Nos. 22-1422, 22-1530 (consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

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

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY and U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

Petition for Review of an Order of the Environmental Protection Administration
(EPA-HQ-OPP-2021-0523)

BRIEF OF *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI*

Amici are 13 nonprofit organizations working to protect the health and well-being of communities across the country, including Latino communities, farmworkers and their families, and children with learning disabilities. For 15 years, they have been working to protect workers and their families from chlorpyrifos. In 2007, two *Amici* – Natural Resources Defense Council ("NRDC") and Pesticide Action Network North America ("PANNA") – petitioned the Environmental Protection Agency ("EPA") to revoke tolerances that allow chlorpyrifos residues on food because low-level chlorpyrifos exposures cause learning disabilities, reduced IQ, and other neurodevelopmental harm to children.[1] In response, EPA made an unbroken series of findings that chlorpyrifos causes neurodevelopmental harm to children at exposures far below those allowed by EPA tolerances, but EPA took no action to protect children from this harm. Several unreasonable delay cases led to court orders requiring EPA to act on the 2007 petition. *In re PANNA*, 798 F.3d 809 (9th Cir. 2015) (directing EPA to end "egregious" delays in addressing the "considerable human health interests" presented by chlorpyrifos); *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016)

[1] No counsel for a party authored this brief, in whole or in part, and no party or counsel for a party, other than *amici* and their counsel, provided funds for preparing or submitting this brief.

(2017 deadline to take final action on 2007 petition); *LULAC v. Wheeler*, 922 F.3d 443, 445 (9th Cir. 2019) (en banc) (2019 deadline to rule on objections).

In 2015, based on the findings by EPA and its Scientific Advisory Panel ("SAP") and EPA's 2014 risk assessment, EPA proposed revoking all chlorpyrifos tolerances, but, after the administration changed, EPA denied the 2007 petition and the subsequent objections. The challenges to those denials led to the Ninth Circuit decision in *LULAC v. Regan*, 996 F.3d 673 (9th Cir. 2021), holding (1) EPA abdicated its statutory duty to protect food safety by leaving tolerances in place without a safety finding; and (2) EPA's denials were arbitrary and capricious because the record demonstrated chlorpyrifos tolerances are unsafe. The court ordered EPA to grant the 2007 petition and issue a tolerance revocation rule by August 2021. *Id*. at 703-04. The *LULAC* decision compelled EPA to issue the Chlorpyrifos Revocation Rule, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Revocation Rule") and subsequent denial of objections, 87 Fed. Reg. 11,222 (Feb. 28, 2022), challenged in this case.

SUMMARY OF ARGUMENT

This case seeks to overturn EPA's long-overdue action to protect children from a pesticide that causes learning disabilities at very low exposure levels. EPA cannot retain tolerances allowing a pesticide on food unless it affirmatively finds reasonable certainty of no harm to children from all aggregate exposures to the

pesticide. Comprehensive reviews of the science by EPA and its SAP repeatedly found chlorpyrifos causes learning disabilities and neurodevelopmental harm at exposures below EPA's tolerances. In *LULAC*, the Ninth Circuit held EPA cannot find reasonable certainty of no harm to children in the face of these findings. By the Ninth Circuit's deadline, EPA appropriately issued the Revocation Rule revoking all chlorpyrifos tolerances because that is the only legally and scientifically defensible course of action.

Petitioners urge this Court to order EPA to vacate the Revocation Rule based on a 2020 proposal it cannot validly finalize. Such an order would require EPA to violate the law. First, the 2020 proposal is based on the regulatory endpoint *LULAC* held will not protect children from learning disabilities. When EPA tried to derive an endpoint that would prevent neurodevelopmental harm, it found chlorpyrifos unsafe every way children are exposed to it—with toddlers exposed to 14,000% of safe levels in food and drinking water. When California similarly derived an endpoint to protect children based on animal studies, it found chlorpyrifos unsafe and initiated cancellation proceedings culminating in Dow Agrosciences, the primary maker of chlorpyrifos at the time, agreeing to cancel almost all chlorpyrifos uses in California and exiting the chlorpyrifos market altogether.

Second, the 2020 proposal was merely a proposal, one garnering extensive critical public comments that, if adopted, would preclude EPA from finalizing the proposal. Indeed, the *LULAC* Court adopted arguments reiterated in comments from leading scientists, *Amici*, and several states that the prior tolerances and the proposal would not protect children from learning disabilities and neurodevelopmental harm. Public comments also revealed fundamental flaws in EPA's novel drinking water assessment suggesting use of chlorpyrifos on 11 food crops in limited geographies and subject to other constraints might be safe. This drinking water assessment marks the first use of untested models, despite highly critical comments from an external peer review and monitoring data documenting unsafe drinking water concentrations. EPA regulations require EPA to address these public comments before it can finalize the proposal and, once EPA does so, it will find all chlorpyrifos uses unsafe. EPA appropriately did not base its tolerance decisions on the proposal.

Third, Petitioners ask the Court to vacate the Revocation Rule in its entirety, even though their reasoning requires revocation of most chlorpyrifos tolerances as unsafe. This Court cannot issue an order directing EPA to violate the law by retaining tolerances for admittedly unsafe chlorpyrifos uses. Even if the 2020 proposal could lawfully be adopted, which it cannot because it is under-protective, that proposal depended on yet-to-be-made changes to pesticide registrations and

labels to eliminate uses and limit application rates and methods. This Court should uphold the Revocation Rule because Congress gave EPA no other option. EPA cannot not retain chlorpyrifos tolerances unless it affirmatively finds all aggregate exposures safe, which it cannot do for chlorpyrifos.

BACKGROUND

Petitioners ask this Court to vacate the Revocation Rule and EPA's subsequent denial of their objections, but selectively omit key statutory provisions, EPA's findings of neurodevelopmental harm to children, and the Ninth Circuit's holding that EPA could not find chlorpyrifos safe in the face of EPA's findings. This *amicus* brief fills in those gaps and shows revoking chlorpyrifos tolerances was compelled by the science and the law.

I. THE CONTROLLING HEALTH-BASED FOOD SAFETY STANDARDS.

Congress overhauled our food safety laws in 1996 when it unanimously passed the Food Quality Protection Act ("FQPA"), amending the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The overhaul responded to a seminal 1993 National Academy of Sciences ("NAS") Report criticizing EPA for failing to address children's unique susceptibility to pesticides based on the foods they eat, their play, metabolism, and sensitive stages of development. Infants drink seven times more per body weight than adults, inhale twice as much air, and put their hands in their mouths far more often than adults. Toxic chemicals can damage the

developing child's brain during sensitive developmental stages (in utero, infancy, and adolescence) at lower exposures than those affecting adults. *Pesticides in the Diets of Infants and Children*, at 9, 60-63, available at https://www.ncbi.nlm.nih.gov/books/NBK236275/pdf/Bookshelf_NBK236275.pdf. Four legislative changes are relevant.

First, Congress prescribed a health-protective standard, allowing EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added); *see id.* § 346a(a)(1) (foods with pesticide residues exceeding or lacking tolerance are unlawful). "Safe" is defined to mean "the Administrator has determined there is a reasonable certainty that no harm will result from aggregate exposure" to the pesticide for the public generally and children specifically. *Id*. § 346a(b)(2)(A)(ii), § 346a(b)(2)(C)(ii)(I) & (II). Congress "abrogated" EPA's prior approach of balancing safety against economic factors. *LULAC*, 996 F.3d at 678.

Second, EPA must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." 21 U.S.C. § 346a(b)(2)(C)(i)(II). Congress required "an additional tenfold margin of safety . . . shall be applied for infants and children 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." *Id.* § 346a(b)(2)(C)-(D). EPA can use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*; *Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1046, 1052 (9th Cir. 2008).

Third, EPA must ensure to a reasonable certainty that no harm will result "from aggregate exposure" to a pesticide, including "all anticipated dietary and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii). Aggregate exposure includes "dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue." *Id.* § 346a(b)(2)(D)(vi). EPA previously considered each food in isolation, but now must aggregate exposures from eating all foods, drinking water, breathing air, and playing on treated fields or carpets.

Fourth, Congress incorporated the new food safety standard into the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA can register a pesticide for use in the United States only if it determines the use will not have "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(a), which FIFRA long defined as "any unreasonable risk to [people] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* §§136a(c)(5); 136(bb). As amended, FIFRA's

definition of "unreasonable adverse effects" now includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [the FFDCA]." *Id.* § 136(bb). If a pesticide fails to meet this strictly health-based standard, it cannot be used on food and registrations for such uses must be canceled.

II. EPA AND ITS SCIENTIFIC ADVISORY PANEL FOUND CHLORPYRIFOS HARMS CHILDREN AT EXPOSURES BELOW EPA'S TOLERANCES.

Chlorpyrifos is an organophosphate, a class of chemicals developed as nerve agents in World War II and later adapted for commercial pesticide use. Organophosphates cause acute poisonings by suppressing an enzyme called cholinesterase that is essential to proper nervous system functioning. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, dizziness, difficulty breathing, vomiting, diarrhea, muscle spasms, rashes, and, at very high exposures, convulsions, respiratory paralysis, and even death.

The FQPA directed EPA to re-register older pesticides within ten years to ensure they comply with the upgraded food safety standards. EPA prioritized the reevaluation of the organophosphates because of their neurotoxicity and prevalence on foods children eat. In 2000, EPA ended chlorpyrifos use in and around homes, schools, parks, and hospitals because of acute poisoning risks to children. 65 Fed.

Reg. 76,233 (Dec. 6, 2000); 66 Fed. Reg. 47,481 (Sept. 12, 2001). In 2006, EPA re-registered dozens of food uses of chlorpyrifos. AR 20. EPA based its safety determinations on a regulatory limit of 10% reduction of cholinesterase in red blood cells, which is believed not to cause acute poisonings, although acute poisonings continued to happen every year. 86 Fed. Reg. at 48,318-19, 48,325; 87 Fed. Reg. at 11,231-33.

Amici's 2007 petition asked EPA to ban chlorpyrifos on food based on published, peer-reviewed studies correlating low-level prenatal exposures with a significantly elevated risk of autism, attention deficit disorders, and reduced IQ. Upon reviewing the science, EPA and its SAP, established to provide peer review on pesticide matters, repeatedly found neurodevelopmental harm from prenatal exposures to chlorpyrifos at levels far below those causing 10% cholinesterase inhibition. 86 Fed. Reg. at 48,321, 48,324-25; 87 Fed. Reg. at 11,232, 11,234-35.

EPA's 2014 revised human health risk assessment found exposures to chlorpyrifos below levels that produce 10% cholinesterase inhibition cause permanent neurodevelopmental harm to children. 2014 Assessment at 26, 48-49 (AR 25). EPA retained the FQPA tenfold safety factor to protect children because of this harm, but it continued to use 10% cholinesterase inhibition as its regulatory endpoint. EPA found chlorpyrifos uses would result in exposures that exceed EPA's drinking water levels of concern. AR 25 at 11; *LULAC*, 996 F.3d at 685.

In 2015, EPA proposed revoking all chlorpyrifos tolerances because it could not find chlorpyrifos safe. 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015). EPA indicated it would try to derive an exposure level that would protect children from neurodevelopmental harm and to refine its drinking water assessment. *Id*. at 69,080, 69,085, 69,104, 69,106.

EPA updated its risk assessment in 2016 by deriving an exposure level that would prevent learning disabilities to children, based on the methodology recommended by the SAP. 86 Fed. Reg. at 48,319, 48,321; 87 Fed. Reg. at 11,235. The update found chlorpyrifos unsafe every way people are exposed. 87 Fed. Reg. at 11,233 (food and drinking water). Food-only exposures for chlorpyrifos were unsafe for all populations, with young children ages 1-2 facing risks more than 14,000% of safe levels in food, *LULAC*, 996 F.3d at 687-89, and drinking water exposures exceeding safe levels. 87 Fed. Reg. at 11,237, 11,249, 11,257.

III. EPA'S 2020 PROPOSED INTERIM REGISTRATION REVIEW DECISION.

EPA's 2017 Order denying the 2007 petition and its 2019 Order denying objections did not make a safety determination. Instead, EPA put off making a safety finding until completion of the chlorpyrifos registration review, a statutorily mandated process to ensure older pesticides meet applicable legal standards, which does not need to be completed for chlorpyrifos until October 1, 2022. 86 Fed. Reg. at 48,319; *see* 7 U.S.C. § 136a(g)(1)(A)(i), (iii)(II). *LULAC* vacated these orders

and directed EPA to grant the petition and issue a tolerance revocation rule by the end of August 2021.

In December 2020, before the *LULAC* decision, EPA released for public comment a revised human health risk assessment incorporating another refined drinking water assessment, along with a proposed interim registration review decision concluding that aggregate exposures from currently registered chlorpyrifos uses are unsafe. 2020 Chlorpyrifos Proposed Interim Registration Review Decision ("PID") at 19 (AR 40). The 2020 proposal and assessment used 10% cholinesterase inhibition as the regulatory endpoint, even though its more protective 2016 risk assessment and a California risk assessment had both found chlorpyrifos unsafe for children at lower exposures.

The 2020 proposal is based, in part, on a new drinking water assessment suggesting 11 chlorpyrifos uses might not exceed EPA's level of concern if used in only limited geographies and subject to substantial usage restrictions. https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941. The drinking water assessment used a new model, despite peer review criticisms and monitoring documenting impermissible chlorpyrifos concentrations. Because EPA's proposed findings as to the 11 uses were limited to specific watersheds, for example use on cherries and asparagus only in Michigan, EPA proposed to cancel registrations for everywhere else and to reduce application rates to align with usage predicted in the

assessment. As required by EPA regulations, EPA solicited public comment on the assessments and proposal, which it must address before issuing a final decision. 40 C.F.R. § 155.58.

IV. THE NINTH CIRCUIT HELD EPA CANNOT FIND CURRENT CHLORPYRIFOS SAFE, LEADING TO REVOCATION OF ALL CHLORPYRIFOS TOLERANCES.

In April 2021, the Ninth Circuit held EPA could not lawfully deny the 2007 petition and leave chlorpyrifos tolerances in place without finding there would be a reasonable certainty of no harm to children. 996 F.3d at 693-94. The court further held EPA could not find chlorpyrifos safe in light of the EPA and SAP findings of harm to children from low-level chlorpyrifos exposures and therefore must revoke tolerances. *Id*. at 686-88, 700-01.

LULAC ordered EPA to grant the 2007 Petition and issue a final rule revoking all chlorpyrifos tolerances or possibly retaining some tolerances if it could find the modified tolerances safe, in the aggregate, for infants and children. *Id*. at 703-04. Echoing earlier Ninth Circuit cases, the court gave EPA an August 2021 deadline to stop the "egregious delay" that "exposed a generation of American children to unsafe levels of chlorpyrifos." *Id*. at 703. To comply, EPA issued the Revocation Rule.

ARGUMENT

This Court should reject Petitioners' challenge. EPA appropriately revoked all chlorpyrifos tolerances because it could not find aggregate exposures to chlorpyrifos safe based on current tolerances. EPA could not base tolerance decisions on the 2020 proposal without correcting the proposal's fundamental flaws documented in public comments and confirmed by *LULAC*.

I. EPA APPROPRIATELY REVOKED ALL CHLORPYRIFOS TOLERANCES BECAUSE IT COULD NOT FIND AGGREGATE CHLORPYRIFOS EXPOSURES SAFE.

In overhauling our food safety laws, Congress put children's health first, prohibiting pesticides on food unless EPA can affirmatively find reasonable certainty of no harm to children from all aggregate exposures. The 1993 NAS Report used chlorpyrifos as a case study to show why aggregate exposures from all foods must be considered, pointing to chlorpyrifos' prevalence in many foods eaten by children and emerging scientific evidence of developmental harm to children. NAS Report at 60-66, 297-307, 318-19. Under the statutory mandates, revocation of chlorpyrifos tolerances became inevitable, albeit delayed for far too long.

The FFDCA dictates how EPA must assess aggregate dietary exposures by making it clear they include dietary exposures from all tolerances in effect for the pesticide. 21 U.S.C. § 346a(b)(2)(D)(vi). While EPA sets a tolerance for each

food individually, it must base its safety determination on all aggregated exposures, *i.e.,* it cannot establish a tolerance for an individual food if it cannot find all aggregate exposures safe.

EPA uses the concept of a "risk cup" to reflect the maximum total exposure an individual can receive without being at risk of developing unacceptable adverse health effects. Exposures exceeding this level are unsafe and impermissible. If the risk cup is full, no new uses can be approved without reducing other exposures. 86 Fed. Reg. at 48,329, 48,332; 87 Fed. Reg. at 11,228-29. And if it is overflowing, as in the case of chlorpyrifos, EPA must revoke tolerances. In this respect, chlorpyrifos differs from the regulatory actions cited by Petitioners and CropLife, where the risk cup was not full, leaving room for new or modified tolerances. Petitioners' Brief at 46-47; CropLife Brief at 12. Rather than establish a new practice, EPA acted in conformance with the law, its past practices, and *LULAC* by revoking all chlorpyrifos tolerances because it could not find aggregate exposures to chlorpyrifos safe. *See* 76 Fed. Reg. 3,421-22 (Jan. 19, 2011) (EPA could not establish new tolerances for sulfluryl fluoride because of unsafe aggregate exposures); 74 Fed. Reg. 23,045-46 (May 15, 2009) (EPA revoked carbofuran tolerances because aggregate exposures were unsafe).

Contrary to Petitioners' argument, Congress's direction to coordinate tolerance revocations and FIFRA cancellations "[t]o the extent practicable," 21

U.S.C. § 346a(l), does not eviscerate the reasonable-certainty-of-no-harm food safety standard. EPA acted in conformity with this direction by revoking chlorpyrifos tolerances because they are unsafe and committing to thereafter cancel the associated registrations.

This Court must reject Petitioners' request to vacate the tolerance revocation rule in its entirety. Petitioners' Brief at 61. Vacatur would reinstate all chlorpyrifos tolerances, exposing children to impermissible risks of learning disabilities that take their toll on children, families, and communities. An order reinstating chlorpyrifos tolerances would violate our food safety laws and impede the action dictated by the Ninth Circuit after exhaustive consideration of the merits, counter to principles of judicial comity. *See Mann Mfg., Inc. v. Hortex, Inc.*, 439 F.2d 403, 407-08 (5th Cir. 1971) (courts avoid "serious interference with or usurpation of" another court's "continuing power" to supervise and modify injunctive relief); *Lapin v. Shulton, Inc*., 333 F.2d 169, 172 (9th Cir. 1964) (same).

II. EPA COULD NOT LAWFULLY CONVERT THE PROPOSED INTERIM REGISTRATION REVIEW DECISION INTO TOLERANCES.

Petitioners contend EPA acted arbitrarily and capriciously by not converting a 2020 proposed interim registration review decision into tolerances decisions. Petitioners are mistaken because the proposal: (1) is predicated on revamping chlorpyrifos registrations and labels to impose geographic and usage limitations,

which has not happened; (2) uses the same regulatory endpoint *LULAC* deemed under-protective of children; and (3) is merely a proposal that received extensive, critical public comments that EPA must address and that would preclude finalizing the proposal.

A. The 2020 Proposal Reflects a Fictional World That Requires Registration Cancellations and Label Changes to Become a Reality.

Petitioners argue EPA erred by not retaining tolerances for 11 uses the 2020 proposal indicated might be safe if revised labels limited chlorpyrifos use to only one crop in a watershed and imposed substantial usage restrictions. 86 Fed. Reg. at 48,322, 48,333; 87 Fed. Reg. at 11,234, 11,244. For each of those preconditions to become a reality, EPA would need to cancel dozens of chlorpyrifos registrations and conform chlorpyrifos labels to new geographic and usage limitations, which has not happened. It is the FIFRA registration and label that establishes the conditions under which a pesticide may lawfully be used, while a tolerance allows a food to be sold, imported, and move through commerce, regardless of where or how the food is grown. Without changes to chlorpyrifos registrations and labels, the 2020 proposal depicts a fictional world, not the real-world harms that will result from lawful chlorpyrifos uses.[2]

[2] EPA published a notice in the Federal Register of 16 voluntary cancellation requests from various registrants, but none from Petitioner Gharda. 87 Fed. Reg. 25,256 (April 28, 2022), in https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0223. Gharda has not made good on what it asserts (at 28, 52) was a firm

Moreover, EPA's proposed interim registration review decision for chlorpyrifos was, as its title indicates, just a proposal, subject to change before being finalized. 85 Fed. Reg. 78,849 (Dec. 7, 2020). FIFRA provides for registration review of a pesticide every 15 years to ensure "each pesticide registration continues to satisfy the FIFRA standard for registration" in light of emerging scientific information. 40 C.F.R. § 155.40(a); *see also* 40 C.F.R. § 155.53(a). EPA has the authority to issue an interim registration review decision to obtain risk mitigation measures and additional information before all aspects of the registration review can be completed. 40 C.F.R. § 155.56; *e.g.*, *NRDC v. EPA*, Nos. 20-70787, 20-70801, 2022 WL 2184936, at *3 (9th Cir., June 17, 2022).

Petitioners argue (at 57) the proposal was final when proposed in December 2020, except for EPA's compliance with the ESA and implementation of endocrine disruption screening. Petitioners are wrong. They confuse the proposal's preliminary status as a proposal with the fact it will lead to an interim, not a final, registration review decision. The proposed decision explains (at 4), when finalized, that it will be an interim decision and require risk mitigation for aspects

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commitment to conform its registrations and labels to the 2020 proposal. CropLife's Brief (at 9) cites the notice's boilerplate language that EPA had identified no risks of concern associated with the pesticide products subject to the notice, but that statement is decidedly not true for chlorpyrifos, as *Amici* pointed out in comments at https://www.regulations.gov/comment/EPA-HQ-OPP-2022-0223-0009.

of the chlorpyrifos registration review that can be completed, even though it will take additional time to comply with the ESA and endocrine disruption screening, which must be complete before a final registration review decision can be made.

When the interim decision is finalized, registrants will need to submit revised labels conforming to the decision and voluntarily cancel noncompliant registrations or be subject to involuntary cancellation proceedings initiated by EPA. Even if EPA could find any of the 11 uses safe, which it could not for the reasons below, it could not do so unless the registrations and labels incorporated geographic and usage limitations to reduce drinking water contamination. EPA would also need to finalize proposed protections to ensure workers will not face unreasonable adverse effects from exposure to chlorpyrifos, including from the 11 uses. *See, e.g.*, PID at 42-49, 55-59, 64-79, 85-106. While an essential step in the registration review process, EPA has many more steps to take, including addressing public comments, before it can adopt and implement any registration review decisions.

B. *LULAC* Precludes Basing Chlorpyrifos Tolerances on the Regulatory Endpoint Used in the 2020 Proposal.

The 2020 proposal, like the 2014 risk assessment and its 2006 predecessor, used 10% cholinesterase inhibition as the regulatory endpoint derived to avoid acute poisonings. However, EPA "has, since [2006], 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." *LULAC*, 996 F.3d at 697. And EPA and the SAP have repeatedly found this harm to children occurs at exposures below those that cause 10% cholinesterase inhibition. *Id*. at 686-88, 701.

For this reason, *LULAC* deemed the 10% cholinesterase inhibition endpoint inadequate to ensure children would be protected from learning disabilities. Specifically, the court stated: "EPA must determine the greatest exposure amount that poses no risk of harm" to children and must ensure children will not be exposed to higher levels of chlorpyrifos. *Id*. at 680. Based on unbroken EPA and SAP findings that chlorpyrifos harms children's brains at exposures below those associated with 10% cholinesterase inhibition, the court concluded:

> On the present record, the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA. The EPA can find a tolerance safe only if there is "a reasonable certainty" of "no harm," and for nearly a decade, the EPA and its SAPs have concluded that there is *not* a reasonable certainty of no harm[.]

Id. at 700 (emphasis added); *see also id.* at 701 ("EPA has not determined, and on this record reasonably could not determine to a 'reasonable certainty' that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm.").

Acknowledging the 2020 proposal, the Ninth Circuit stated: "If … 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. But *LULAC* made it clear EPA had to use a regulatory endpoint that would prevent neurodevelopmental harm to children.

As CropLife rightfully acknowledges, chlorpyrifos is *sui generis* because of the *LULAC* decision, but not because of the deadline the court gave EPA or what CropLife calls "an administrative sequencing problem." CropLife Brief at 11, 18. Chlorpyrifos is *sui generis* because *LULAC* held EPA cannot retain tolerances without affirmatively finding all exposures in the aggregate safe, which EPA cannot do.

C. EPA Had to Address Public Comments Before Finalizing and Implementing the 2020 Proposal.

The EPA could not just take the 2020 proposal off the shelf and convert it into tolerance decisions because the proposal garnered extensive critical comments that EPA has a legal duty to address before it finalizes the 2020 proposal (and which almost certainly would cause EPA to abandon the proposal embraced by Petitioners). EPA regulations establish the notice and comment procedures for the pesticide registration review process. 40 C.F.R. §§ 155.56, 155.58. These regulations require that EPA solicit public comments on proposed registration review decisions and underlying risk assessments and address significant comments in the ultimate decision.

Adhering to these regulations, EPA solicited public comment on the 2020 chlorpyrifos proposal and risk assessment. EPA acknowledges it must address the comments before making a final decision. 86 Fed. Reg. 48,315, 48,334; 87 Fed. Reg. 11,234, 11,244-45. This acknowledgement is in keeping with well-settled administrative law principles that agencies must "consider and respond to significant comments received" during the public comment period. *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015); *see also* 5 U.S.C. § 553(c) (agency must consider relevant matter presented in the public comment period and incorporate its response in its justification for the final rule).

EPA received comments calling into question whether using the 10% cholinesterase inhibition endpoint would protect children and identifying flaws in the drinking water assessment. *See infra* at 22-27. These consequential comments, if adopted by EPA, would fundamentally change the outcome of the proposal. EPA must abide by its regulation and respond to these significant comments before finalizing or implementing the proposal. *See NRDC v. EPA*, 676 F. Supp. 2d 307 (S.D.N.Y. 2009) (vacating EPA pesticide registration because EPA violated notice-and-comment requirements); *see also City of Portland, Oregon v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (agency must address comments that would change the decision). EPA has yet to fulfill its legal duty to address these public comments and therefore could not convert the 2020 proposal in final tolerance decisions.

1. *Public Comments Show the 2020 Proposal and Risk Assessment Do Not Protect Children from Neurodevelopmental Harm.*

EPA's 2020 risk assessment indicates the agency's historical practice of basing safety findings on 10% cholinesterase inhibition "may not be protective of neurodevelopmental outcomes." PID at 84; *see also id.* at 86, 88 (epidemiology and toxicology studies find adverse outcomes at lower chlorpyrifos exposures). Public comments emphasized EPA must prevent exposures below this level to protect children from neurodevelopmental harm.

Fifty leading scientists and health professionals presented compelling evidence that "prenatal exposure at low levels is putting children at risk for cognitive and behavioral deficits and for neurodevelopmental disorders." Comments at 1 (https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-1008/attachment_1.pdf). The scientists explained that reliance on cholinesterase inhibition "obscures the serious threat that chlorpyrifos poses to early brain development and represents an unscientific and inadequate approach. *Id*. at 2. Nearly two dozen academic scientists likewise cited published scientific research documenting neurodevelopmental harm from prenatal exposures too low to cause cholinesterase inhibition. Comments at 1-5 (https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-1036/attachment_1.pdf).

Amici's comments and objections explain that using 10% cholinesterase inhibition as the regulatory endpoint is under-protective and foreclosed by *LULAC*. https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1107; AR 74. In deciding the objections, EPA did not address these arguments because it was leaving no tolerances in place, but it committed to do so before making registration review decisions or considering future petitions for new chlorpyrifos tolerances. 87 Fed. Reg. at 11,270-71.

Nine states criticized EPA for reverting to an under-protective endpoint that is "manifestly insufficient" given "the body of evidence demonstrating that adverse brain impacts occur at much lower exposure levels of chlorpyrifos than those that cause 10% [cholinesterase] inhibition." States Comments at 2, 15-16 (https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077). The California Department of Pesticide Regulation ("CDPR") explained that EPA's 2020 risk assessment "does not adequately protect against the potentially profound and debilitating human health effects of exposure to this pesticide." CDPR Comments at 1 (https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1067). CDPR described its comprehensive scientific evaluation finding chlorpyrifos is a neurodevelopmental toxicant, which led to cancellation of almost all chlorpyrifos

uses in California by December 31, 2020. *Id*.[3] Using recent low-dose animal studies, CDPR derived a limit to protect children that is far lower than the 10% cholinesterase inhibition limit used in EPA's 2020 assessment. *Id*. at 9-10. Because developmental toxicity is the most sensitive endpoint, resulting from exposures below those that cause 10% cholinesterase inhibition, CDPR concluded EPA's 2020 risk assessment "is not sufficiently health protective." *Id*. at 9-10.

The court's rationale in *LULAC* adopted the substance of these comments. Indeed, *LULAC* held EPA could not find "reasonable certainty of no harm" because exposures below EPA's regulatory endpoint cause neurodevelopmental harm to children. 996 F.3d at 700. EPA could not validly rely on the 2020 proposal because it conflicts with *LULAC* and EPA has yet to address the many comments making the same arguments *LULAC* adopted.

Not only do EPA regulations require it to address these public comments before finalizing the 2020 proposal, but the comments present precisely the type of "available information" EPA has a statutory obligation to consider in addressing food risks. 21 U.S.C. § 346a(b)(2)(C)(i)(II); 21 U.S.C. § 346a(b)(2)(D). While FIFRA establishes the registration review process, registration review must determine whether a pesticide satisfies all legal standards, including the

[3] Several other states have also adopted chlorpyrifos bans, as have many countries. States Comments at 21-27.

reasonable-certainty-of-no-harm food safety standard incorporated into FIFRA. 7 U.S.C. § 136(bb). In determining whether a pesticide satisfies the food safety standard, EPA has a statutory duty to consider "available information … concerning the special susceptibility of infants and children to the pesticide chemical residues, including … neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." 21 U.S.C. § 346a(b)(2)(C)(i)(II). The comments raise serious concerns about children's special sensitivities to chlorpyrifos, particularly to neurodevelopmental harm from in utero exposures. EPA could not implement the 2020 proposal without considering all available information regarding such effects, which go to the heart of whether it could find reasonable certainty of no harm to children. *See Cigar Assoc. of Am. v. U.S. FDA*, 964 F. 3d 56, 63 (D.C. Cir. 2020) (EPA must address significant comments in explaining the basis for a final rule); *United Food & Com. Workers Union, Loc. No. 663 v. Dep't of Agric.*, 532 F. Supp. 3d 741, 773, 776 (D. Minn. 2021) (agency's dismissal of comments addressing worker safety concerns was "not merely a technicality" but had "wide-reaching implications" on worker safety the agency had to address).

2. Public Comments Exposed Critical Flaws in the 2020 Drinking Water Assessment.

The 2020 drinking water assessment used new modeling that has never been applied in EPA's pesticide risk assessments before or since. 87 Fed. Reg. at

11,228, 11,254. An EPA SAP peer review of the new model found it had inadequate sample sizes and recommended the model be based on 30 samples per year, but the 2020 drinking water assessment required only 13 samples per year and repeatedly noted low sample frequencies in almost all watersheds and likely underestimated chlorpyrifos concentrations. SAP Review at 13, 58-61, 76-77 (AR 13); 2020 Drinking Water Assessment at 44, 77-80 (AR 38). Even more troubling, monitoring data documented numerous exceedances of EPA's drinking water levels of concern, even where the model predicted no exceedances. AR 38 at 9, 12, 15, 41, 76, 81.

Public comments criticized the drinking water assessment because, in addition to using the under-protective 10% cholinesterase inhibition endpoint, EPA had not changed the new model to address the external peer review's concerns about the small sample sizes or monitoring data. LULAC Comments at 36-37. The comments flagged the fact that monitoring documented real-world drinking water contamination as a particular concern:

> EPA's new drinking water modeling is also flawed because it underestimates exposures. . . . EPA acknowledged that real-world water monitoring has detected chlorpyrifos at levels above EPA's drinking water levels of concern. . . . It also noted that drinking water levels of concern might be exceeded if chlorpyrifos is used on more than one crop in the watershed.

Id. at 9; *see also id*. at 36-41.

EPA could not finalize the 2020 proposal until it addressed these comments, just as it had to address the holdings in *LULAC*. The flaws documented in the comments go to the heart of whether aggregate exposures to chlorpyrifos are safe and, if adopted, would preclude all tolerances for chlorpyrifos on any crops anywhere in the country. EPA could not base its tolerance decisions on that proposal and appropriately revoked chlorpyrifos tolerances because it could not find aggregate exposures under current tolerances safe.

CONCLUSION

The Court should uphold the Revocation Rule and objections denial.

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Respectfully Submitted,

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Pineros y Campesinos Unidos del Noroeste, United Farm Workers, and United Farm Workers Foundation

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(5) and 27(d)(2), the undersigned certifies that this brief complies with the applicable type-volume limitations and that, exclusive of the parts exempted by Federal Rule of Appellate Procedure 32(f), this motion contains 5,788 words. This certificate was prepared in reliance on the word count of the word processing system (Microsoft Word) used to prepare this brief. The undersigned also certifies pursuant to Eighth Circuit Local Rule 28A(h)(2) that the electronic copy of the brief has been scanned for viruses and the electronic copy of the brief is virus free.

Dated: July 29, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on this date, the foregoing BRIEF OF AMICI CURIAE IN SUPPORT OF RESPONDENTS was filed with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit via the Court's CM/ECF system and served on all parties of record.

Dated: July 29, 2022.

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