet after more than a decade of administrative

review of the safety of chlorpyrifos tolerances, the Final Order announces three more years of delay before EPA takes regulatory action.

Under any reasonable view, the appropriate time for EPA to take such action and revoke chlorpyrifos tolerances has long since expired. More than four years ago, this Court found EPA's delay in addressing chlorpyrifos's risks "egregious" and "unreasonable." *PANNA,* 798 F.3d at 811, 814-15. More than three years ago, this Court found EPA's delay in addressing chlorpyrifos's risks "objectively extreme." *PANNA,* 840 F.3d at 1015.

Human health and welfare are at risk: as this Court observed in 2015, "considerable human health interests [are] prejudiced" by EPA's delay. *PANNA*, 798 F.3d at 809. EPA's most recent human health risk assessment, in November 2016, commented on the "breadth of information available" on neurological damage to infants and children from prenatal exposure to chlorpyrifos. (ER1256.) The costs of intellectual disability caused by exposure to organophosphate

pesticides—of which chlorpyrifos is the most widely used—have been estimated at more than $44 billion per year.[18]

In short, although mandamus is an "extraordinary remedy," *see PANNA,* 798 F.3d at 809, it is warranted here.

[18] *See* T.M. Attina *et al.*, "Exposure to Endocrine-Disrupting Chemicals in the USA: A Population-Based Disease Burden and Cost Analysis," Lancet Diabetes Endocrinology 4(12):996 at 1000 (2016), available at https://doi.org/10.1016/S2213-8587(16)30275-3 (last visited December 5, 2019).

CONCLUSION

For the foregoing reasons, the States respectfully request that the Court set aside the Final Order and grant a writ of mandamus compelling EPA to revoke the tolerances for chlorpyrifos.

Dated: Albany, New York
December 6, 2019

Respectfully submitted,

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ADDENDUM OF STATUTORY PROVISIONS AND EXCERPTS OF RECORD

The States adopt the Addendum of Statutory Provisions and Excerpts of Record filed with LULAC's brief (No. 19-71979, consolidated with 19-71982).

STATEMENT OF RELATED CASES

This case is related to:

1. *Pesticide Action Network North America et uno. v. U.S. Environmental Protection Agency,* No. 12-71125 (9th Cir.);

2. *Pesticide Action Network North America et al. v. U.S. Environmental Protection Agency*, No. 14-72794 (9th Cir.);

3. *League of United Latin American Citizens et al. v. Wheeler*, No. 17-71636 (9th Cir.); and

4. *League of United Latin American Citizens et al. v. Wheeler,* No. 19-71979 (9th Cir.).

CERTIFICATE OF COMPLIANCE

9th Cir. Case Number 19-71979 and 19-71982 (consolidated)

I am the attorney in 19-71982.

This brief contains 12,515 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

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Signature ____s/Frederick A. Brodie_____

Date: December 6, 2019

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2019, I served the Opening Brief for the Petitioners-Intervenors on the parties of record in this case by filing same with the United States Court of Appeals for the Ninth Circuit via CM/ECF.

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