February 10, 2025

Re: Chlorpyrifos: Tolerance Revocation (EPA-HQ-OPP-2024-0431)

Dear Director Messina:

The Attorneys General of New York, California, Hawaii, Maryland, Massachusetts, Oregon, Vermont, Washington, and Washington, D.C. submit these comments on the U.S. Environmental Protection Agency's (EPA or Agency) proposed rule Chlorpyrifos: Tolerance Revocation (Proposed Rule), 89 Fed. Reg. 99184 (Dec. 10, 2024). In the Proposed Rule, EPA proposes to revoke all tolerances for residues of the organophosphate pesticide chlorpyrifos except those associated with its use on 11 crops—alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and wheat—and, with respect to those 11 crops, purports to make a determination of safety supporting the tolerances that are not revoked.[1]

For the past two decades, the signatory States have worked hard to address the harms from human exposure to chlorpyrifos, including by engaging the federal government through comments pursuant to the FFDCA and FIFRA, requesting that EPA ban chlorpyrifos.[2] While States have authority to regulate the application of pesticides to crops within their borders under FIFRA, 7 U.S.C. § 136v, because of the extensive national and international markets for food, any such regulation of chlorpyrifos's use cannot protect our residents from potentially dangerous exposures to chlorpyrifos residues on food.

Now, consistent with our longstanding efforts to press EPA to revoke all tolerances for chlorpyrifos on food and considering the ever-growing body of scientific evidence against a safety finding, as well as the Ninth Circuit Court of Appeals' decision in *League of Latin American Citizens v. EPA*, 996 F.3d 673 (9th Cir. 2021) ordering EPA to either revoke all chlorpyrifos tolerances or modify chlorpyrifos tolerances based on adequately protective

[1] To allow a pesticide to be used on food, EPA must comply with both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136f(f).

[2] *See e.g.*, Attorney General of New York's 2002 Supplement to 1999 and 2000 Comments on the Chlorpyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision; Docket Control Number OPP-34203G, (Jan. 30, 2002); *see also* Objections of the States of New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont to EPA's March 29, 2017 Order Denying Petition to Revoke Tolerances for Chlorpyrifos and Leaving Tolerances in Effect (June 5, 2017) at 2-3, Doc. ID EPA-HQ-OPP-2007-1005-0522, *available at* https://ag.ny.gov/sites/default/files/2017_06_05_objections_final.pdf; Multistate Comments on EPA's to 2021 Proposed Interim Decision, Revised Draft Human Health Risk Assessment, and Ecological Risk Assessment for Chlorpyrifos (Mar. 12, 2021) (Multistate Comments to 2021 PID and HH DRA), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077.

regulatory endpoints and a concomitantly issued safety finding, the undersigned States urge EPA to revoke all chlorpyrifos tolerances. Here, the proposed finding of safety for the 11 tolerances is based on an insufficiently protective regulatory endpoint and does not sufficiently consider reliable, available data, including previous critical comments by the undersigned and others. Accordingly, the Proposed Rule does not meet EPA's statutory mandates and should not be finalized with the current tolerance exceptions.

I. Legal Background and Standard for Chemical Residue Tolerance Review

Under the FFDCA, food containing "any pesticide chemical residue" shall, in the absence of a tolerance or exemption, be "deemed unsafe,"[3] adulterated,[4] and therefore barred from interstate commerce.[5] The FFDCA grants EPA limited authority to promulgate pesticide tolerances for both raw agricultural commodities and processed foods.[6] 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.[7] When a tolerance is in effect, a food containing pesticide residues within that tolerance can move in interstate commerce.[8]

The FFDCA generally provides that food containing pesticide residue is considered to be unsafe and is prohibited.[9] Since its amendment by the Food Quality Protection Act of 1996 (FQPA),[10] 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."[11] 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."[12] In determining allowable levels of pesticide

[3] 21 U.S.C. § 346a(a)(1).

[4] 21 U.S.C. § 342(a)(2)(B).

[5] *See* 21 U.S.C. §331(a)-(c).

[6] 21 U.S.C. § 346a(b).

[7] 21 U.S.C. § 346a(b)(1).

[8] *See* 21 U.S.C. § 346a(a)(4).

[9] 21 U.S.C. §§ 331, 342(a)(2)(B), 346a(a)(1).

[10] Pub. L. No. 104-70 (1996).

[11] 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added).

[12] 21 U.S.C. § 346a(b)(2)(A)(ii).

residues in food, EPA must, among other things, perform a comprehensive assessment of each pesticide's risks, considering: aggregate exposure (such as from food, drinking water, worker and bystander exposure and residential uses); cumulative effects from all pesticides sharing a common mechanism of toxicity; possible increased susceptibility of infants and children; and possible endocrine or estrogenic effects.[13]

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.[14] 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.[15] 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.[16]

Thus, when "leaving in effect" a tolerance for a pesticide on food, 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."[17] Additionally, EPA must "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." The 1996 amendments to the FFDCA further set a schedule for EPA to review existing tolerances to ensure they met the statute's additional safety standard, requiring the completion of all such review by 2006.[18]

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.[19] If EPA cannot find existing tolerances safe, it is required to revoke them,[20] and also "[t]o the extent practicable" to

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[13] 21 U.S.C. § 346a(b)(2)(D).

[14] 21 U.S.C. § 346a(b)(2)(C)(i).

[15] 21 U.S.C. § 346a(b)(2)(C)(ii).

[16] *Id.*

[17] *Id.*

[18] 21 U.S.C. § 346a(q)(1)(C).

[19] 21 U.S.C. § 346a(b)(2)(D).

[20] 21 U.S.C. §§ 346a(b)(2)(A)(i)

coordinate the revocation with "any related necessary action" under FIFRA, such as cancelling the pesticide's registration.[21]

Separately, under FIFRA, every pesticide distributed or sold in the United States must be registered by EPA (with limited exceptions).[22] "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used."[23] The purpose of the registration process is to protect public health and the environment.[24] FIFRA requires EPA to review pesticide registrations at least every fifteen years to "assess any changes that may have occurred since EPA's last registration decision" and "determine . . . whether the insecticide still satisfies the FIFRA standard for registration."[25] 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, 2026.[26] When reviewing a registration, EPA must determine that the pesticide will not cause "unreasonable adverse effects on the environment."[27] These effects are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any insecticide, or (2) a human dietary risk . . . inconsistent with [federal standards]."[28]

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[21] 21 U.S.C. § 346a(l)(1).

[22] *See* 7 U.S.C. § 136a(a): "[n]o person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter." Insecticides are a class of pesticides used specifically to target, manage, and kill insects. See id. § 136 (defining "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer," with certain exceptions not applicable here).

[23] *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

[24] S. Rep. No. 92-838 (1972), reprinted in 1972 U.S.C.C.A.N. 3993, 3993.

[25] 40 C.F.R. § 155.53(a); *see also id.* § 155.40(a)(1) ("Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment."); *see also* 7 U.S.C. § 136a(g)(1)(A).

[26] The FFDCA set the original deadline for October 1, 2022, but Congress later extended the deadline. 7 U.S.C. § 136a(g)(1)(A); Pub. L. 117-328, div. HH, title VIT, § 711, Dec. 29, 2022, 136 Stat. 6083.

[27] 7 U.S.C. § 136a(c)(5)(C)-(D).

[28] 7 U.S.C. § 136(bb).

II. Low Dose Chlorpyrifos Exposure in Children Causes Serious, Irreparable Damage

Chlorpyrifos is an organophosphate pesticide, a class of chemical poisons that also includes nerve gas, used to control a wide range of insects. After approval for use as a pesticide in the United States in 1965, chlorpyrifos quickly became one of the most widely used pesticides in the country. EPA is now proposing to retain chlorpyrifos tolerances for 11 crops, including the following food crops: apple, asparagus, tart cherry, citrus, peach, soybean, strawberry, sugar beet and wheat. In recent years, the United States Department of Agriculture has not tested most of the food crops with currently-proposed food tolerances for chlorpyrifos.

Chlorpyrifos is a powerful neurotoxicant, adversely affecting the functioning of the human nervous system and developing brain. It is well known that chlorpyrifos binds to and inhibits acetylcholinesterase (AChE), an enzyme critical to normal neurological functioning and early-life stage neurological development.[29] AChE breaks down the primary neurotransmitter of the parasympathetic nervous system, acetylcholine. Higher levels of chlorpyrifos exposure can lead to a dangerous accumulation of acetylcholine, causing the nervous system to be overstimulated. Symptoms of acute chlorpyrifos poisoning include nausea, dizziness, confusion, respiratory paralysis, and death.[30] Researchers, however, understand that using AChE inhibition– a measurement of acute poisoning–is an inadequate and unprotective measurement of harm from very low dose exposure to chlorpyrifos, doses much lower than those that cause poisoning.[31]

Low level, pervasive exposures to chlorpyrifos are of great concern. The developing brains of fetuses, infants and small children are "uniquely vulnerable to toxic chemical exposures."[32] Lower doses of chlorpyrifos exposure, including doses so low they do not cause measurable AChE inhibition, can cause adverse neurodevelopmental effects during gestation and early infant development. These early neurodevelopmental effects are long-term and can be irreversible and lifelong.[33] Pre-natal exposure to very low doses of chlorpyrifos has been

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[29] *See* FIFRA Scientific Advisory Panel Meeting, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos: Analysis of Biomonitoring Data* (Apr. 19-21, 2016) at 10 and 28, Doc. ID EPA-HQ-OPP-2016-0062.

[31] *See* EPA Office of Pesticide Programs, *Interim Reregistration Eligibility Decision for Chlorpyrifos* (Feb. 2002) at 2, Doc. ID EPA 738-R-01-007.

[31] *See* Rahman et al., *A comprehensive review on chlorpyrifos toxicity with special reference to endocrine disruption: Evidence of mechanisms, exposures, and mitigation strategies*, Sci. Total Env't 755 (2021).

[32] Grandjean & Landrigan, *Neurobehavioural effects of developmental toxicity*, 13 Lancet Neurology 330-338 (2014).

[33] *See* Rauh et al., *Prenatal Exposure to the Organophosphate Pesticide Chlorpyrifos and Childhood Tremor*, 51 Science 80-86 (2015).

associated with lower birth weight and adverse neurodevelopmental effects on children.[34] Early childhood low-level exposure is also associated with decreased pulmonary function and may result in chronic respiratory disease.[35] Epidemiologic results from low-dose exposure are consistent with results from toxicological studies performed on laboratory animals, which found adverse cognitive changes in test animals following low-dose perinatal chlorpyrifos exposure.[36]

III. States' Interests

States have unique sovereign interests and act as *parens patriae* for millions of residents who are potentially exposed to unsafe levels of chlorpyrifos. States have an interest in ensuring that their residents are afforded the benefits and protections of federal pesticide safety standards through the strict enforcement of those standards.

States also have a related interest in ensuring that health care and other associated costs within their jurisdictions do not increase because of the adverse health effects that may be caused by continued exposure to chlorpyrifos residues at levels that are not safe. The signatory States have made significant efforts to prevent chlorpyrifos from causing unreasonable risks to human health or the environment, including acting to ensure chlorpyrifos does not present risks to humans from the pesticide's use on food. Beginning as early as 1999, States have submitted many comments in EPA's pesticide re-registration dockets, strongly urging EPA to ban all uses of chlorpyrifos.[37] Most recently, the undersigned attorneys general submitted comments critical

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[34] Rauh et al., *Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children*, 118 Pediatrics e1845-e1859 (2006); *see also* Perera et al., *A Summary of Recent Findings on Birth Outcomes and Developmental Effects of Prenatal ETS, PAH, and Pesticide Exposures*, 26 Neurotoxicology 573-87 (2005); Rauh et al., *Prenatal Exposure to the Organophosphate Pesticide Chlorpyrifos and Childhood Tremor*, 51 Neurotoxicology 80-86 (2015); Rauh et al., *Brain Anomalies in Children Exposed Prenatally to a Common Organophosphate Pesticide*, 109 PNAS 7871-76 (2012).

[35] *See* Raanan et al., *Decreased Lung Function in 7-Year-Old Children With Early-Life Organophosphate Exposure*, 71 Thorax 148-53 (2015).

[36] *See* Levin et al., *Persistent behavioral consequences of neonatal chlorpyrifos exposure in rats*, 130 Brain Res. Dev. Brain Res. 83-89 (2001); Slotkin & Seidler, *The alterations in CNS serotonergic mechanisms caused by neonatal chlorpyrifos exposure are permanent*, 158 Brain Res. Dev. Brain Res. 115-119 (2005); Aldridge et al., *Developmental exposure of rats to chlorpyrifos leads to behavioral alterations in adulthood, involving serotonergic mechanisms and resembling animal models of depression*, 113 Envtl. Health Perspectives 527-531 (2005); CDPR, *Final Toxic Air Contaminant Evaluation for Chlorpyrifos: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders* (July 2018), available at https://www.cdpr.ca.gov/docs/whs/pdf/chlorpyrifos_final_tac.pdf, at Section II.I.

[37] *See, e.g.,* Attorney General of New York's 2002 Supplement to 1999 and 2000 Comments on the *Chlopyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision*, Docket Control Number OPP-34203G (Jan. 30, 2002).

of EPA's 2020 *Chlorpyrifos Proposed Interim Decision* (2020 PID) and its 2020 *Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review* (2020 HH DRA), raising concerns about EPA's regulatory endpoint and its assessment of the available scientific data.[38] Despite having these latest comments for nearly four years, EPA has yet to respond. In 2017, a multistate coalition intervened in support of a lawsuit before the Court of Appeals for the Ninth Circuit challenging EPA's denial of a petition to revoke all food tolerances for chlorpyrifos.[39]

Given EPA's failure to act on the federal level, in 2018, States began banning or phasing out chlorpyrifos from use due to their concerns for children's health and worker safety. Five States have passed legislation or taken administrative action to ban or phase out chlorpyrifos for any application, while at least another eight States have state legislation under recent consideration.[40] That multiple States – including the most productive agricultural state in the country (California) – have successfully banned chlorpyrifos directly contradicts any claims that the pesticide is critical to pest control and growers' economic liability. Even with these State bans, State residents remain vulnerable to harmful exposure through consumption of food from States in which chlorpyrifos is still allowed.

Despite these efforts, the States and their residents will continue to incur costs associated with chlorpyrifos exposure as long as unsafe tolerances remain in effect. Very low levels of pre-natal exposure to organophosphate pesticides can reduce cognitive ability (lowered IQ), cause poorer working memory, delays in motor development, hand tremors as the children reach school age, and changes in brain structure when children reach ages 6-11.[41] Each IQ point lost reflects an approximately 2% reduction in earnings.[42]

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[38] *See* Multistate Comments to 2021 PID and HH DRA, *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077.

[39] *See, e.g.*, Objections of the States of New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont to EPA's March 29, 2017 Order Denying Petition to Revoke Tolerances for Chlorpyrifos and Leaving Tolerances in Effect (June 5, 2017) at 2-3, Doc. ID EPA-HQ-OPP-2007-1005-0522, *available at* https://ag.ny.gov/sites/default/files/2017_06_05_objections_final.pdf.

[40] In addition, in 2022, Connecticut banned the use of chlorpyrifos on golf courses and for cosmetic, non-agricultural uses. Conn. Sen, Bill 120 (2022), approved, *available at* https://www.cga.ct.gov/2022/ba/pdf/2022SB-00120-R01-BA.pdf (last accessed Jan 23, 2025).

[41] *See supra* note 35.

[42] *See* Salkever, *Assessing the IQ-earnings link in environmental lead impacts on children: Have hazard effects been overstated?* 131 Envtl. Res. 219-30 (May 2014).

IV. Recent Federal Circuit Court Litigation and Subsequent EPA Rulemaking

Since the undersigned States submitted their comment letter on EPA's 2020 PID and 2020 HH DRA,[43] two federal circuit courts of appeals have issued relevant decisions in this regard. First, in *League of United Latin American Citizens v. Regan (LULAC)*, 996 F.3d 673 (9th Cir. 2021)–in which the States of New York, California, Hawaii, Maryland, Vermont, Washington, the Commonwealth of Massachusetts, and the District of Columbia intervened–the Ninth Circuit Court of Appeals found that EPA had failed to timely respond to a petition from two environmental organizations asking that EPA revoke all chlorpyrifos food tolerances. As relevant here, the court ordered EPA to either revoke all chlorpyrifos tolerances or modify chlorpyrifos tolerances based on adequately protective regulatory endpoints and concomitantly issue a safety finding.[44] The court in *LULAC* detailed EPA's inaction in response to the revocation petitions, despite its growing certainty, over nearly a decade, of chlorpyrifos's neurotoxic effects on children and infants, even at levels below the regulatory endpoint of 10% AChE inhibition.[45] The court also quoted EPA's 2015 proposed chlorpyrifos revocation, in which the Agency "acknowledged 'significant uncertainties . . . about the actual exposure levels experienced by mothers and infant participants in the three children's health cohorts,' but found that the measured exposures 'are likely low enough that they were unlikely to have resulted in AChE inhibition.'"[46] Further, the court highlighted that in its 2016 Human Health Risk Assessment, the Agency "determined that chlorpyrifos tolerances were not safe—even considering food alone, without aggregating other exposure sources, like drinking water," and noted that "EPA has never retracted the findings in its 2016 Revised Human Health Risk Assessment." [47] In light of this evidence, the court determined that EPA's uncertainty about exactly how chlorpyrifos harms infants and children was not a rational basis for failing to take action on the revocation petitions because "[e]ven if the mechanism is unknown, if a tolerance is unsafe, then the EPA must revoke it."[48] The court concluded that the 2007 petitions "met the low bar of stating 'reasonable grounds' for revocation with an 'assertion of facts' in support."[49]

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[43] Multistate Comments to 2021 PID and HH DRA, https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077.

[44] 996 F.3d at 703.

[45] *Id.* at 682-84.

[46] *Id.* at 688 (quoting Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080, 69,093 (Nov. 6, 2015)).

[47] *Id.* at 688-89.

[48] *Id.* at 698.

[49] *Id.* at 697.

In the *LULAC* litigation, the States had noted that their residents consume foods grown throughout the United States that contain chlorpyrifos residues. Both EPA's 2017 and 2019 orders[50] result in the continued sale and consumption of food commodities with chlorpyrifos residues that EPA has not found to be safe, as required by FFDCA Section 408(b), 21 U.S.C. § 346a(b)(2)(A). Indeed, EPA has previously stated that chlorpyrifos tolerances cannot be found safe under the FFDCA standard.[51] In their briefing as intervenors, the States demonstrated a significant interest in curtailing exposure to their residents to pesticide chemicals that are not found to be safe.[52]

Thereafter, EPA granted the petitions and revoked all chlorpyrifos tolerances, concluding that, based on available scientific information (including the 2016 report from EPA's FIFRA Science Advisory Panel and EPA's 2020 HH DRA), it could not determine that chlorpyrifos, at any level of exposure, was safe.[53] In response to a challenge to the revocation from agricultural industry groups, the Eighth Circuit Court of Appeals remanded the matter to EPA, concluding that EPA's revocation rule had arbitrarily not considered the option of modifying the existing tolerances.[54] Notably, the Eighth Circuit's remand explicitly stated that EPA could exercise its discretion to revoke all chlorpyrifos tolerances "as long as it considers all important aspects of the problem and gives a reasoned explanation for whichever option it chooses."[55]

V. EPA Has Failed to Make an Adequate Determination of Safety.

The Proposed Rule fails to account for children's and infants' neurological vulnerability. EPA's conclusion that the remaining tolerances "will be safe," relies on an inappropriate regulatory endpoint, and is not supported by the available, reliable data as required by statute. By claiming that scientific uncertainty regarding dose-response relationship justifies its use of 10%

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[50] On March 29, 2017, then EPA Administrator Scott Pruitt denied the 2007 PANNA/NRDC petition, and left chlorpyrifos tolerances in effect. The 2017 order did not specifically refute EPA's findings in either the 2014 or 2016 revised human health risk assessments or the agency's other scientific findings in the record regarding the adverse effects to infants and children from chlorpyrifos exposure at low levels. Nor did the order contain any safety finding or discussion of the FFDCA safety standard for leaving chlorpyrifos tolerances in effect. The July 24, 2019 final order similarly did not contain any finding of safety, and stated EPA wanted to address concerns with low-dose exposure in a future re-registration review.

[51] *See* 81 Fed. Reg. at 81,050 (EPA's analysis of chlorpyrifos "continues to indicate that the risk from potential aggregate exposure does not meet the FFDCA safety standard").

[52] States' Intervenor Brief at 3-5, *LULAC*, 996 F.3d 673 (9th Cir. 2021).

[53] 86 Fed. Reg. 48,315, 48,316-17.

[54] *Red River Valley Sugarbeet Growers Ass'n v. Regan*, 85 F.4th 881, 890 (8th Cir. 2023).

[55] *Id.*

AChE inhibition and retaining the default tenfold safety factor,[56] EPA is making a twofold error. As explained above, under the FFDCA, EPA may leave a tolerance in place "only if the [EPA] Administrator determines that the tolerance is safe," meaning that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical."[57] EPA's safety determination does not meet this statutory standard because it is based on an under-protective regulatory endpoint that fails to account for the particular neurodevelopmental vulnerability of children and infants, at doses so low AChE inhibition is not detected. And despite over a decade of critical comments about EPA's chosen regulatory endpoint, the Agency has yet to respond any of these comments and, thus, cannot rely on any of its conclusions in its iterative risk assessments and proposed registration decision.

A. EPA Cannot Rely on the 2020 Revised Draft Human Health Risk Assessment Because It Uses an Insufficiently Protective Regulatory Endpoint for Assessing Risk Based on Adverse Neurodevelopmental Effects at Low Doses.

EPA's proposed safety determination for the 11 remaining chlorpyrifos tolerances relies almost exclusively on its 2020 revised draft human health assessment—the 2020 HH DRA—which is based on 10% AChE inhibition, a regulatory endpoint designed to prevent acute pesticide poisonings. In the States' 2021 comment letter on EPA's 2020 HH DRA, we questioned EPA's proposal to revert to 10% AChE inhibition as its regulatory endpoint, despite the Agency's previous conclusion that it was not sufficiently protective.[58] The 2020 HH DRA recognized that a "body of studies has raised concerns that EPA's historical practice of using AChE inhibition as the critical effect for deriving PODs may not be protective of neurodevelopmental outcomes,"[59] that there is "concern . . . that 10% RBC AChE inhibition is not sufficiently protective of human health," and that "both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures … at lower doses."[60] Nonetheless, EPA decided to retain 10% AChE inhibition as its regulatory endpoint because it has the "most robust quantitative dose-response data."[61] However, in doing so, the Agency conflated uncertainty surrounding a dose-response relationship at low doses with the certain knowledge that neurodevelopmental harms exist at low doses, including "through

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[56] 89 Fed. Reg. at 99, 192-99, 193.

[57] 21 U.S.C. § 346a(b)(2)(A)(i-ii) (emphasis added).

[58] Multistate Comments to 2021 PID and HH DRA, https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077.

[59] EPA, 2020 HH DRA, https://beta.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944, at 84.

[60] *Id.* at 86.

[61] 89 Fed. Reg. at 99,192; *see also* 2020 HH DRA, https://beta.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944.

modes of action…distinct from the classical mode of action of AChE inhibition."[62] And in its review of new laboratory studies, EPA found more recent research that "provides strong support for the conclusion that effects on the developing brain may occur below a dose eliciting 10% AChE."[63] Additionally, a 2020 academic review of 26 different animal studies, many not yet considered by EPA, also demonstrated "weight-of-evidence for low-dose chlorpyrifos neurotoxicity and noncholinergic mechanisms" in subjects treated with doses at or below the threshold for AChE.[64] In light of this, EPA failed in 2020—and continues to fail now—to explain how using the regulatory endpoint of 10% AChE inhibition is an appropriate benchmark for safety.

By relying on the less sensitive regulatory endpoint from the 2020 HH DRA, EPA in the Proposed Rule is contradicting both its own policy[65] of ensuring that its risk assessments and pesticide regulations are based on the most sensitive endpoint and ignoring the approach established by Congress in the FQPA for protecting against prenatal toxicity.[66] Given the body of evidence demonstrating that adverse brain impacts occur at much lower exposure levels of chlorpyrifos than those that cause 10% AChE inhibition, EPA's pivot back to the under-protective regulatory endpoint of AChE inhibition lacks sufficient justification, fatally compromises the assessment's integrity, puts the future of our children's health at risk, and is arbitrary and capricious.

Further, in the 2020 HH DRA and Proposed Rule, EPA has failed to identify an established level of exposure that is without risk, and hence simply cannot calculate a safe food tolerance. We know more protective approaches can be taken. For example, as we described in our 2021 letter, California initiated a state-wide prohibition of chlorpyrifos based on thorough study of chlorpyrifos's effects on human health. Importantly, California based its risk evaluations on the "critical endpoint" of developmental neurotoxicity and established a "no observable effect

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[62] 89 Fed. Reg. at 99,192.

[63] *Id.* at 88.

[64] Silva, *Effects of low dose chlorpyrifos on neurobehavior and potential mechanisms: A review of studies in rodents, zebrafish, and Caenorhabditis elegans*, 112 Birth Defects Research 455-79 (Apr. 2020), *available at* https://doi.org/10.1002/bdr2.1661 (last accessed Jan. 24, 2021).

[65] CDPR, *Chlorpyrifos Risk Characterization Document: Spray Drift, Dietary and Aggregate Exposures to Residential Bystanders* (Dec. 31, 2015), *available at* https://www.cdpr.ca.gov/docs/risk/rcd/chlorpyrifos_draft.pdf.

[65] CDPR, *Final Toxic Air Contaminant Evaluation for Chlorpyrifos: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders* (July 2018), *available at* https://www.cdpr.ca.gov/docs/whs/pdf/chlorpyrifos_final_tac.pdf, at 1.

[65] *Id*. at 81-83.

[65] *Id.* at 1, 59-61.

[66] *See* 21 U.S.C. § 346a(b)(2)(C)(i).

level" (NOEL) which assumes a single exposure at that very low level during a sensitive developmental time, could result in "chlorpyrifos-mediated developmental toxicity"[67] in infants and children. This is in stark contrast to EPA's approach to base risk thresholds of off an acute poisoning benchmark in 2020 and 2024 (AChE inhibition). In our 2021 letter, States urged EPA to revoke all tolerances due to this failure to generate the necessary data to determine a safe level of exposure to children and support re-registration, and we maintain the same position now.

Despite the States and other commenters raising these serious concerns about EPA's under-protective regulatory endpoint in the 2020 HH DRA nearly four years ago, EPA has failed to address or even respond to any of these concerns in its Proposed Rule. Instead, EPA merely says "the Agency is not ignoring or dismissing the extensive data concerning the potential for adverse neurodevelopmental outcomes" and notes EPA's use of a tenfold default safety factor as "addressing the uncertainties surrounding the potential for adverse neurodevelopmental outcomes."[68] But EPA's use of a default tenfold safety factor cannot compensate for its reliance on a fundamentally faulty regulatory endpoint.[69] In its Proposed Rule, EPA has effectively ignored *its own findings* that children and infants experience neurological harm when exposed to chlorpyrifos at levels below those that cause 10% AChE inhibition,[70] and has failed to make a specific determination regarding the safety of chlorpyrifos for infants and children in light of

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[67] CDPR, *Chlorpyrifos Risk Characterization Document: Spray Drift, Dietary and Aggregate Exposures to Residential Bystanders* (Dec. 31, 2015), *available at* https://www.cdpr.ca.gov/docs/risk/rcd/chlorpyrifos_draft.pdf, at 60.

[68] 89 Fed. Reg. at 99,193.

[69] Additionally, EPA has still not responded to extensive public comments explaining why 10% AChE inhibition is an inappropriate regulatory endpoint and urging EPA to consider a more protective regulatory endpoint.

[70] *See* EPA, *Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization* (Aug. 21, 2008) at 12-13, 31-40, 43-44, a*vailable at* https://nepis.epa.gov/Exe/ZyPDF.cgi/P100638T.PDF?Dockey=P100638T.PDF; EPA, FIFRA Scientific Advisory Panel Meeting, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects* (Apr. 10-12, 2012), Doc. ID EPA-HQ-OPP-2012-0040-0029_content.pdf at 19-21, 45-58; EPA, *Revised Human Health Risk Assessment for Registration* (2014), Doc. ID EPA-HQ-OPP-2008-0850- at 6-7, 32-33; EPA, FIFRA Scientific Advisory Panel Meeting, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos: Analysis of Biomonitoring Data* (Apr. 19-21, 2016), Doc. ID EPA-HQ-OPP-2016-0062 at 18-19, 52-53; EPA, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review Memorandum: Office of Chemical Safety and Pollution Prevention* (Nov. 3, 2016), at 13-21. Doc. ID EPA-HQ-OPP-2015-0653 10-13.

those findings, as required by statute.[71] EPA cannot issue a final rule retaining the proposed tolerances without doing so.

The recent circuit court decisions do not alter EPA's statutory obligations under the FFDCA. Indeed, the Ninth Circuit explained that, based on the available data, EPA could not determine a tolerance safety using 10% AChE inhibition as a regulatory endpoint.[72] In response to the Ninth Circuit's directive to respond to the petition seeking all tolerance revocation, EPA granted the 2007 petition and revoked all chlorpyrifos tolerances in 2021, concluding that, based on available scientific information, it could not determine that chlorpyrifos, in any exposure, was safe.[73] In response to the Ninth Circuit's directive, EPA could have modified the existing tolerances, but it did not. The Eighth Circuit's later remand did *not* direct the Agency to reinstate tolerances, but rather only to consider and address the potential harms from modifying the existing tolerances, while still following its statutory mandate to determine that the remaining tolerances were "safe."[74] Instead, in its Proposed Rule, EPA justifies retaining the remaining tolerances by arbitrarily sweeping aside its prior concerns about the effects of chlorpyrifos on children and infants at levels below that which causes 10% AChE inhibition and concludes, without explanation, that the tenfold default safety factor will be sufficiently protective.[75] Such an unsupported conclusion fails to meet the FFDCA's statutory requirements.

B. EPA's Proposed Partial Tolerance Revocation Fails to Consider the Best Available Science Regarding Chlorpyrifos' Potential Effects on Neurodevelopment in Infants and Children.

In the Proposed Rule, EPA continues to disregard scientific research that demonstrates serious neurodevelopmental toxicity risk from low-dose chlorpyrifos exposure in infants and children, claiming that these studies contain "notable uncertainties" including uncertainties "about the dose-response relationships."[76] EPA's disregard of peer-reviewed epidemiological studies and other relevant scientific research is arbitrary and capricious. Long-established EPA policy mandates that one of its priorities is to "identify, assess, conduct, and apply the best available science to address current and future environmental hazards."[77] EPA may not disregard

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[71] 21 U.S.C. § 346a(b)(2)(C)(ii)(II).

[72] *LULAC*, 996 F.3d at 698.

[73] 86 Fed. Reg. 48,315, 48,316-17.

[74] 85 F.4th 881, 890.

[75] 89 Fed. Reg. at 99,193.

[76] *Id.* at 99,192.

[77] EPA, *Working Together: FY 2018-2022 EPA Strategic Plan* (2018) at 42, *available at* https://www.epa.gov/sites/production/files/2019-09/documents/fy2018-2022-epa-strategic-plan.pdf.

critical epidemiological studies based on criteria–such as availability of the underlying data and ability to independently validate underlying data–that are not determinative of whether the studies or information constitute the best available science.[78] To do so here would violate the FFDCA, which requires EPA to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to chlorpyrifos.[79] These peer-reviewed studies demonstrate that no such reasonable certainty exists. EPA may not rely on an explanation for its decision that runs counter to the evidence before the Agency.[80] And, of course, EPA may not adopt or implement regulations that conflict with the statutes under which they are promulgated.

C. EPA Cannot Rely Upon Its Human Health Risk Assessments Without Responding to Comments.

Finally, as noted above, EPA has yet to respond to any of the public comments submitted in response to its successive chlorpyrifos safety and human health risk assessments and proposals since at least 2015. Under fundamental notice and comment requirements in the Administrative Procedure Act and the Agency's own regulations, EPA must respond to these critical comments before finalizing these assessments and proposals prior to relying on them.[81] In fact, EPA's FIFRA regulations specifically lay out the procedure for responding to comments on human health risk assessments and proposed interim decisions. EPA must first open a 60-day comment period in the Federal Register for any proposed registration review decision and the underlying risk assessments, then explain any changes made and respond to significant comments in the final registration review decision.[82] EPA must also respond to comments on risk assessments that precede issuance of a PID.[83]

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[78] *See* Comments of Attorneys General of New York, et al. (May 29, 2020) at 5-6, Doc. ID EPA-HQ-OA-2018-0259-12715, *available at* www.regulations.gov.

[79] 21 U.S.C. § 346a(b)(2)(C)(ii).

[80] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[81] *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015); *see also* 5 U.S.C. § 553(c) (agency must respond to relevant public comments in its justification for the final rule); *City of Portland, Oregon v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (agency must address comments that, if adopted, would change the decision); *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, 676 F. Supp. 2d 307 (S.D.N.Y. 2009) (vacating EPA pesticide registration because EPA violated notice-and-comment requirements).

[82] 40 C.F.R. §§ 155.56, 155.58

[83] *See id.* § 155.53(c) ("[t]he Agency will publish a notice in the Federal Register announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments.").

Not only is EPA required to consider and respond to comments under foundational procedural tenets of administrative law, but EPA must consider the comments raised over the past decade because they are precisely the sort of "available information" that EPA must consider in addressing food risks under the FFDCA.[84] For example, in the States' 2021 comment to the 2020 PID, we raised serious concerns about EPA's use of the 10% AChE inhibition as a regulatory endpoint, presented alternative approaches for analytical methodology, and objected to EPA's treatment of relevant scientific research.[85] The concerns about the risks of chlorpyrifos exposure, as well as EPA's assessments, raised by the States and other commenters *over the past decade* and most recently the 2020 HH DRA and the 2020 PID are sufficiently significant that they could change EPA's safety findings. EPA itself has repeatedly acknowledged that it must respond to comments before relying on the conclusions in its 2020 PID, calling it "a proposal," in keeping with its title, "not a final Agency determination" and noting that it "could be subject to change following public comment."[86] As such, EPA must follow its own process by considering and responding to those concerns prior to finalizing any decision on retaining any chlorpyrifos tolerances.

VII. EPA Unlawfully Shifts the Burden to Petitioners to Prove that Chlorpyrifos Is Unsafe.

The FFDCA places a heavy burden on EPA when deciding whether to retain pesticide tolerances: the Agency 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."[87] The FFDCA authorizes "[a]ny person [to] file . . . a petition proposing the issuance of a regulation establishing, modifying, or revoking a tolerance."[88] EPA requires that such petitions state "reasonable grounds for the action sought," including "an assertion of facts."[89] If EPA determines that a petition has met these threshold requirements, the Agency must publish the petition within 30 days.[90] After considering the petition and any other available information,

[84] 21 U.S.C. § 346a(b)(2)(C)(i)(II); 21 U.S.C. § 346a(b)(2)(D).

[85] Multistate Comments to 2021 PID and 2020 HH DRA, https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077.

[86] *See*, *e.g.*, Objections Denial, 87 Fed. Reg. 11,222, 11,234 (Feb. 2, 2022).

[87] 21 U.S.C. § 346a(b)(2)(A)(ii).

[88] *Id.* § 346a(d)(1).

[89] *Id.* § 346a(d)(2)(A).

[90] *Id.* § 346a(d)(3).

EPA must do one of three things: issue a final regulation, issue a proposed regulation, or issue an order denying the petition.[91]

Despite the Ninth Circuit's extensive discussion of EPA's burden of persuasion under the FFDCA, the Agency continues to inappropriately shift the burden to the petitioners. The Agency does so when it justifies maintaining 10% AChE inhibition by saying "until there are any updates to the state of the science for chlorpyrifos, the agency is relying on the 2020 HHRA for this rule."[92] Contrary to EPA's assertion in its Proposed Rule, it is not the petitioners' duty to prove that tolerances are unsafe but rather EPA's mandate under the FFDCA to determine that any chemical pesticide residue on food is statutorily safe. As the Ninth Circuit noted, even though the Agency may not know the most vulnerable limit for exposure, or the exact mechanism by which infants and children are harmed by chlorpyrifos, EPA is unable to demonstrate, based on available data, that any chlorpyrifos exposure is safe under the meaning of the FFDCA.[93]

[91] *Id.* § 346a(d)(4)(A).

[92] 89 Fed. Reg. at 99,192.

[93] *LULAC*, 996 F.3d at 698, 701.

VIII. Conclusion

As set forth above, multiple academic, administrative, state, and international bodies have repeatedly and unambiguously demonstrated that the risk of continued chlorpyrifos use is unacceptable. Likewise, EPA's decades-long administrative review has repeatedly failed to find a safe level of exposure to chlorpyrifos, particularly as to our most vulnerable populations. In a misguided effort to support such a finding now, and contrary to the Ninth Circuit's directive, EPA's Proposed Rule relies on a risk assessment for the pesticide that fails to use, as it must, the most protective regulatory endpoint and the best available science, while dismissing the Agency's own findings documenting low dose adverse neurological effects associated with chlorpyrifos. A growing number of States and countries have banned this dangerous pesticide, in contrast to EPA allowing its continued use notwithstanding its failure to generate, because it likely cannot generate, the data to support a finding that there is a safe level of exposure to children and support continued chlorpyrifos tolerances. Based on the science and lack of the necessary findings of safety, EPA must revoke all food tolerances for chlorpyrifos and cancel the registrations for all ongoing uses of the pesticide.

Respectfully submitted,

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