Petition to Revoke Food Tolerances and Cancel Registrations for Harmful Organophosphate Uses

Petitioners:

United Farm Workers
United Farm Workers Foundation
Earthjustice
California Rural Legal Assistance Foundation
Farmworker Association of Florida
Farmworker Justice
GreenLatinos
Labor Council for
Latin American Advancement
League of United Latin American Citizens
Learning Disabilities Association of America
Pesticide Action Network North America
Pineros y Campesinos Unidos del Noroeste

November 18, 2021

TABLE OF CONTENTS

INTRODUCTION AND SUMMARY

United Farm Workers, United Farm Workers Foundation, Earthjustice, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens, Learning Disabilities Association of America, Pesticide Action Network North America, and Pineros y Campesinos Unidos del Noroeste (Petitioners) hereby petition the Environmental Protection Agency (EPA) to revoke tolerances and cancel registrations for the remaining organophosphate pesticides (OPs). This petition is submitted pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(d), the Administrative Procedure Act, APA, 5 U.S.C. § 551, and the First Amendment Constitutional Right to Petition.

By the October 1, 2022, registration review deadline, this petition seeks final EPA actions – tolerance revocations and registration cancellations – to protect people from unsafe exposures to OP pesticides documented in EPA risk assessments. It also seeks updates to EPA's human health risk assessments (HHRAs) for the OP pesticides to use a regulatory endpoint that protects children from learning disabilities and other neurodevelopmental harm.

ORGANOPHOSPHATES HARM PUBLIC HEALTH

Organophosphates are a class of neurotoxic pesticides originally developed by the Nazis as nerve agents in World War II. OPs cause acute pesticide poisonings by suppressing acetylcholinesterase (AChE or cholinesterase), an enzyme that regulates nerve impulses throughout the body. In addition, a growing body of scientific literature establishes that OPs cause neurodevelopmental harm to children at exposures far below those that cause 10% cholinesterase inhibition, EPA's current regulatory endpoint. Published, peer reviewed studies correlate OP exposure with impaired motor and mental development, reduced IQ, attention disorders, and autism at low exposures. Some OPs are also linked to cancer and reproductive harm.

People are exposed to OP pesticides through residues on the food they eat, contamination of the water they drink, and when the pesticides drift from where they are applied to where people work, go to school, or play. Children often have greater exposure than adults to OPs due to their increased hand-to-mouth activity, and relative to adults they eat more fruits and vegetables, drink more water, and breathe more air for their body weight. Each year of delay in ending OP uses exposes children to impairments in learning, social skills, motor function, and their development.

The farmworkers who grow our food face the highest exposures and risks from OP pesticides. In addition to exposures through food and drinking water, they are exposed when they apply the pesticides or enter fields that have been sprayed, and they and their families are more likely to be harmed by pesticide drift because they live and go to school near where OP pesticides are sprayed. Farmworkers and their families are majority people of color and low-income. This administration has committed to addressing the disproportionate harms communities of color and low-income communities face. On his first day in office, President

Biden declared that the policy of his administration is to "listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; [and] to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities…." Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (Jan. 20, 2021).[1] The science, the law, and principles of environmental justice require EPA to ban OP uses that are unsafe and that harm workers and their families.

EPA'S DELAY IN PROTECTING PEOPLE FROM OPS

EPA has long prioritized OPs in its reviews of pesticides because of their widespread use and their pervasive harm to workers and children. As in the past, EPA prioritized the OPs in this round of pesticide reviews, called registration review, with chlorpyrifos at the front of the queue because of a 2007 petition to ban chlorpyrifos from food because of the neurodevelopmental harm it causes to children at low exposure levels. The Trump administration put the brakes on the OP review process. It refused to finalize a 2015 proposed revocation of chlorpyrifos tolerances by a court deadline of March 31, 2017, to continue studying the science. It took administrative objections and court orders to force EPA's hand, but the Trump EPA still refused to ban chlorpyrifos food uses. After a scathing 9th Circuit decision with yet another court deadline, the Biden EPA adopted a final tolerance revocation in August 2021.

The Trump EPA likewise went into a stalling pattern on the remaining OPs. The OP workplans scheduled registration review decisions for 2015-2017. EPA had been releasing preliminary human health risk assessments finding risks of concern from individual OPs, but the Trump administration took the OPs off the registration review schedule altogether. As a result, the risk assessment findings have languished in the agency without any measures being put in place to protect children, workers, and others in harm's way. EPA has put the OPs back in the registration review queue, but the lost years in the Trump administration will make it hard for EPA to take actions to protect people from the OPs by the October 1, 2022, deadline unless it redoubles its efforts.

EPA'S RISK ASSESSMENTS FAIL TO PROTECT CHILDREN FROM NEURODEVELOPMENT HARM.

EPA's OP risks assessments use 10% cholinesterase inhibition as the regulatory endpoint, even though EPA has determined that neurodevelopmental harm to children results from lower exposures. In 2015, EPA conducted a literature review of the studies documenting neurodevelopmental harm from organophosphates and concluding that the neurodevelopmental effects are the most sensitive endpoint related to OP toxicity and reconfirmed these findings when it updated the literature review in 2016. As explained in a recent OP draft human health risk assessment, "exposure levels in the range measured in the epidemiology studies are likely low enough that they are unlikely to result in AChE" inhibition. Naled Draft HHRA at 31. EPA policy requires selection of the most sensitive endpoint for quantitative evaluation in risk assessments because it is presumed that doing so will also protect against any other effects that

[1] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

occur at higher levels of exposure. The opposite is also true. If EPA regulates a pesticide based on an exposure level associated with one type of harm and other harms occur at lower exposures, EPA's regulation will not be sufficiently protective. In that instance, EPA cannot find reasonable certainty of no harm – the standard for allowing a pesticide on our food – because of the harm at lower exposures.

Based on the 2015 OP Literature Review, EPA retained the Food Quality Protection Act (FQPA) 10X safety factor designed to protect children from neurotoxicity and to account for uncertainties and gaps in information. However, the risk assessments use a regulatory endpoint of 10% cholinesterase inhibition. This endpoint is underprotective because the damage to children's brains occurs at far lower levels of exposure. Indeed, the 2016 chlorpyrifos risk assessment, which appropriately used neurodevelopmental harm as the regulatory endpoint, shows that there may be no safe level, particularly when exposures occur during pre-natal development or in early life, as does California's risk assessment predicated on animal studies finding neurodevelopmental harm at low exposures. In its August 2021 final chlorpyrifos tolerance revocation rule, EPA abandoned its attempt to find a safe exposure level for damage to children's brains. This petition explains that EPA cannot make a reasonable certainty of no harm finding using 10% cholinesterase inhibition when harm to children's brains occurs at lower exposure levels.

SUMMARY OF THE PETITION

End the Delay in Protecting Children and Workers

This petition asks EPA to put an end to the delay in protecting children and workers from OP pesticides by ending unsafe OP uses no later than October 1, 2022. While EPA has other legal obligations that, by statute, must be completed by the October 1, 2022, deadline, it has acknowledged that it will not be able to do so. Specifically, EPA must complete Endangered Species Act (ESA) consultations and ensure its registrations comply with the ESA, and it must conduct endocrine disruptor screening of all pesticides. EPA must also complete a cumulative risk assessment for all the OPs to address their cumulative acute poisoning and neurodevelopmental effects. EPA should not delay taking action to protect people from each individual OP by waiting to complete these additional analyses. It should revoke food tolerances and end unsafe uses of the individual OPs immediately and conduct the additional analyses later for any uses that remain.

Protect Our Food and Drinking Water

EPA should act immediately to protect our food supply by revoking food tolerances and cancelling registrations for all OP food uses EPA cannot find safe. EPA's OP risk assessments already document unsafe exposures to OPs in our food, drinking water, and pesticide drift. These food uses are illegal and must end. EPA will also need to update its OP risk assessments so they use an appropriate endpoint that protects children from learning disabilities and other neurodevelopmental harm. Without such an endpoint, EPA cannot rely on its risk assessments to make safety findings. When it updates the risk assessments to protect children, even more OP food uses will fail to pass master under the FQPA's reasonable certainty of no harm standard.

EPA must revoke tolerances and cancel registrations for OP uses on food that it cannot find safe for children.

Protect Workers

EPA should cancel registrations for nonfood uses that cause unreasonable adverse effects to workers, taking into account all of the routes of exposure, the full range of harms, and environmental justice concerns. EPA's OP risk assessments document risks of concern from many activities workers perform, yet EPA has delayed taking action to protect workers from these risks. For many OPs, this might require ending aerial spraying, requiring closed cabs for airblast and ground boom applications, requiring closed mixing and loading systems for applications, and lengthening the re-entry intervals for field workers to enter fields after pesticide spraying. Like its dietary risk assessments, EPA's worker risk assessments use an underprotective endpoint based on acute poisoning risks. EPA needs to update the risk assessments to protect women of childbearing age from lower-level exposures that cause learning disabilities and other neurodevelopmental harm. Once it does so, EPA will almost certainly be unable to find that benefits to growers outweigh the risks and harm to the women and their children. In other words, it will find that OP uses with any significant worker exposure cause unreasonable adverse effects in violation of FIFRA. By October 1, 2022, EPA must cancel OP registrations to eliminate all such unreasonable adverse effects.

PETITIONERS

United Farm Workers (UFW)

UFW is the nation's largest farm workers union. Since 1962, UFW has worked to protect and expand farm workers' rights and to protect the health of farm workers and their families, including by limiting their exposure to toxic pesticides. The UFW continues to actively champion legislative and regulatory reforms for farm workers covering issues such as worker protections, pesticides, and immigration reform.

United Farm Workers Foundation

The UFW Foundation's core purpose is to empower communities to ensure human dignity. The UFW Foundation mobilizes farm workers and their organizations across the country to advocate for more equitable policies, such as immigration reform, pesticide protections, heat standards, hazard pay, and other worker protections. The UFW Foundation engages constituents in systemic change to break the cycle of poverty while also providing critical services.

California Rural Legal Assistance Foundation (CRLAF)

CRLAF is a non-profit civil legal aid organization that was founded in 1981 and provides free legal services and policy advocacy for California's rural poor. CRLAF's mission is to achieve social justice and equity in partnership with farm workers and all low-wage workers and their families in rural communities through community, legislative and legal advocacy. By engaging in community education and outreach, impact litigation, legislative and administrative advocacy, and public policy leadership at the state and local level, CRLAF aims to improve working and living conditions for farm workers and other low-wage workers.

Farmworker Association of Florida (FWAF)

The Farmworker Association of Florida's long-standing mission is to build power among farmworker and rural low-income communities, to respond to and gain control over the social, political, economic, workplace, health, and environmental justice issues that impact their lives. FWAF's programs and activities build leadership, civic engagement, and activist skills among low-income communities of color who are disproportionately affected by pesticide exposure/health problems, environmental contamination, institutional racism, harassment and intimidation, exploitation, and political under-representation.

Farmworker Justice (FJ)

FJ is a national nonprofit advocacy and education organization whose mission is to support farmworkers in their efforts to improve their living and working conditions, including their occupational health and safety. FJ's activities include educating the public, government officials and lawmakers about the adverse health impacts to farmworkers and their families from exposure to pesticides, and the need to reduce their exposure to such toxins. For decades, FJ has worked with farmworkers and community-based organizations across the U.S. to help workers and their families understand these occupational hazards and prevent pesticide-related illnesses and injuries.

GreenLatinos

GreenLatinos is a national non-profit organization that convenes a broad coalition of Latino leaders committed to addressing national, regional, and local environmental, natural resources and conservation issues that significantly affect the health and welfare of the Latino community in the United States.

Labor Council for Latin American Advancement (LCLAA)

LCLAA was founded in 1972 out of the need to improve workers' rights and increase the influence of Latino workers in the political process by educating, organizing, and mobilizing Latinos within and outside of the labor movement. As part of its mission, LCLAA focuses on raising awareness about occupational and environmental health and safety issues that disproportionately impact Latino and immigrant workers, including farmworkers and pesticide applicators.

League of United Latin American Citizens (LULAC)

Founded in 1929, LULAC is the country's oldest and largest Hispanic organization and LULAC's mission is to advance the economic condition, educational attainment, political influence, housing, health, and civil rights of the Hispanic population of the United States. With approximately 132,000 members and supporters throughout the United States and Puerto Rico, and 600 councils nationwide, LULAC's programs, services and advocacy address the most important issues for Latinos, meeting the critical needs of today and the future.

Learning Disabilities Association of America (LDA)

LDA's mission is to create opportunities for success for all individuals affected by learning disabilities through support, education, and advocacy. Founded in 1964, LDA has state and local chapters throughout the country. It provides support, information, and advocacy on behalf of individuals with learning disabilities. LDA established the Healthy Children Project (HCP) in 2002 to raise awareness of environmental factors, particularly toxic chemicals, linked to problems with brain development and function, and to reduce and prevent toxic chemical exposures, especially among pregnant women, infants, and children, through educating and advocating for changes in products, practices, and policies.

Pesticide Action Network North America (PANNA)

PANNA is a non-profit advocacy and education organization that was founded in 1982 and is dedicated to preventing harm to the public from pesticides. PANNA focuses on two related goals: (1) protecting people from exposure to dangerous pesticides; and (2) promoting a shift to less toxic alternatives. PANNA is the North American branch of the Pesticide Action Network, an international coalition of hundreds of public interest organizations in more than 90 countries. The network challenges the global proliferation of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable society.

Pineros y Campesinos Unidos del Noroeste (PCUN)

PCUN's mission is to empower farmworkers to recognize and take action against systematic exploitation and all of its effects. To this end, PCUN is involved in community and workplace organizing on many levels. Based in Woodburn, Oregon—the center of Oregon's agricultural industry— PCUN is Oregon's only farmworker union and the largest Latino organization in the state.

These farmworker, labor, civil rights, environmental, health, and children's advocacy groups submitted comments on EPA's OP human health risk assessments, urging EPA to protect against brain damage to children from early life exposures, to take actions to end food uses of these unsafe pesticides, and to protect workers and bystanders from harm from OP uses. They have substantial interests in eliminating exposures to pesticides that harm workers, children, and communities, including their members.

THE PESTICIDES AND DOCKETS

This petition seeks EPA action on the following pesticides and incorporates by reference EPA's risk assessments and registration review dockets. We ask that this petition be added to each of these registration review dockets. All of EPA's HHRAs, except for Chlorpyrifos, are in drafts or preliminary.

Acephate (EPA-HQ-OPP-2008-0915)
Bensulide (EPA-HQ-OPP-2008-0022)
Chlorethoxyfos (EPA-HQ-OPP-2008-0843)
Chlorpyrifos-methyl (EPA-HQ-OPP-2010-0119)
Diazinon (EPA-HQ-OPP-2008-0351)
Dichlorvos (EPA-HQ-OPP-2009-0209)
Dicrotophos (EPA-HQ-OPP-2008-0440)

Dimethoate (EPA-HQ-OPP-2009-0059)
Ethoprop (EPA-HQ-OPP-2008-0560)
Malathion (EPA-HQ-OPP-2009-0317)
Naled (EPA-HQ-OPP-2009-0053)
Phorate[2] (EPA-HQ-OPP-2007-0674)
Phosmet (EPA-HQ-OPP-2009-0316)
Terbufos (EPA-HQ-OPP-2008-0119)
Tribufos (EPA-HQ-OPP-2008-0883)

This petition is based on and incorporates the registration review administrative records before EPA and specifically on EPA findings, plus scientific evidence credited by EPA that neurodevelopmental harm to children occurs at exposures below those that cause 10% cholinesterase inhibition. Like comments submitted by petitioners on OP risk assessments, this petition seeks an update of the risks assessment to protect children from neurodevelopment harm from such low-level exposures.

LEGAL BACKGROUND

I. THE FFDCA MANDATES ELIMINATION OF HARMFUL PESTICIDES FROM OUR FOOD SUPPLY.

EPA regulates allowable contaminants, including pesticides, in our food supply under the FFDCA. For a pesticide to be permitted on food and imported or sold in interstate commerce, EPA must issue a tolerance that establishes the maximum residue of a pesticide allowed on food. 21 U.S.C. § 346a(b) & (c). EPA may "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." *Id*. § 346a(b)(2)(A)(i) (emphasis added). Under the Food Quality Protection Act (FQPA), which passed unanimously in 1996 and amended the FFDCA, "safe" means that EPA can "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to pesticides. 21 U.S.C. § 346a(b)(2)(C)(ii)(I), (II).

The 1996 passage of the FQPA responded to a seminal 1993 National Academy of Sciences (NAS) report criticizing EPA for regulating pesticides based on the effects on a 150-pound adult male.[3] Children should not be treated as "little adults" because "[i]nfants and children are growing and developing," "[t]heir metabolic rates are more rapid than adults," and "[t]here are differences in their ability to activate, detoxify, and excrete xenobiotic compounds."[4] Children also eat and drink more than adults in proportion to their body weight, consume large quantities of certain fruits and vegetables, and engage in behaviors that expose them to pesticides

[2] EPA has not released a human health risk assessment for phorate since 1999, although its registration review schedule indicates it may do so soon. EPA's 1999 risk assessment found risks of concern to occupational handlers from phorate exposures, which were not mitigated or eliminated in the re-registration process completed for the OPs in 2006.
[3] National Research Council, *Pesticides: Diets of Infants and Children* (1993) ("NAS Report"), https://www.nap.edu/catalog/2126/pesticides-in-the-diets-of-infants-and-children.
[4] NAS Report at 3-7.

such as playing on floors or lawns or putting objects in their mouths.[5] For example, a 6-month old child drinks seven times more per body weight than an adult, inhales twice as much air, and puts its hands in its mouth more than is common later in life. The report also highlighted the windows of vulnerability — *in utero*, infancy, and adolescence — where children are particularly susceptible to the impacts of even small exposures chemicals on their development.

The NAS recommended that EPA revamp and strengthen its regulation of pesticides to account for children's vulnerabilities, consumption patterns, and exposures. Because it would take time to fill gaps in knowledge, safeguards and methodologies, the NAS recommended that additional protection be afforded in the form of "uncertainty" or "safety factors." The NAS first described how EPA has regularly used uncertainty factors and then proposed an additional uncertainty factor for toxicity to infants and children and where data are incomplete on such toxicity or on children's exposures:

> In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption, the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity.

NAS Report at 9-10.

Heeding the NAS recommendations, the FQPA directs EPA to afford added protection to children based on their exposure patterns, their special sensitivities, such as during early or adolescent development, and gaps in available data to assess such risks. 21 U.S.C. § 346a(b)(2)(C)-(D). The statute explicitly requires EPA to assess the risk that a pesticide poses particularly to infants and children. *Id*. § 346a(b)(2)(C). Before EPA can establish a tolerance, the agency shall "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the pesticide, and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." *Id*. §§ 346a(b)(2)(C)(ii)(I), (II). In ensuring that the statutory safety standard is met, 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." *Id.* § 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decision on available information about "food consumption patterns unique to infants and children." *Id*. §§ 346a(b)(2)(C)(i)(I), (III).

One of the FQPA's key provisions is the requirement that EPA use an additional margin of safety to protect infants and children when establishing tolerances. The statute requires that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure 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

[5] *Id.* at 3-7, 77. EPA-funded research confirmed and strengthened the NAS findings. *See* Centers for Children's Environmental Health & Disease Prevention Research, Exposures & Health of Farm Worker Children in California.

children." *Id*. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id*.

This tenfold safety factor (called the FQPA safety factor or kids safety factor or 10X) is in addition to two safety factors that have been longstanding features in pesticide risk assessment. The interspecies factor accounts for the uncertainty in extrapolating data from animals to humans. It is used because "[t]here are major uncertainties in extrapolating both from animals to humans and from high to low doses. There are important species differences in uptake, metabolism, and organ distribution of carcinogens, as well as species and strain differences in target-site susceptibility."[6]

The intra-species uncertainty factor accounts for the uncertainty in extrapolating data across the human population and accounts for "variations in susceptibility within the human population (inter-human variability) and the possibility (given a lack of relevant data) that the database available is not representative of the dose/exposure-response relationship in the groups of the human population that are most sensitive to the health hazards of the chemical being assessed."[7] It can account for the inherent differences from person to person in the human population due to such factors as genetic predisposition, other illnesses, exposure to other toxicants, and susceptibility due to poverty or poor access to health care.

Each of these traditional uncertainty factors has a default value of 10X for a total of 100X together, increased to 1000X when the FQPA safety factor is added.[8] In addition, if EPA is basing the regulatory endpoint on a study that failed to find a no-observed-adverse effect level (NOAEL) and is instead using a low-observed-adverse effect level (LOAEL), EPA policy requires an additional tenfold uncertainty factor.[9]

Moreover, because "[e]xposure to pesticide residues from ambient air sources is generally higher in areas close to agricultural lands," and "[b]ecause infants and children are subject to nondietary sources of exposure to pesticides," the NAS found that "it is important to consider total exposures to pesticides from all sources combined." NAS Report at 307, 309, 319. The FQPA requires EPA to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to a pesticide from all sources. 21 U.S.C. § 346a(b)(2)(C)(ii)(I), (II) (emphasis added). "Aggregate exposure" includes "all anticipated dietary exposures and all other exposures for which there is reliable information," including pesticide drift exposures. 21 U.S.C. § 346a(b)(2)(A)(ii); *see also id*. § 346a(b)(2)(D)(vi). The

---

[6] EPA, Office of the Science Advisor, An Examination of EPA Risk Assessment Principles and Practices (Mar. 2004) at 30, https://nepis.epa.gov/Exe/ZyPDF.cgi/100045MJ.PDF?Dockey=100045MJ.pdf.
[7] *Id.*
[8] The National Academy of Sciences has endorsed the use of default uncertainty factors to address uncertainties in risk assessments in pivotal studies. *See, e.g.*, NAS, *Science and Decisions* at 7-8, 192 (2009).
[9] EPA, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment at 8-9 (2002), https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf; EPA, A Review of the Reference Dose and Reference Concentration Processes at 4-44 (2002), https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.

FQPA, therefore, requires an assessment based on aggregation of all exposures to a pesticide whether from eating foods, drinking water with residues of the pesticide, or contacting pesticide residues in and around the home or other places where people can be exposed. *Id.* §§ 346a(b)(2)(A)(ii), (C)(i)(I), (D)(vi). The FQPA also requires EPA to assess and protect against unsafe risks posed by cumulative exposures to all pesticides that share a "common mechanism of toxicity," as is the case with pesticides in the organophosphate family. *See id*. §§ 346a(b)(2)(C)(i)(III)-(D)(v).

The FQPA safety standards governs EPA actions in its periodic registration review of tolerances and registrations, as well as its actions on petitions. As the 9th Circuit recently held with respect to chlorpyrifos, the FQPA is clear: EPA cannot leave tolerances in place without affirmatively finding the uses safe. *League of United Latin American Citizens v. Wheeler (LULAC)*, 996 F.3d 673, 693-94 (9th Cir. 2021). Even more on point, where there is evidence correlating learning disabilities and neurodevelopmental harm from exposures to the pesticide at levels below EPA's regulatory endpoint, which is based on exposures that cause 10% cholinesterase, the agency cannot find reasonable certainty of no harm to children. *Id*. at 700-01.

II. UNDER FIFRA, EPA MUST ENSURE THERE ARE NO UNREASONABLE ADVERSE EFFECTS FROM USE OF PESTICIDES IN THE UNITED STATES.

While the FFDCA regulates whether pesticides residues are allowed on food, a different statute – the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – regulates whether and, if so, how a pesticide may be used in the United States. EPA must register a pesticide for each allowable use, and to do so, EPA must find the pesticide use will not generally cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5); *see also id*. § 136d(b) (providing for cancellation of registrations for uses that pose unreasonable adverse effects).

Under FIFRA, EPA may register or maintain a registration of a pesticide only if EPA determines that it will not have "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). An "unreasonable adverse effect[] on the environment" includes "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*. § 136(bb).

The FQPA amended FIFRA's definition of "unreasonable adverse effects" to include "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." 7 U.S.C. § 136(bb). If a pesticide fails to meet the FFDCA "reasonable certainty of no harm" standard, it cannot be used on food and registrations for the food uses must be cancelled.

In 2009, EPA recognized the environmental justice ramifications of applying different scientific standards to food safety and worker risks from pesticides by adopting the Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses (2009)[10]. The 2009 revised methods recognize that the scientific risk

[10] http://lib.ncfh.org/pdfs/2k9/8356.pdf

assessment methods developed to comply with the FQPA, including the FQPA's kids safety factor, had become sound and standard science. It directed EPA to apply them in assessing pesticide risks to workers and their children, and from nonfood pesticide uses.

EPA must review pesticides every fifteen years, in a process called registration review, to ensure they meet both FFDCA and FIFRA legal standards. 7 U.S.C. § 136a(g)(1)(A)(i), (iii)(II). Registration review is designed to "ensure[] that older pesticides meet contemporary health and safety standards."[11] As passed in 1996, registration review had a hortatory 15-year goal. FQPA, Pub. L. 104-170, § 106(b), 110 Stat. 1489 (Aug. 3, 1996). A 2007 amendment replaced that goal with a hard 15-year deadline for registration review and set the deadline for review of the older pesticides as October 1, 2022. Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94, § 3, 121 Stat. 1000 (Oct. 9, 2007).

III. EPA MUST CONSIDER AND SEEK TO REDUCE THE ENVIRONMENTAL JUSTICE IMPACTS OF OP USE.

EPA must assess the environmental justice impacts of drift, food, drinking water, and worker exposures (including take-home exposures) and that assessment should inform EPA's regulatory decisions and mitigation measures. The 1994 Environmental Justice Executive Order requires EPA to ensure that its actions do not have disproportionate impacts on low-income and/or minority populations. *Exec. Order No. 12,898*, 59 Fed. Reg. 7,629 (Feb. 11, 1994). Specifically, EPA and other executive agencies must, to the maximum extent practicable, "identify[] and address[] . . . disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations." *Id.* at § 1-101. In furtherance of this mandate, EPA is required to "collect, maintain, and analyze information assessing and comparing environmental and human health risks borne by populations identified by race, national origin, or income" and "use this information to determine whether their programs, policies, and activities have disproportionately high and adverse human health or environmental effects on minority populations and low-income populations . . . ." *Id.* at § 3-302(a).

Likewise, the 1997 Executive Order on Children's Health requires EPA to protect children from environmental health and safety risks. *Exec. Order No. 13,045*, 62 Fed. Reg. 19,885 (Apr. 23, 1997). Specifically, EPA is required to "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health or safety risks . . . that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breath [sic], the food we eat, the water we drink or use for recreation, the soil we live on, and the products we use or are exposed to)." *Id.* at §§ 1-101(b), 2-202(b). Viewed together, these two executive orders require EPA, in making pesticide registration and tolerance decisions, to assess pesticide drift exposures and all other pesticide exposures to ensure that OP exposures do not disproportionately impact children, low-income populations, and/or minority populations.

[11] EPA, Evaluation of the U.S. EPA Pesticide Product Reregistration Process: Opportunities for Efficiency and Innovation at 1-1 (Mar. 2007), https://www.epa.gov/sites/production/files/2015-09/documents/eval-epa-pesticide-product-reregistration-process.pdf; 40 C.F.R. § 155.40.

President Biden and EPA Administrator Regan have made advancing environmental justice and using the best science central in how EPA makes its decisions. Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021);[12] Executive Order 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (Jan. 20, 2021);[13] https://www.epa.gov/speeches/administrator-michael-regan-remarks-nejac-meeting-prepared-delivery. The EPA has translated the commitments of these Executive Orders into its current Draft Strategic Plan, published on October 1, 2021. Specifically, the strategic plan adds "advance[ing] justice and equity" as a fourth "foundational principle," which is to be "infuse[d]" into "all" of EPA's work:

> In this Strategic Plan, the Agency renews its commitment to the three principles articulated by William Ruckelshaus, who served as the EPA's first Administrator (1970 – 1973, and then again from 1983 – 1985), to: follow the science, follow the law, and be transparent. The Agency also adds a fourth foundational principle: advance justice and equity. We add this principle to infuse the consistent and systematic fair, just, and impartial treatment of all individuals into all EPA policies, practices, and programs. These principles form the basis of the Agency's culture and will guide our operations and decision making now and into the future….[14]

Objective 2.2, "Embed Environmental Justice and Civil Rights into EPA's Programs, Policies, and Activities," provides that EPA will "[i]ntegrate environmental justice and civil rights in all of the Agency's work to maximize benefits and minimize impacts to underserved and overburdened communities."[15] Among the strategies identified to meet this Objective 2.2. is "[e]nsuring that EPA decision making incorporates meaningful community involvement and *analyzes for disproportionate impacts*."[16] Under Cross-Agency Strategy 2, EPA's Draft Strategic Plan commits to "[c]onsider the health of children at all life stages and other vulnerable populations" and to "strengthen protections" for children and vulnerable populations:

> To best protect children's environmental health at all life stages and vulnerable populations, EPA will identify, evaluate, develop, and promote the use of science to support its policies, decisions, and actions, including regulations and voluntary programs. EPA will ensure that Agency toxicity, exposure, and risk assessments consider all relevant and available science to address the unique vulnerabilities of children and vulnerable populations, including disproportionate impacts related to racial, ethnic, income, or other social determinants of health. These assessments will inform the evaluation and selection of the levels of exposure for regulatory action that are protective of children and vulnerable populations, including the extent to which cumulative or

---

[12] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/

[13] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

[14] EPA, Draft FY 2022-2026 EPA Strategic Plan 4 (Oct. 1, 2021), at https://www.epa.gov/system/files/documents/2021-10/fy-2022-2026-epa-draft-strategic-plan.pdf.

[15] *Id.* at 25 (emphasis added).

[16] *Id*. (emphasis added).

> concurrent exposures to chemical and social stressors can modify exposure or hazard considerations."[17]

It continues, under the subtitle "Address Disparities," to state:

> EPA will protect children and vulnerable populations who live in disproportionately impacted communities. EPA will consider how social determinants of health affect children and vulnerable populations, especially as these challenges may reduce resiliency or ability to recover from exposure to environmental hazards.[18]

Most U.S. farmworkers are of Latin American origin—approximately 83% of U.S. farmworkers are of Latin American ancestry.[19] Children of farmworkers live and go to school near the agricultural fields where their parents work. For example, in California over 73% of children attending schools within 1.5 miles of sites where at least 10,000 pounds of pesticides were applied in 1998 were people of color.[20] Moreover, farmworker families tend to be poor—on average, a farmworker family earns an annual income ranging from $20,000-$24,999.[21] In the top five agricultural counties in Texas (the state with the most acres of agriculture), between 21.2 to 35.2% of children live in poverty.[22] Likewise, in California (the top agricultural state by revenue), between 24 to 32% of children under the age of 17 live in poverty in the top three agricultural counties (compared with the state average poverty rate of 12.4%).[23]

Farmworkers' persistent exposure to harmful pesticides has resulted in an average of 57.6 out of every 100,000 agricultural workers reporting acute pesticide poisoning, illness, or injury each year.[24] These numbers exclude the many workers who suffer chronic health problems as a result of pesticide exposures, and do not factor in the known under-reporting of pesticide poisonings and illnesses—as many as 88% of acute poisoning incidents are not reported to public health authorities.[25] In its proposed Worker Protection Standard revisions, EPA rightly

---

[17] *Id*. at 81-83.
[18] *Id.* at 82.
[19] Findings from the National Agricultural Workers Survey (NAWS) 2015-2016 (NAWS 2015-16): A Demographic and Employment Profile of United States Farmworkers, Research Report No. 13 (Jan. 2018), https://www.dol.gov/sites/dolgov/files/ETA/naws/pdfs/NAWS_Research_Report_13.pdf.
[20] Environmental Working Group, *Every Breath You Take: Airborne Pesticides in the San Joaquin Valley* (Jan. 2001).
[21] NAWS 2015-16.
[22] U.S. Department of Agriculture, 2018 County-Level Poverty Rates for Texas, https://data.ers.usda.gov/reports.aspx?ID=17826; *see also* USDA 2017 Census of Agriculture State Profile: Texas, https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/County_Profiles/Texas/cp99048.pdf (listing top counties with land in farms as Pecos, Hudspeth, Brewster, Webb, and Presidio).
[23] Alice C. Larson, *Migrant and Seasonal Farmworker Enumeration Profiles Study: California* (Sept. 2000).
[24] Geoffrey M. Calvert *et al*., *Acute Pesticide Poisoning Among Agricultural Workers in the United States*, 1998-2005, 51 Am. J. Indus. Med. 883, 890 (2008).
[25] *See* Joanne Prado, et al., *Acute Pesticide-Related Illness Among Farmworkers: Barriers to Reporting to Public Health Authorities*, 22(4) J. Agromedicine 395 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5846675/pdf/nihms939406.pdf.

acknowledges that "[u]nderreporting of pesticide incidents is a challenge," and assumes that only 25% of acute pesticide incidents are reported.[26] Farmworkers are deterred from reporting pesticide illnesses due to fear of retaliation, health care workers often lack the training to diagnose illnesses from pesticide exposures, and there is no national pesticide incident reporting system that could be utilized by clinicians and others who work with farmworkers.[27] Other factors contributing to under-reporting include language barriers, lack of access to medical care, lack of information for workers about hazards they face, workers' lack of awareness of poisoning symptoms, and lack of health care professionals trained in diagnosis of pesticide illness.[28]

Agricultural workers need effective workplace protections because they represent some of the most economically and educationally disadvantaged people in the United States.[29] And as recent times have so painfully shown, farmworkers face harms not only from their exposures to toxic pesticides, but those harms are exacerbated by extreme temperatures and wildfire smoke they often have to endure, as well as their vulnerability to COVID-19.[30]

When working on revisions to the Worker Protection Standard, EPA described some of the disproportionate burdens borne by these workers:

> According to information published by the Department of Labor's (DOL) NAWS in 2001-2002, 75% of agricultural workers in the United States were born in Mexico and 2% in Central America. A majority (81%) of this group speaks Spanish as a native language, but a growing percentage speaks languages such as Creole, Mixteco, and indigenous languages. Approximately 44% could not speak English at all, and 53% could not read any English. . . .
>
> In general, agricultural workers surveyed by NAWS do not use health care facilities. Estimates of agricultural workers lacking health insurance range

---

[26] Worker Protection Standard Revisions, 79 Fed. Reg. 15,444, 15,453, 15,459 (Mar. 19, 2014). Focus groups conducted by the Washington Department of Health revealed that 75% of the workers reported that they or someone close to them had become ill from pesticides at work and often they did not seek medical care because they could not afford losing wages, feared losing their jobs, didn't know worker's compensation would pay for the visit, or mistrusted the health care providers as being aligned with the employers. Washington State Department of Health, *Learning from Listening: Results of Yakima Farmworker Focus Groups About Pesticides and Health Care* (June 2004).

[27] U.S. Gen. Accounting Office, Pesticides on Farms: Limited Capability Exists to Monitor Occupational Illnesses and Injuries at 9 (Dec. 1993), http://archive.gao.gov/t2pbat4/150612.pdf; *see also* Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States*, 1998-2005, 51 Am. J. Indus. Med. 883, 894-95 (2008) (discussing reasons why agricultural workers are deterred from seeking health care and why health care professionals misdiagnose acute pesticide poisonings).

[28] *Id.*

[29] Daniel Carroll et al., *Changing Characteristics of U.S. Farm Workers: 21 Years of Findings from the National Agricultural Workers Survey* (May 12, 2011), https://migrationfiles.ucdavis.edu/uploads/cf/files/2011-may/carroll-changing-characteristics.pdf.

[30] Rafter Ferguson, Kristina Dahl, and Marcia DeLonge, *Farmworkers at Risk: The Growing Dangers of Pesticides and Heat*, Union of Concerned Scientists (Dec. 2019), https://www.ucsusa.org/resources/farmworkers-at-risk.

from 77% to 85% and estimates from the late 1990s indicate only 20% of those surveyed had visited a health care facility in the preceding 2 years. U.S. Department of Agriculture (USDA) research, based on NAWS data, also reports that workers have difficulty entering the health care system to receive treatment. Cost was a significant barrier for two-thirds of farmworkers, while about a third listed language barriers as an impediment to receiving care. The problem is more severe among undocumented workers because they fear seeking treatment will lead to deportation or other adverse legal action.[31]

EPA must account for these disproportionate vulnerabilities and the heightened exposures farmworkers and their families face to OP pesticides. Only with such a full accounting can EPA meet its statutory obligations to ensure reasonable certainty of no harm from food uses and no unreasonable adverse effects from other uses of the OPs.

REGULATORY BACKGROUND OF THE ORGANOPHOSPHATES

Organophosphates are a class of pesticides developed as nerve agents in World War II. Sarin gas is the best-known OP used in chemical warfare. After the war, chemical companies adapted OPs for commercial pesticide use, mostly as insecticides. The OPs began to be used in the U.S. in the 1950s and became some of the most widely used pesticides in the U.S. The most recent data from the U.S. Geological Survey (USGS) on OP usage on agricultural crops is reflected in the table below:

Table 1: OP Pesticide Usage Aggregated Across the United States

	E-Pest Low*		**E-Pest High****	
Pesticide Name	**Total Volume (kg)**	**Total Volume (lb)**	**Total Volume (kg)**	**Total Volume (lb)**
Acephate	**1,669,553.10**	**3,680,734.52**	**3,291,062.40**	**7,255,550.61**
Bensulide	279,711.49	616,658.29	291,404.59	642,437.16
Chlorethoxyfos	8,630.30	19,026.55	66,809.70	147,290.18
Chlorpyrifos-methyl	-	-	-	-
Diazinon	51,812.60	114,227.23	790,138.40	1,741,956.99
Dichlorvos	-	-	-	-
Dicrotophos	373,657.70	823,774.22	404,729.60	892,276.03
Dimethoate	251,771.20	555,060.48	790,138.40	**1,741,956.99**
Ethoprop	59,515.80	131,209.88	404,881.10	892,610.03
Malathion	234,353.70	516,661.47	370,103.70	815,938.99
Naled	120,985.00	266,726.27	202,638.80	446,742.09
Phorate	226,552.80	499,463.43	384,089.70	846,772.84

[31] 79 Fed. Reg. at 15,444, 15,452 (internal citations omitted).

	E-Pest Low*		E-Pest High**	
Pesticide Name	**Total Volume (kg)**	**Total Volume (lb)**	**Total Volume (kg)**	**Total Volume (lb)**
Phosmet	287,528.20	633,891.17	311,102.60	685,863.83
Terbufos	173,587.30	382,694.49	935,773.10	**2,063,026.55**
Tribufos	**1,055,683.00**	**2,327,382.63**	**1,191,828.70**	**2,627,532.52**

* EPest-low estimates rely on models that assume zero use for any crop where pesticide use data was not reported within a crop reporting district, or CRD, and thus more accurately reflect state-based pesticide use restrictions.

**EPest-high estimates rely on pesticide use data from crops in neighboring or regional CRDs to estimate unreported crop-specific pesticide use data.

Note: pesticide use volumes greater than 1 million pounds or kilograms are bolded. Recent USGS pesticide use data was not available for chlorpyrifos-methyl or dichlorvos.

OPs are used on a wide variety of foods from fruits, nuts, vegetables, wheat, alfalfa, corn, and soy. They are widely used on foods eaten by children like apples, pears, berries, oranges, tomatoes, potatoes, green beans, and peas.

OPs cause acute pesticide poisoning when people come into contact with them. OPs suppress an enzyme called cholinesterase that regulates nerve impulses through the body. When levels of cholinesterase are inhibited, people can experience a range of symptoms from nausea, vomiting, headaches, and dizziness to seizures, paralysis, and even death in some instances.

Every year, OPs are linked to pesticide poisonings. The reported incidents are merely the tip of the iceberg as pesticide poisonings are significantly under-reporting due to such factors as inadequate reporting systems, fear of retaliation from employers, and reluctance to seek medical treatment.

I. EPA'S 2006 REREGISTRATION OF OPS UNDER THE FQPA

It was not until after Rachel Carson published *Silent Spring* that U.S. law was amended to require EPA approval before pesticides could be marketed, sold, and used in the U.S. Older pesticides, like the organophosphates, were grandfathered so they could remain on the market without EPA approval. That changed when Congress passed the FQPA in 1996 to strengthen food safety laws for pesticides and particularly to protect children. The FQPA gave EPA a 2006 deadline to ensure older pesticides met federal food safety and environmental standards through a reregistration process.

Scientists at the forefront of the NAS study committee believed the reregistration process would lead to a ban on chlorpyrifos and other OPs because of the risks to children and emphasis

placed by the FQPA on protecting against neurodevelopmental harm.[32] However, reregistration ended some uses, but allowed extensive use of the OPs to continue.

EPA prioritized the organophosphates in its FQPA reregistration schedule because they "pose the greatest risk to public health." 65 Fed. Reg. 42,021 (Aug. 4, 1997). EPA conducted individual risk assessments for each organophosphate and eventually did a cumulative risk assessment of this class of pesticides because they cause acute pesticide poisonings of people in the same way; in the language of the FQPA, they have a common mechanism of toxicity, cholinesterase inhibition. When some individual risk assessments revealed unsafe exposures, EPA took action to reduce or eliminate them, for example, by ending residential use of several of the OPs. It did so before it completed a cumulative risk assessment for all the OPs as a class. Once EPA completed that cumulative risk assessment in 2006, it re-registered nearly three dozen organophosphate pesticides.

Based on its individual risk assessments for some OPs, EPA decided that most home uses had to be banned because of children's exposures when they crawl on carpets and lawns or hug pets treated with flea bombs. It did this for chlorpyrifos, diazinon, dimethoate. With chlorpyrifos, EPA made a deal with Dow Agrosciences in which Dow agreed to voluntarily cancel in-home uses and in return most agricultural uses were allowed to continue.

As reregistration neared its conclusion, Local Presidents of EPA unions representing scientists, risk managers, and related staff, sent a letter to the EPA Administrator expressing their concern that "EPA could betray the public trust by violating the intention of the Food Quality Protection Act (FQPA) to protect the Nation's infants, children, and susceptible subpopulations, unless the Agency adheres to principles of scientific integrity and sound science in the pesticide tolerance reassessments it is undertaking."[33] The letter cited concerns expressed by the SAP that "the Pesticide Program's current approaches may not be sufficiently conservative, may underestimate the risks to infants and children, and do not adequately identify individuals that may be inherently sensitive to neurotoxicants. (May 25, 1999 SAP meeting)." The unions also criticized EPA for failing to address *in utero* exposures when pregnant women handle pesticides or enter treated fields, exposure to neurotoxic pesticides by infants and children who commonly enter fields treated with these pesticides while accompanying their parents employed to perform post-application tasks, and farmworker children's exposures through pesticide drift onto outdoor play areas and through exposure to pesticide residues on their parents' hair, skin, and clothing. Finally, the letter asked that

> EPA issue an interim reregistration decision mandating that maximum protections - engineering controls for handlers and longer re-entry intervals for postapplication labor- be put into place for agricultural uses of these pesticides; where this is not feasible, cancel

---

[32] Philip J. Landrigan & Charles Benbrook, *Opinion: To Get High-Risk Pesticides Out of Our Bodies, Insulate the EPA from Politics and Follow the Science* (Aug. 3, 2021), https://www.ehn.org/pesticide-solution-2654345160.html.

[33] Letter from Local Presidents of EPA Unions to EPA Administrator Stephen L. Johnson (May 24, 2006).

these registrations, as EPA promised before. EPA issued PR Notice 2000-9 in 2000 to this effect[.]

In its response to comments on this PR notice, EPA stated that the Agency will seek cancellation of uses if available risk mitigation measures, such as engineering controls and extended REI's, do not provide an adequate margin of safety and the risks outweigh the benefits: (http://www.epa.gov/PR_Notices/draftprworker-response.htm).[34]

The reregistration process eliminated or reduced some food uses of the OPs, but EPA allowed a lot of food uses to continue. Even though scientific studies had documented neurodevelopmental harm to children from OP exposures, EPA did not address such harm in its risk assessments or the reregistration process. Nor did EPA address children's exposures to pesticides through drift, volatilization, or residues brought home by workers on their clothing. EPA also failed to heed the unions' request that EPA adopt maximum protections for workers to avoid risks of concern or cancel uses where that is not possible.

II. REGISTRATION REVIEW OF THE OPS

EPA has on ongoing obligation to ensure pesticide use and exposures will comply with federal health and environmental standards through a process called registration review. EPA has a hard statutory deadline of October 1, 2022, to complete registration review of all pesticides registered before 2007, which includes the organophosphates. "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." 40 C.F.R. § 155.40(1). Before EPA's registration review got underway, about one dozen of the OPs re-registered in 2006 had all uses cancelled and are no longer used in the U.S. Use of other OPs declined. This petition addressed 16 OPs that have substantial agricultural use and harmful human health impacts.

A. EPA Prioritized the OPs Because of Their Risks

EPA prioritized the organophosphates in establishing schedules for registration review because of growing scientific evidence of damage to children's brains from exposures. In 2008 and 2009, it solicited public comment and adopted work plans for each organophosphate pesticide. The work plans generally gave EPA six years or until 2014-2015 to complete registration review for each pesticide. Available through individual pesticide searches at https://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1.

It put chlorpyrifos, a widely used OP. at the head of the line because of an administrative petition filed in 2007 by Pesticide Action Network and Natural Resource Defense Council to revoke all food tolerances and food uses of chlorpyrifos. The petition raised two issues that EPA had failed to address in reregistering chlorpyrifos and the other OPs: (1) neurodevelopmental harm to children at low-level exposures; and (2) exposure through pesticide drift and volatilization.

[34] *Id*.

1. Integrating Epidemiology and Biomonitoring into Risk Assessments.

To address the first issue, EPA developed methods to integrate epidemiology studies into risk assessments in a draft framework subsequently finalized in 2016.[35] Using the draft framework, EPA conducted extensive reviews of the scientific literature correlating chlorpyrifos exposures with damage to children's brains, including lower IQs, loss of working memory, developmental delays, attention deficit disorders, and structural changes in the brain. It found that these types of neurodevelopmental harms occurred at exposures below those that cause 10% cholinesterase inhibition. In 2014, it released its revised human health risk assessment incorporating these findings and documenting risks of concern from drinking water exposures, and on October 30, 2015, it proposed a rule to revoke all tolerances for chlorpyrifos, which would end all food uses because of drinking water contamination that exposes infants to unacceptable risks. 80 Fed. Reg. 69,080 (Nov. 6, 2015).

In 2015, EPA completed a literature review of the studies documenting neurodevelopmental harm from organophosphates. This review similarly correlated OP exposure with learning disabilities and other neurodevelopmental harm to children. EPA retained the FQPA kids 10X safety factor in the OP risk assessments because of the neurodevelopmental harm to children.

The OP literature review concluded that the neurodevelopmental harms occurred at exposures below those that cause 10% cholinesterase inhibition. OP Literature Review at 77.[36] As explained in a recent OP draft human health risk assessment, "exposure levels in the range measured in the epidemiology studies are likely low enough that they are unlikely to result in AChE" inhibition. Naled Draft HHRA at 31; Ethoprop HHRA at 22. This petition explains below that using 10% cholinesterase inhibition is underprotective given that neurodevelopmental harm to children occurs from lower exposures and asks EPA to update its OP risk assessments to ensure children are protected from neurodevelopmental harm.

2. Addressing Drift and Volatilization

EPA also developed methods to assess risks from spray drift and pesticide volatilization. EPA did so both to respond to the chlorpyrifos petition and to a 2009 farmworker-led petition – the Kids' Drift Petition – seeking protections for children from spray drift for pesticides generally and for OPs and other nerve-toxic pesticides specifically. *Pesticides in the Air—Kids*

---

[35] EPA OPP, *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (Dec. 28, 2016) at 4, https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.

[36] EPA Office of Pesticide Programs, Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides, D331251 (Sept. 15, 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0062-0055; EPA Office of Pesticide Programs, Updated Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides, D437043 (Dec. 29, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0316-0029.

at Risk: Petition to EPA to Protect Children from Pesticide Drift (Oct. 13, 2009), at EPA-HQ-OPP-2009-0825. The Kids' Drift Petition asked EPA to correct its earlier failure to address exposure to pesticides drift in its pesticide re-registration decisions and, while it corrects that legal error, to interim spray buffer zones around homes, schools, playgrounds, and any other areas where children play or gather in order to protect children from health risks associated with drift. In the course of addressing both the 2007 chlorpyrifos petition and the Kids' Drift Petition, EPA acknowledged that it has a legal duty to protect children from pesticide drift and that it had failed to do so in its pre-2007 re-registrations.

EPA also stated that it had prioritized and put the organophosphates at the front end of the registration review process. Agency Response to "Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift" at 35 (2014). In a subsequent legal challenge, EPA defended its refusal to require interim buffers by telling the court that it would develop pesticide-specific buffers as part of its final registration review decisions in 2015 and 2016 for all the pesticides, except one that would occur in 2017. *See Pesticide Action Network N. Am. v. EPA*, No. 14-71514, Docket No. 41 at 4 (9th Cir. May 4, 2016). In July 2016, the Ninth Circuit upheld EPA's denial of the request for interim buffers. 654 Fed. Appx. 887, 2016 WL 3619950 (9th Cir. July 5, 2016).

EPA developed a spray drift model to assess risks from spray drift in its human health risk assessments. It first applied that model to assess spray drift risks from chlorpyrifos and found spray drift risks of concern from various applications of chlorpyrifos. In 2012, pursuant to its policy of mitigating risks that emerge during registration review even before that review has been completed, EPA pressed chlorpyrifos registrants to amend their labels to require 10-100 foot buffers around schools, homes, and other populated areas to protect bystanders from pesticide drift outside of the registration review process. *See* 2014 Chlorpyrifos HHRA at 82; Spray Drift Mitigation Decision for Chlorpyrifos (July 2012) ("Where risks are identified early in the registration review process and opportunities for early mitigation exist, the Agency will pursue those opportunities as they arise, rather than waiting for completion of a chemical's registration review in order to mitigate the risks.").[37] By December 2012, chlorpyrifos labels included reduced application rates and no-spray buffers of different sizes depending on the spray application method around sensitive sites, which are defined as areas frequented by non-occupational bystanders, especially children, including homes, farmworker housing, schools, day care centers, nursing homes, hospitals, residential lawns, pedestrian sidewalks, and outdoor recreational areas such as school grounds, athletic fields, and parks. 2020 Chlorpyrifos HHRA at 48.

EPA used its spray drift methodology in its OP risk assessments to assess the risks from spray drift. For every OP sprayed through the air, EPA found pesticide drift posing risks of concern outside the fields where the OP is sprayed. EPA also developed a model to assess volatilization, but it has yet to apply that model to most of the OPs.

[37] EPA, *Chlorpyrifos Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures* at 7 & Appendix C (July 13, 2012) (EPA-HQ-OPP-2008-0850-0105).

B. The Trump Administration Stalled Registration Review of the OPs

Before the 2016 election, EPA had lagged behind its timeline for reviewing and taking action on the OPs, but it had been steadily releasing draft health risk assessments and had continued to schedule interim and final OP decisions in its registration review schedules. EPA had released draft human health risk assessments for almost all the organophosphates by 2017. During the first half of 2017, its registration review schedule indicated that draft health risk assessments for the remaining organophosphates would be released in fiscal year 2017, and it would begin issuing interim and then final decisions for these pesticides. Schedule as of January 19, 2017 available at https://19january2017snapshot.epa.gov/pesticide-reevaluation/registration-review-schedules_.html.

In September 2018, EPA posted its fiscal year 2018 registration review schedule, which listed no OPs. Available at https://www.epa.gov/pesticide-reevaluation/registration-review-schedules. EPA had purged the schedule of all OPs. It took no actions on OP pesticides in fiscal year 2019 and listed only a couple actions on OPs with minor usage on the registration review schedule. *Id*. As a result, the OP risk assessments languished in the agency without measures being put in place to protect children, workers, and others in harm's way.

THE PETITION ASKS

This petition asks EPA: (1) to reprioritize the OPs in the registration review process; (2) to revoke food tolerances and cancel associated registrations for all OP uses EPA cannot find safe; (3) to cancel registrations for OP uses that cause unreasonable adverse effects to workers; and (4) to update its human health risk assessments to ensure they are using a regulatory endpoint that will prevent neurodevelopmental harm to children from exposures below those that cause 10% cholinesterase inhibition.

I. EPA MUST END ITS UNREASONABLE DELAY AND ACT EXPEDITIOUSLY TO PROTECT PEOPLE FROM THE OPS.

Recently, EPA has put the OPs back in the registration review queue, but the incessant delays will make it hard for EPA to take actions to protect people from the OPs by the October 1, 2022, registration review deadline unless it redoubles its efforts. This petition asks EPA to do just that. It should put an end to the delays in protecting people from OP pesticides.

In keeping with its policy of putting mitigation in place or ending harmful uses before completion of the registration review process, it should act expeditiously to eliminate unsafe food uses. EPA adhered to this policy when it required no-spray buffers for chlorpyrifos in 2012, long before the end of registration review of the pesticide, which still has not been completed. EPA similarly put immediate warnings and requirements in place in 2016 to reduce poisonings and suicides from exposure to paraquat in the middle of the registration review of that pesticide. Paraquat Dichloride Human Health Mitigation Decision, EPA-HQ-OPP-2011-0855-0112 (Dec. 14, 2010). EPA also structured the re-registration process to act on the risks of concern documented in individual OP risk assessments through interim re-registration decisions, long before completion of a cumulative risk assessment for all the OPs. It is pursuing an analogous interim decision-making process for the OP registration reviews. This petition asks

EPA to take action to protect people from the risks of each individual pesticide as soon as possible, without waiting for ESA consultations, implementation of the endocrine disruptor screening program, and the cumulative OP risk assessment.

This petition also asks EPA to revoke tolerances as soon as possible based on the risks documented in its OP risk assessments to date. However, these risk assessments are based on an underprotective endpoint. To comply with its legal obligations, EPA will need to update these risk assessments to ensure children are protected from neurodevelopmental harm from lower-level exposures. Hopefully, that can be done expeditiously. If not, EPA must revoke all tolerances and cancel all registrations for OP uses it cannot find safe in the aggregate based on its risk assessments and take further action later to address remaining uses that also prove unsafe under the updated risk assessments.

While this administration cannot turn back the clock and undo harm OPs have caused to children in the past years of delay, it can move swiftly to prevent such harm going forward. It should learn from the chlorpyrifos saga that it must revoke tolerances and cancel registrations if it is unable to find the OP use is reasonably certain to cause no harm to children. And it cannot make such a finding in the face of the scientific evidence that children suffer from learning disabilities and other neurodevelopmental harm from exposures below EPA's regulatory endpoint.

II. EPA MUST REVOKE TOLERANCES AND CANCEL REGISTRATIONS FOR FOOD USES ITS RISK ASSESSMENTS FIND UNSAFE.

Due to their serious health effects, growers have decreased their use of many OPs and shifted to other pest control methods. Nearly three dozen OPs were re-registered during the re-registration review process that ended in 2006. Before this round of registration review, about a dozen OPs were phased out due to their health risks, and several have only minimal remaining usage. This petition focused on 15 OPs that going through registration review that pose serious risks of concern.

Using 10% cholinesterase inhibition as the regulatory endpoint, EPA began releasing preliminary human health risk assessments for OPs in 2011. This petition addresses later why 10% cholinesterase inhibition is an under-protective endpoint. Even using that endpoint, EPA's risk assessments document unsafe exposures from OPs that warrant revocation of food tolerances and cancellation of registrations for the associated food uses.

As the 9th Circuit explained recently with respect to chlorpyrifos:

> once the EPA has become aware, through a petition or otherwise, of genuine questions about the safety of an existing tolerance, the EPA has its own continuing duty under the FFDCA to determine whether a tolerance that was once thought to be safe still is, and here the EPA's own studies and pronouncements still in effect show that it regards chlorpyrifos as harmful at levels below the existing tolerances.

LULAC, 996 F.3d at 691. In the face of such evidence, EPA cannot leave a tolerance in place without making an affirmative safety finding under the FFDCA. *Id*. As with chlorpyrifos,

EPA's risk assessments for the OP pesticides document pervasive risks of concern. EPA cannot, in the face of these risk assessments, find these pesticide uses safe. It cannot find "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii). Because EPA can "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," *id*. § 346a(b)(2)(A)(i) (emphasis added), EPA must revoke the tolerances for these uses. It has a nondiscretionary duty to revoke the tolerances. *LULAC*, 996 F.3d at 700-01. And because a pesticide cannot be registered for a food use if it fails to pass muster under the FFDCA safety standard, EPA must cancel the registrations for these food uses. 7 U.S.C. § 136(bb).

A. OPs That Pose Risks of Concern to People Through All Routes of Exposure

For all of 15 OPs, EPA has documented exposures that are unsafe and violate the law. All pose risks of concern, meaning risks above the level that EPA believes it could find to be safe and in compliance with the law.

The risks of concern can be categorized by the type of exposures, e.g., food, drinking water, drift, and workers. The table below depicts EPA's the risks of concern documented in EPA's risk assessments for the OPs in registration review:

Table 2: Exposure Pathways of Concern

	Exposure Pathways of Concern			
Pesticide Name	**Food and/or Drinking Water**	**Spray Drift**	**Occupational Handlers**	**Occupational Field Workers**
Acephate	●	●	●	●
Bensulide	●	●	●	●
Chlorethoxyfos	●	N/A	●	N/A
Chlorpyrifos-methyl	●	N/A	●	N/A
Diazinon	●	●	●	●
Dichlorvos	●	N/A	●	N/A
Dicrotophos	●	●	●	●
Dimethoate	●	●	●	●
Ethoprop	●	●	●	N/A
Malathion	●	●	●	●
Naled	●	●	●	●
Phorate*	-	-	●	-
Phosmet	●	●	●	●
Terbufos	●	N/A	●	N/A
Tribufos	●	●	●	●

● = an exposure pathway that is associated with risk levels of concern, according to EPA's human health risk assessments

N/A = an exposure pathway that is not expected for this pesticide based on typical application methods

* = this table does not reflect any exposure pathways for phorate other than occupational handler exposures because EPA has not conducted a human health risk assessment for phorate since 1999.

Some OPs pose risks of concern through every way people can be exposed, as illustrated by the following examples.

1. Dimethoate

Dimethoate is registered for use on a wide variety of agricultural crops, Christmas trees and other tree crops, ornamentals, and non-cropland adjacent to agricultural fields. In 2002 as part of the re-registration process, all residential uses were cancelled due to the risks to children. In addition to corn, alfalfa, and wheat, it is used on broccoli, cauliflower, tomatoes, celery, lettuce, peas, oranges, and peppers, among other fruit and vegetable crops.

EPA's 2015 human health risk assessment documents risks of concern to people every way they are exposed to dimethoate.

- Risks from food exceed EPA's level of concern for the U.S. population as a whole and for children 1-2 years old, the most highly exposed subgroup from food. The steady-state risks from food alone are 410% EPA's safety level for the general population and 810% the safety level for 1-2-year old children. Dimethoate HHRA at 6, 36.[38]
- Steady-state drinking water risks from drinking water alone also exceed EPA's safety levels for infants, the most highly exposed population from drinking water, for almost all dimethoate uses. *Id*. at 6, 42-46. The risks to infants are 4100% safe levels for broccoli and cauliflower in California, 3600% for citrus in Florida, 4700% for peppers in Florida, 1100% for corn in Illinois, and 5200% for tomatoes in Pennsylvania. *Id*.
- When drinking water and food risks are aggregated, the total dietary risks (steady-state) the results are over 970-1200% for infants for scenarios where they are the most highly exposed subpopulation, and 810-880% of safe levels for children 1-2 years old, for the scenarios where they are most highly exposed subpopulation. *Id*. at 6, 36.
- Both children and adults face risks of concern from pesticide drift from many exposure scenarios, some at distances greater then 300 feet from the field. Aerial spraying poses the highest risks to bystanders.
- Occupational handlers face risks of concern from combined dermal and inhalation exposures from almost all scenarios under the current label conditions. Only 5 out of 40 scenarios did not pose risks of concern with PPE or engineering controls above what is currently required on the labels. *Id*. at 7, 53. EPA documented risks of concern from all application methods, including aerial, airblast, groundboom, and backpack applications. *Id*. at 54-57. Aerial, airblast, and backpack applications pose the highest risks.
- Field workers face risks of concern for many activities, like harvesting, thinning, and irrigating, without longer re-entry intervals than currently required. For some tasks, the risks persist for more than 30 days, while current labels impose REIs ranging from 2-24 days. *Id*. at 7, 60-71. The risk assessment includes recommendations to lengthen the REIs required for 20 crops and for 8 of these crops to 26-30 days. *Id*. at 70-71.

[38] Steady-state assessment considers the risk from a 21-day exposure duration.

2. Ethoprop

Ethoprop is used on a variety of vegetable and fruit crops, including potatoes, sugarcane, cabbage, green beans, and cucumbers. It is extremely acutely toxic and, like all the OPs, causes neurodevelopmental harm to children. In addition, it is classified as a likely carcinogen, posing cancer risks above EPA's safe levels in food and even higher risks in drinking water and to workers who apply the pesticide. The re-registration led to the cancellation of uses of ethoprop on peanuts, citrus seedlings, and golf courses, ended aerial spraying, and required closed cabs, closed mixing systems, and respirators. It also required reformulation of granular formulations to reduce dust and inhalation exposures, which pose the greatest risks.

EPA's 2015 human health risk assessment documents risks from ethoprop that are above EPA's safety levels to people however they are exposed.

- Both acute and steady-state dietary risks from food exceed EPA's level of concern for the general population. The steady-state dietary risks are 780% safe levels for the general U.S. population and 1800% safe levels for infants. Ethoprop HHRA at 5, 38-39. Infants are particularly at risk from bananas and banana baby food. Ethoprop HHRA at 38.
- Drinking water risks are also above levels of concern, posing risks that are 3200% EPA's level of concern for the general population and risks over 10,000% EPA's level of concern for infants. Ethoprop HHRA at 5, 39.
- Children 1-2 years old and adults are face extremely high risks from groundboom applications more than 300 feet from the fields where the pesticide is sprayed. *Id*. at 47-51.
- Workers face risks of concern from all mixing, loading, and application tasks. The risks are 1-2 orders of magnitude greater than EPA's risks of concern level for almost all application tasks. Biomonitoring also found risks of concern to workers applying ethoprop even with more PPE than required under current labels. *Id*. at 6-7, 53-63. Ethoprop also poses cancer risks above EPA's safety level to handlers. *Id*. at 7, 64-71.[39]

3. Acephate

Acephate is another OP that poses risk of concern every way people are exposed to it. Acephate is used on a variety of agricultural crops, in outdoor non-agricultural settings, for indoor treatment of commercial and industrial buildings, and in greenhouses. Prominent uses include cotton, celery, lettuce, peppers, cauliflower, and soybeans where the amount used has been increasing significantly. Acephate degrades to methamidophos, which is a more potent neurotoxin. EPA's 2018 human health risk assessment documents risks of concern via dietary, residential, and occupational exposures.

- The dietary risk assessment shows that there are risk estimates of concern even when looking at exposures to drinking water alone or food only exposures at the acute and steady state duration. Acephate HHRA at 6-7. Steady state food only risks are 400% safe levels for the U.S. population and 580% safe levels for children 3-5 years old, the

[39] Field workers do not face risks of concern because ethoprop is applied pre-plant.

most highly exposed population subgroup.

- Drinking water exposures from use on cotton, a high-end-use, are 2400% acute risk of concern levels and 1800% steady state levels for infants, the most highly exposed via drinking water, and from use on celery, a low-end use, they are 1000% acute risk of concern levels and 700% steady state levels for infants. Acephate HHRA at 6-7.

- Unlike most other OPs, acephate continues to be used in and around buildings, including in residential settings, and for other nonagricultural uses where there is significant post-application exposure. Dermal exposures from use of acephate on ornamentals are far above risks of concern for both adults and children. The risks from post-application indoor uses are even more troubling with very severe risks of concern to adults and even more horrific risks to children 1-2 years of age. Acephate HHRA at 48-53.

- Acephate also produces risks of concern from spray drift. The buffers necessary to protect adults and children from risks from exposures to spray drift-deposited residues are up to 300 feet. The major spray-drift risk concerns are from aerial applications. *Id*. at 8, 55-56.

- The vast majority of occupational handler scenarios on agricultural crops pose risks of concern under the current labels. While some risks can be reduced below levels of concern with additional PPE or engineering controls, a third of the occupational handler scenarios assessed still pose risks of concern with additional PPE and/or engineering controls. *Id*. at 8, 60-61.

- In sprayed areas, the minimum time needed to reach acceptable levels of risk before workers can re-enter to perform post-application activities is longer than the 2 days currently required. Risks remain of concern in some situations for more than 30 days after application. The risk assessment indicates that REIs of up to 30 days would be necessary for some crops (citrus, cauliflower, and Brussels sprouts) to reach acceptable dermal risk levels from exposure to the combined residues of acephate and methamidophos. *Id*. at 8, 63-69.

B. <u>OPs That Pose Dietary Risks of Concern</u>

All of the 15 OPs with human health risk assessments as part of the registration review process pose dietary risks of concern. They pose risks of concern in our food or our drinking water or both.

The table below shows the dietary risks of concern found in EPA's human health risk assessments prepared for the ongoing registration review process:

Table 3: Dietary Exposure Risks of Concern for OPs

	Steady State Dietary Exposures	
Pesticide Name	**Food**	**Drinking Water**
Acephate	●	●
Bensulide	○	●
Chlorethoxyfos	○	●[a]
Chlorpyrifos-methyl	●	N/A
Diazinon	○	●
Dichlorvos	●	N/A
Dicrotophos	○	●[a]
Dimethoate	●	●
Ethoprop	●	●
Malathion	○	●
Naled	○	●[a]
Phosmet	●	○
Terbufos	●	●
Tribufos	○	●

● = an exposure pathway that is associated with risk levels of concern for one or more age groups examined in EPA's human health risk assessments

●[a] = drinking water is a main contributor for aggregate (food + drinking water) dietary risk

○ = risk was not identified by EPA for this exposure pathway

N/A = an exposure pathway that is not expected for this pesticide based on typical application methods

Note: all pesticides indicated in this table are associated with one or more dietary exposure routes of concern and have risk assessments currently undergoing registration review.

EPA assesses the risk to the general population and also to subpopulations, including infants and children of various ages. For the OPs, infants and children are the most heavily exposed population because of the foods they eat and amount of water they drink. The table below shows the highest risk subpopulation and level of risk they face for each OP.

Table 4: Dietary Risk of OPs in Children and Infants

	Steady State Dietary Exposure Subpopulation Analysis				
Pesticide	**Highest Risk Subpopulation**	**Highest Risk Subpopulation Exposure Pathway**	**%ssPAD***	**Times Higher Than Risk Level of Concern**	**Percentile**
Acephate	Infants (<1 year old)	Drinking Water	1,800	18	99.9
Bensulide	Infants (<1 year old)	Food + Drinking Water	>10,000	>100	99.9
Chlorethoxyfos	Infants (<1 year old)	Drinking Water**	24,000	240	99.9
Chlorpyrifos-methyl	Children (1-2 years old)	Food	140	1.4	99.9
Diazinon	Infants (<1 year old), Children (1-2 years old)	Drinking Water	>10,000	>100	95
Dichlorvos	Infants (<1 year old)	Food + Drinking Water	590	5.9	99.9
Dicrotophos	Infants (<1 year old)	Drinking Water**	320	3.2	95
Dimethoate	Infants (<1 year old)	Food + Drinking Water	1,200	12	99.9
Ethoprop	Infants (<1 year old)	Drinking Water	>10,000	>100	95
Malathion	Infants (<1 year old)	Drinking Water	480	4.8	99.9
Naled	Infants (<1 year old)	Drinking Water**	550	5.5	99.9
Phosmet	Infants (<1 year old), Children (1-2 years old)	Food	1,900	19	99.9
Terbufos	Infants (<1 year old)	Food + Drinking Water	>10,000	>100	95
Tribufos	Infants (<1 year old)	Food + Drinking Water	226	2.26	95

Note: only pesticides with dietary risks of concern (from food, drinking water, or food + drinking water) are shown in this table.

*%ssPAD refers to the steady state population adjusted dose, and an ssPAD value of 100% is the risk level of concern used by EPA. SsPAD values greater than 100% indicate dietary risk.

**%ssPAD values associated with this exposure route were calculated by aggregating food and drinking water exposures, but drinking water is the likely contributor since risk was not found from food exposures alone.

In the context of determining whether a pesticide is safe, it is somewhat artificial to address food and drinking water risks separately, since all exposures must be found safe in the aggregate under the FQPA. For many OPs, food and drinking water risks pose risks of concern independently and then of course also when they are aggregated. That is the case for dimethoate, ethoprop, and acephate, all discussed above.

It is also the case with terbufos, which is used on field and sweet corn, grain sorghum, and sugar beets. EPA's 2015 dietary risk assessment for terbufos documents dietary risks of concern from food and drinking water exposures separately and when aggregated. The risks to the general U.S. population are 530% safe levels in food alone, 3600% safe levels in drinking water alone, and 3800% when food and drinking water exposures are aggregated. Terbufos HHRA at 15. For infants, the risks of concern are horrific. Infants and 1-2-year-olds face 1100% safe levels from food alone. From drinking water, infants face risks of concern 10,000% of EPA's safe levels with even higher risks when food and drinking water risks are combined. *Id*. Even if EPA required a vegetative buffer to reduce the migration of pesticide residues into drinking water supplies, risks of concern would remain. *Id*. at 17.

1. OPs That Pose Food Risks of Concern

Some of the OP risk assessments document risks of concern from food alone, but not from drinking water exposures. Phosmet is an example of an OP that poses dietary risks of concern from food alone. It is used on a wide variety of orchard crops, including apples, blueberries, cherries, nectarines, oranges, peaches, and pears. The general population has risks of concern 720% safe levels, while infants face the highest risks at 320%-1900% safe levels. The main contributors to these risks are peaches, apples, pears, blueberries, grapes, peas, water, and milk.

Phosmet also poses risks of concern to children and adults from exposures at pick-your-own farms after phosmet has been sprayed. Children and adults who pick blueberries, apples, apricots, cherries, nectarines, peaches, pears, and plums at pick-your-own farms face unacceptable risks. They need to be prohibited from picking the fruit for 19 to more than 30 days after spraying, but current labels prohibit picking for only 3-14 days after spraying.[40]

Chlorpyrifos-methyl is another OP that poses dietary risks of concern from food alone. As its name suggests, it is a cousin of chlorpyrifos marketed for use in grain silos and other structures. EPA's 2015 risk assessment documented risks of concern to children from food with wheat being the primary driver of the risks of concern. Children ages 1-12 face risks of concern as high as 170% from acute exposures and children ages 1-5 face risks of concern as high as 140% from steady state exposures. In December 2016, EPA proposed an interim registration decision that would end use of chlorpyrifos-methyl on wheat due to risks to children from eating cereal.[41]

---

[40] One other OP – malathion – is also used on pick-your-own farms, and it also poses risks of concern from this use.

[41] Chlorpyrifos-methyl is missing studies on inhalation and dermal exposures, as well as cholinesterase inhibition in the young. EPA set a 30X FQPA uncertainty factor due to these data gaps. It did, however, require a developmental neurotoxicity study, without providing a rationale for not doing so.

2. *OPs That Pose Risks of Concern Due to Drinking Water Contamination*

While many OPs are unsafe in both food and drinking water alone, as discussed above, EPA's OP risk assessments identify drinking water of the driver for dietary risks of concern for several of the OPs. The following are illustrative.[42]

Bensulide

EPA's 2016 OP risk assessment found no risks of concern from bensulide on food, but risks of concern in drinking water. Bensulide is used on onion, garlic, shallots, leafy vegetables, and cucurbit vegetables. EPA's risk assessment document extreme risks from drinking water. Acute risks are more than 10,000% EPA's safe level in the highest scenarios and 1600% in the lowest ones, with infants having the highest exposure levels. EPA found risks of concern for all populations. The steady state exposures also were also far above levels of concern (over 10,000% EPA's safe level for the highest exposure levels and over 2900% for the lowest). Bensulide HHRA at 5-6, 36-37.

Malathion

Malathion is widely used in agricultural production on crops such as asparagus, avocado, blueberries, Brussel sprouts, cabbage, cranberries, carrots, celery, cherries, citrus, garlic, grapes, lettuce, onions, pumpkins, strawberries, tomatoes, walnuts, and wheat. Unlike some other OPs, malathion remains available "to the home gardener for residential outdoor uses," including use on vegetable gardens, home orchards, various ornamentals, and lawns. Malathion HHRA at 4. EPA's 2016 risk assessment finds no risks of concern from food alone, but both acute and steady state risks of concern from drinking water. Infants face risks that are 160% to 690% EPA's safe level and 1-2-year-olds face exposures 130%-360% EPA's safe levels from malathion use on FL cabbage, FL strawberry, and WA cherry. Steady state exposures pose risks of concern for the U.S. population with the risks infants face being 470% EPA's safe exposure level.

Diazinon

Diazinon is used on a wide variety of orchard and row crops, including apricots, blueberries, Brussels sprouts, cabbage, raspberries, cantaloupes, carrots, lettuce, onions, plums, and spinach. As with chlorpyrifos, all residential uses were cancelled in 2001 due to risks to children. EPA's 2016 risk assessment did not document risks of concern from food exposures, although children 1-2 years old used 100% of the allowable exposure, meaning EPA left no margin of error. If it protected children from neurodevelopmental harm, children would face unsafe exposures from food alone. EPA's risk assessment documented drinking water exposures above risks of concern, particularly for infants and 1-2-year-olds, who face risks more than 10,000% EPA's steady state risks of concern level for apples and risks are an order of magnitude higher risks that EPA's safe levels for the other foods modeled. Diazinon HHRA at 6, 37, 39.

[42] The dicrotophos and naled human heath risk assessments also document dietary risks of concern primarily from drinking water exposures.

Diazinon is one of the pesticides most frequently detected in surface waters and has been detected in 46 states and every major river basin.

Chlorethoxyfos

Chlorethoxyfos is not widely used. It is used only on corn (field corn, sweet corn, and popcorn) in the Midwest and the Pacific Northwest. It is used only in ground applications in the soil and harvesting is largely done mechanically. It therefore does not pose risks of concerns from spray drift or to field workers. Nor did EPA's 2016 risk assessment document food risks of concern. However, steady state dietary risks, largely from drinking water exposures, are at 8000% EPA's safe levels for the U.S. population as a whole and at 24,000% safe levels for infants under one year of age.

C. OPs That Cause Toxic Drift

Children can be exposed to pesticides through pesticide drift—the airborne movement of pesticides off the target application site. The 1993 NAS observed that "[e]xposure to pesticide residues from ambient air sources is generally higher in areas close to agricultural lands and in communities surrounding pesticide manufacturing factories." NAS Report at 309. To guard against harms associated with pesticide exposures, NAS recommended "exposure from all sources—not just ingestion—must be considered when estimating total [pesticide] exposure and risk to children." *Id.* at 307.

Pesticide incident reports include numerous reports of acute pesticide poisonings from drift of OP pesticides. For example, in California, 60 incidents involving dimethoate were reported between 2008-2013; 43 involved residents or field workers experiencing poisoning symptoms after being exposure to pesticide drift after aerial spraying of dimethoate. An incident was reported in Washington in 2002 when 24 children and their bus driver were exposed when drift from an aerial application came through the windows of their bus on the way home from school.

The California pesticide reports also include instances of poisonings from spray drift from bensulide. On October 1, 2015, a school was sprayed with bensulide, sickening 28 students and staff members who reported symptoms including weakness, irritated throat, burning eyes, nausea, rapid heartbeat, vomiting, headache coughs, shortness of breath, and dizziness. The incident report shows bensulide residues at least 100 feet away from the treated field. The incident report likely does not even include all those sickened or exposed since a questionnaire was never circulated to students and staff. State of California Dept. of Pesticide Regulation, Pesticide Episode Investigation Report at 1, 3-4, 8 (Oct. 1, 2015).

EPA's OP risk assessments found that every OP that is applied in the air through aerial or ground spraying drifts in toxic amounts away from the fields where the pesticide is sprayed. EPA estimated the distances around the fields that would need no-spray buffers to prevent toxic drift to schools, homes, playfields, and other places people gather. Its model stopped at 300 feet. As a result, for some OPs, like ethoprop, phosmet, and tribufos, the risk assessments indicated

buffers of more than 300 feet would be required.[43] EPA did not fully assess volatilization risks for all the OPs, although it did find risks of concern for a few pesticides like diazinon where the State of California had conducted air monitoring that provided evidence of risks of concern. The following chart presents the results of EPA's spray drift assessments:

Table 5: OPs Applied in a Manner that Produces Toxic Spray Drift on Agricultural Crops[44]

Pesticide	Application Methods That Pose Risks of Concern	Distances (in feet) at Which Spray Drift Poses Risks of Concern
Acephate	Aerial, airblast, groundboom; aerial spraying poses greatest risks	For children: • > 300 For adults: • 100
Bensulide	Groundboom; liquid formulation poses greatest risks	For children: • 75 For adults: • 25
Diazinon	Aerial, Airblast, groundboom, aerial and high application rates pose greatest risks	For children: • > 300 For adults: • > 300
Dicrotophos	Aerial, groundboom	For children: • > 300 For adults: • > 300
Dimethoate	Aerial, airblast, groundboom; aerial spraying poses the greatest risks	For children: • > 300 For adults: • > 300
Ethoprop	Extremely high risks of concern to children and adults from groundboom spraying; aerial and airblast spray were ended in re-registration	All application scenarios pose extreme risks to adults and children at > 300

[43] EPA's spray drift model is underprotective because it does not account for inhalation exposures. The model estimates how far residues travel and deposit in the fields and subsequent human exposure dermally from touching the treated surfaces, and for kids, also from putting their hands in their mouth. It ignored inhalation and other exposures to direct pesticide drift onto people because the labels prohibit direct drift onto people and EPA views direct drift to be an enforcement issue, not a regulatory one. Farmworker and Conservation Comments on Chlorpyrifos 2020 HHRA and Proposed Interim Registration Review Decision at 44-47, 58-59.

[44] Phorate is not included in this analysis because EPA has yet to release a draft HHRA for phorate's registration review.

Pesticide	Application Methods That Pose Risks of Concern	Distances (in feet) at Which Spray Drift Poses Risks of Concern
Malathion	Aerial, airblast, groundboom	For children: • > 300 For adults: • > 300
Naled	Aerial, airblast, groundboom	For children: • > 300 feet For adults: • > 300
Phosmet	Aerial, airblast, groundboom; aerial spraying poses the greatest risks, but all application methods pose risks > 300 feet for some application scenarios	For children: • > 300 feet For adults: • > 300
Tribufos	Aerial, groundboom; airblast is not used for tribufos	All application scenarios pose extreme risks to adults and children at > 300

EPA has not changed other OP registrations or labels to require the no-spray buffers its risk assessments deem necessary. Because the children most often exposed to pesticides are the children of farmworkers, this harm falls disproportionately on children in low-income families and communities of color. By way of example, in April of 2014, the California Department of Public Health issued a report showing that thousands of children, disproportionately people of color, attend school in close proximity to pesticide use.[45]

III. EPA MUST UPDATE ITS OP RISK ASSESSMENTS TO USE A REGULATORY ENDPOINT THAT WILL PROTECT CHILDREN FROM NEURODEVELOPMENTAL HARM.

EPA's reliance on greater than 10 percent (10%) red blood cell acetylcholinesterase (RBC AChE) inhibition as the critical effect for OP risk assessments is scientifically inappropriate because harm to children's brain development can occur at much lower levels of exposure. By relying on 10% RBC AChE inhibition, the agency is deriving population adjusted doses or reference doses — effectively, the acceptable levels of exposure to OP pesticides — that may be many times larger than true safe levels. This can lead to false conclusions that dangerous levels of exposure to OPs are safe. EPA must use neurodevelopmental toxicity as the critical effect for OP risk assessments.

[45] California Environmental Health Tracking Program, *Agricultural Pesticide Use Near Public Schools in California* ("Schools Report") (Apr. 2014), http://www.phi.org/wp-content/uploads/migration/uploads/application/files/m0lvrkqvtqh6897fl65fyegso0p8qqqudkrto9v13d6uiocq0r.pdf.

A. EPA's Reliance on 10% Red Blood Cell Acetylcholinesterase Inhibition for OP Risk Assessments Is Under-protective of Children's Health.

The essence of a risk assessment is a comparison of an acceptable level of exposure — known as a population adjusted dose or reference dose — with the level of exposure that is expected to occur in a population. If the expected level of exposure is less than the acceptable level, EPA will conclude there is reasonable certainty of no harm. However, the agency errs if the acceptable level it sets is too high, which can occur when the level is not derived from a point of departure based on the most sensitive effect, *i.e.*, the effect that occurs at the lowest level of exposure. EPA's *Guidelines for Developmental Toxicity Risk Assessment* state that the most sensitive effect is to be used for risk assessment.[46] In August 2021, in the final chlorpyrifos tolerance revocation rule, the agency stated that "[t]he risk assessment process involves…choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide"[47] and that "PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario."[48] EPA must apply this criterion when choosing the critical effect that provides the foundation for OP risk assessments.

Yet EPA has continued to utilize 10% RBC AChE inhibition as the critical effect for OP risk assessments despite compelling evidence and its own conclusions that neurodevelopmental toxicity can occur at lower levels of exposure. In epidemiologic and animal studies in which both types of effect were measured, neurodevelopmental effects were observed even when AChE inhibition was less than 10% or absent. In CHAMACOS, a prospective birth cohort at University of California, Berkeley, for example, numerous associations between OP exposure in pregnant women and neurodevelopmental toxicity in children have been reported.[49] Yet EPA noted that investigators "measured AChE activity and showed that no inhibition in AChE activity [was] observed." 2016 Chlorpyrifos Revised HHRA at 13. In a literature review, the primary investigators of CHAMACOS and other major birth cohorts in which OP pesticides have been studied similarly concluded that: "Generally, levels of exposure in these studies are too low to induce measurable depression of cholinesterase in adults."[50] Furthermore, the review notes, "[E]ffects on cognition, motor activity, and social behaviors were repeatedly demonstrated in rodents dosed in early life with concentrations of OPs eliciting little to no inhibition of AChE in the brain."[51] OP risk assessments based on AChE inhibition are wholly inconsistent with this science.

[46] EPA, Guidelines for Developmental Toxicity Risk Assessment at 42 (1991), https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.
[47] 86 Fed. Reg. 48315, 48317 (Aug. 30, 2021).
[48] *Id*. at 48322.
[49] *E.g.*, Bouchard et al. (2011); Marks et al. (2010))
[50] Irva Hertz-Picciotto et al., *Organophosphate Exposures During Pregnancy and Child Neurodevelopment: Recommendations for Essential Policy Reforms*, PLOS Med. (Oct. 24, 2018) at 2.
[51] *Id*.

B. Dozens of Epidemiologic and Toxicologic Studies Demonstrate that Prenatal OP Exposure Harms Children's Brain Development.

1. Children's Increased Susceptibility

Scientists describe the period of early development of the brain and nervous system as a "critical window" of susceptibility, when the fetus is undergoing rapid cell growth, migration, differentiation, nutrition uptake, and formation of the final organ structure. The entire period of neurodevelopment – beginning in the womb and extending throughout childhood – is considered a critical window of increased susceptibility to toxic chemicals. For this reason, scientific experts have warned that exposure to harmful chemicals at any time during neurodevelopment, even at low levels or for only a short time, may lead to long-lasting physical, cognitive, and behavioral impairments.[52]

The increased risk from pesticides is described in detail in the landmark 1993 NAS Report: "[s]tudies in animals suggest that the nature of an injury is determined by the stage of brain development at the time of exposure rather than by the relationship of the insult to the time of the birth event." NAS Report at 60. That is, it is not only the dose that makes the poison, but also the timing of exposure relative to critical windows of development. Additionally, it matters whether exposure occurs during prenatal development because the placenta is not an adequate barrier to passage of many toxic chemicals, like OP pesticides, from the mother to the fetus.[53]

2. Epidemiological Studies

There are dozens of epidemiological studies in pregnant women and children demonstrating that prenatal exposure to OP pesticides leads to long-term and likely permanent harm to children's brain development and function. In a published systematic review, "all but one of the 27 studies evaluated showed some negative effects of [organophosphate] pesticides on neurobehavioral development."[54] In newborns, OP pesticides were associated with abnormalities in primitive reflexes, suggesting harm to the development of the central nervous system.[55] In children, they were associated with reduction in motor function,[56] decreases in working and visual memory, processing speed, verbal comprehension, perceptual reasoning, and full-scale IQ,[57] and increases in problems including ADHD, pervasive developmental disorder, and behaviors typical of autism spectrum disorders.[58] These studies also found that certain

---

[52] Heindel et al., *Developmental Origins of Health and Disease: Integrating Environmental Influences*, 156 (10) Endocrinology 3416-21 (Oct. 2015), doi: 10.1210/EN.2015-1394, https://bit.ly/3b3ibNZ; Bennett et al., *Project TENDR: Targeting Environmental Neuro Developmental Risks The TENDR Consensus Statement*, 124 (7) Environ Health Perspect. A118-22 (Jul. 1, 2016), doi: 10.1289/EHP358, https://ehp.niehs.nih.gov/doi/10.1289/ehp358.

[53] Whyatt et al. (2005); Rauh et al. (2011).

[54] Muñoz-Quezada et al., (2013).

[55] Engel et al. (2007); Young et al. (2005).

[56] Eskenazi, et al. (2007); Rauh et al. (2006); Grandjean et al. (2006); Handal et al. (2008); Rauh et al. (2015).

[57] Bouchard et al. (2011); Engel et al. (2011); Rauh et al. (2011); Handal, et al. (2008).

[58] Rauh et al. (2006); Marks et al. (2010); Furlong et al. (2014).

subpopulations have greater vulnerability to OPs, including children of farmworkers[59] and those who have reduced capacity to detoxify the pesticides.[60]

EPA's reviews of epidemiology studies on OP pesticides have focused on studies from prospective birth cohorts based at University of California-Berkeley, Mount Sinai School of Medicine, and Columbia University. 80 Fed. Reg. at 69,091. For these studies, investigators enrolled pregnant women, measured exposure to one or more OP pesticides during pregnancy or at delivery, and assessed neurodevelopment in their children at multiple time points after birth. *Id*.

Studies conducted by UC Berkeley and Mount Sinai School of Medicine found that prenatal exposures to OP pesticides were associated with neurodevelopmental harm to children. The UC Berkeley study followed a cohort of children born to farmworkers in Salinas Valley, California, and found reduced IQ, verbal comprehension, perceptual reasoning, and working memory.[61] The Mount Sinai study observed a New York City Hispanic population and found similar effects in the exposed children.[62]

A third study, conducted by the Columbia Center on Children's Environmental Health, found that levels of chlorpyrifos, an OP pesticide, in African American and Dominican pregnant women in New York City were associated with adverse neurodevelopmental effects in their children. The study began before and continued after a residential chlorpyrifos ban in 2000. The mothers of children born after the ban had dramatically lower chlorpyrifos levels than mothers of children born before the ban. Peer-reviewed scientific articles document that, at age three, the highly exposed children had statistically significant delays in motor and mental development, and attention and behavior problems.[63] At age seven, they experienced reduced IQ and loss of working memory.[64] At age 11, the children had more arm tremors and reduced fine motor control that affected the children's ability to draw shapes.[65] Subsequent testing using magnetic resonance imaging ("MRI") revealed physical brain abnormalities in an area of the brains of highly exposed children linked to learning, cognition, and social behaviors.[66]

As EPA reported, "across these three children's environmental health studies, authors consistently identified associations with neurodevelopmental outcomes in relation to OP exposure." 80 Fed. Reg. at 69,092. EPA has noted many of the outcomes listed above, including abnormal reflexes in newborns, mental and psychomotor developmental delays and attention and behavior problems in early childhood, and impaired cognition in middle childhood. *Id*. at 69,091-93.

[59] Castorina et al. (2010); Engel et al. (2016).
[60] Engel et al. (2016).
[61] Bouchard et al. (2011).
[62] Engel et al. (2011).
[63] Rauh et al. (2006).
[64] Rauh et al. (2011).
[65] Rauh et al. (2015).
[66] Rauh et al. (2012).

3. Toxicological Studies

The epidemiological evidence is consistent with data from toxicological studies that evaluated the neurodevelopmental effects of pre- and/or post-natal exposure to OPs in laboratory animals. In 2015, EPA found "a considerable and still-growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals." *Id*. at 69,090. In 2016, EPA wrote, "[T]he information on neurobehavioral effects as a whole provides evidence of long-lasting neurodevelopmental disorders in rats and mice following gestational exposure to OPs."[67] The consistent results across epidemiological and toxicological studies are notable because the strengths of epidemiological studies tend to balance the limitations of toxicological studies, and *vice versa*.[68] For example, unlike toxicological studies in laboratory animals, epidemiological studies evaluate exposures in the populations of interest — in this case, pregnant women and children. Unlike epidemiological studies in human beings, however, toxicological studies can assign exposure to a toxic pesticide at random to ensure that any differences between exposed and control animals are due to OPs. These complementary lines of evidence make it clear that OP pesticides harm children's brain development.

C. EPA and the FIFRA Scientific Advisory Panel Reviews Agree that OPs Harm Children's Brain Development.

EPA has conducted weight-of-evidence analyses that integrate the complementary lines of evidence from epidemiology and toxicology.[69] In particular, EPA has highlighted again and again the strengths of epidemiological studies finding associations between prenatal exposure to OP pesticides and harm to children's brain development. These include both studies using non-specific biomarkers of OP exposure (urinary dialkyl phosphates collected from pregnant women) as well as studies using a specific biomarker of chlorpyrifos exposure (umbilical cord blood chlorpyrifos collected at delivery). In 2012, EPA wrote:

> Overall, these are well performed studies which are shielded from several major sources of bias in the interpretation of results due to the strong design, conduct and analyses utilized in these investigations. While factors are present across these studies which may have led to either false positive or negative associations, it is notable that positive associations were observed as EPA believes the

[67] 2016 HHRA at 11.
[68] EPA, Preamble to the Integrated Science Assessments at 14 (2015), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=526136.
[69] EPA, Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides (Sept. 15, 2015) at 76, https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0062-0055; EPA Office of Pesticide Programs, Updated Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides, D437043 (Dec. 29, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0316-0029.

> possibility of under-estimation of effect size is more likely than factors that would lead to over-estimation of effect size.[70]

And in 2015, the agency wrote, "EPA believes these are strong studies which support a conclusion that OPs likely played a role in these outcomes." 80 Fed. Reg. at 69,091. The agency again reviewed the threats to inference that can arise in epidemiological research, but it "believes that random or systematic errors in the design, conduct, or analysis of these studies were unlikely to fully explain observed positive associations between in utero OP exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years)." *Id*.

EPA has stressed that sound epidemiological studies can support risk assessments. EPA's *Guidelines for Developmental Toxicity Risk Assessment* state, "Good epidemiologic studies provide the most relevant information for assessing human risk."[71] As noted in EPA's *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*, epidemiological studies provide extremely valuable information to inform risk assessments:

> Specifically, these types of human information provide insight into the effects caused by actual chemical exposures in humans and thus can contribute to problem formulation and hazard/risk characterization. In addition, epidemiologic and human incident data can guide additional analyses or data generations (e.g., dose and endpoint selection for use in *in vitro* and targeted *in vivo* experimental studies), identify potentially susceptible populations, identify new health effects, or confirm the existing toxicological observations.[72]

The chlorpyrifos risk assessments provide a good example of how EPA and the FIFRA Scientific Advisory Panel (SAP) have integrated epidemiological and toxicological data to conclude that OP pesticides can cause neurodevelopmental toxicity even at low levels of exposure. In 2008, the FIFRA SAP concluded that maternal exposure to chlorpyrifos was associated with adverse neurodevelopmental outcomes in children.[73] In 2012, the SAP reviewed epidemiological and toxicological studies, and wrote, "In summary, these lines of evidence suggest that chlorpyrifos can affect neurodevelopment[.]"[74] In 2016, the SAP "agree[d] that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes

---

[70] EPA, Draft Issue Paper: Scientific Issues Concerning Health Effects of Chlorpyrifos, for Meeting of FIFRA Scientific Advisory Panel (April 2012) ("2012 FIFRA SAP Issue Paper") at 71, https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0040-0002.

[71] EPA, Guidelines for Developmental Toxicity Risk Assessment (1991) at 23, https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.

[72] EPA OPP, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides (Dec. 28, 2016) at 4, https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.

[73] SAP Minutes of September 16-18, 2008 Meeting on Agency's Evaluation of Toxicity Profile of Chlorpyrifos ("2008 SAP Report") at 13, https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0274-0064.

[74] EPA, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held April 10-12, 2012 on "Chlorpyrifos Health Effects" (2012) ("2012 SAP Report") at 53, https://www.epa.gov/sites/production/files/2015-06/documents/041012minutes.pdf.

associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition."[75] In 2016, EPA responded that it "agree[d] with the 2016 [SAP] (and previous [SAPs]) that there is a potential for neurodevelopmental effects associated with chlorpyrifos exposure." 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016). Notably, much of the evidence supporting these conclusions, including the epidemiological studies conducted at UC Berkeley and Mount Sinai, is applicable to OP pesticides generally, not just chlorpyrifos.

D. EPA Cannot Evade the Scientific Evidence and the Agency's Own Conclusions that OPs Harm Children's Brain Development at Lower Levels of Exposure.

EPA has attempted to evade the scientific evidence and its own conclusions that neurodevelopmental toxicity is a more sensitive endpoint than AChE inhibition by claiming several uncertainties exist with respect to the epidemiological data. These uncertainties, to the extent they exist, cannot justify basing OP risk assessments on 10% RBC AChE inhibition. If anything, the uncertainties claimed by EPA would prevent the agency from finding that OP pesticide tolerances are safe and compel it to revoke these tolerances.

1. Federal Law Requires EPA To Use A Regulatory Endpoint That Protects Children.

Congress mandated that EPA revoke food tolerances for pesticide uses that the agency cannot find "safe," and "safe" means that EPA "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). Congress also specifically directed EPA to assume that children face a ten times greater risk than adults unless it has reliable data showing a different margin will be safe for infants and children. 21 U.S.C. § 346a(b)(2)(C); *Nw. Coal. for Alts. to Pesticides*, 544 F.3d 1043, 1046 (9th Cir. 2008). If uncertainty prevents EPA from making an affirmative safety finding, EPA must revoke the tolerances.

In *LULAC*, the 9th Circuit soundly rejected various justifications EPA had offered for not revoking chlorpyrifos tolerances in ways that make it clear EPA must base its tolerance and registration decisions on a regulatory endpoint that is safe for children. The court explained that, "[i]n setting chlorpyrifos tolerances, the EPA must determine the greatest exposure amount that poses no risk of harm, which is known as a "point of departure." 996 F.3d at 680. Because chlorpyrifos causes learning disabilities and other neurodevelopmental harm in children at exposures below those that cause 10% cholinesterase inhibition, the court indicated that EPA likely could not make a reasonable certainty of no harm based on 10% cholinesterase inhibition. *Id*. at 700-01. In referencing sufficient evidence that neurodevelopmental effects are occurring at exposures below those that cause 10% cholinesterase inhibition to require EPA to prevent such exposures, the 9th Circuit cited human cohort studies on OPs other than chlorpyrifos. *Id*. at 687-88. The court elaborated:

[75] EPA, Transmittal of Meeting Minutes of the April 19-21, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with "Chlorpyrifos: Analysis of Biomonitoring Data" (2016) ("2016 SAP Report") at 52-53, https://www.epa.gov/sites/production/files/2016-07/documents/chlorpyrifos_sap_april_2016_final_minutes.pdf.

> the EPA has spent more than a decade assembling a record of chlorpyrifos's ill effects and has repeatedly determined, based on that record, that it cannot conclude, to the statutorily required standard of reasonable certainty, that the present tolerances are causing no harm. Yet, rather than ban the pesticide or reduce the tolerances to levels that the EPA can find are reasonably certain to cause no harm, the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties. The FFDCA permits no further delay.

996 F.3d at 678.

The 9th Circuit found fault in EPA refusing to revoke tolerances because of scientific uncertainties and addressed specifically uncertainties in the precise exposure that causes the harm, in the mechanism by which chlorpyrifos harms children's brains, and the lack of public access to the raw data from the Columbia study due to privacy concerns. None of these uncertainties justified using 10% cholinesterase inhibition as the regulatory endpoint or putting off revocation of the tolerances to protect children.

2. An Inability to Pinpoint the Levels of Exposure that Cause Harm Does Not Make the Pesticides Safe.

EPA tried to justify using 10% RBC AChE inhibition as the regulatory endpoint because of the challenges in identifying the specific lower exposures that caused neurodevelopmental harm. 86 Fed. Reg. at 48,322. The fact that such harm has occurred, however, means 10% cholinesterase inhibition is not a safe exposure level and EPA cannot find reasonable certainty of no harm to children from such exposures. As the 9th Circuit held, "[t]he 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." 996 F.3d at 700. The 9th Circuit refused to allow such uncertainties surrounding the specific exposure level to justify retaining tolerances. Because EPA had found chlorpyrifos caused harm "at levels below the existing tolerances," *id*. at 691, and EPA must use an exposure amount that poses no risk of harm in setting tolerances, *id*. at 680, using 10% cholinesterase inhibition as the regulatory endpoint will not ensure to a reasonable certainty that chlorpyrifos will cause no harm to children.

3. Uncertainties Surrounding the Mechanism by Which OPs Harm Children's Brains Do Not Justify Ignoring the Harm.

EPA also sought to justify not revoking the chlorpyrifos tolerances because there are uncertainties about the mode of action by which chlorpyrifos harms children's brains. EPA policy, however, does not require that EPA be able to identify the precise mechanism by which a pesticide harms children's brains to be obligated to protect against such harm. *See* 2014 Chlorpyrifos HHRA at 48-49. Indeed, the 9th Circuit squarely rejected an analogous argument:

> the EPA argues that it does not know *how* chlorpyrifos's neurotoxic effects harm infants and children. But that is not the question before the EPA. The question is

whether chlorpyrifos causes such harms. Even if the mechanism is unknown, if a tolerance is unsafe, then the EPA must revoke it.

996 F.3d at 698.

The court cited *Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1055 (D.C. Cir. 1999), which held that EPA was not required to prove "'how particles actually interact with cells and organs to cause sickness and death' to find a correlation, *aff'd in part and rev'd in part on other grounds sub nom. Whitman v. Am. Trucking Assn's*, 531 U.S. 457, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001)." 996 F.3d at 698 n.142. The court also cited EPA's own finding that uncertainties surrounding the mechanism by which the effects occur and the precise window of susceptibility do not undermine or reduce confidence in the epidemiology studies. 996 F.3d at 687-88, citing 2016 RHHRA. As EPA's *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* states, "lack of established [modes of action] is not necessary knowledge when using epidemiology data and epidemiology associations may still be valid even in the absence of an established [mode of action][.]"[76] EPA must protect children from adverse neurodevelopmental effects that occur at doses below those that cause cholinesterase inhibition, even if it has not yet identified the precise mechanism by which chlorpyrifos causes these effects.

4. The Lack of Access to Raw Data Does Not Justify Dismissing Leading Epidemiological Studies.

The Trump EPA tried to justify dismissing the Columbia study that linked chlorpyrifos to neurodevelopmental harm to children because the raw data had not been made public to protect the study participants' personal privacy. This purported need for the raw data ignored EPA policies and the harm to personal privacy that public release of the data would cause.

EPA policies allow it to use epidemiology studies and articles in the open literature in EPA health assessments where the agency cannot access the raw data due, for example, to compelling interests in safeguarding personal privacy; it can employ other checks, such as peer review, to ensure the robustness of the analytical results.[77] EPA adhered to its policies and utilized a series of internal and external reviews by scientific experts to ensure the validity and robustness of the OP epidemiology studies. Not only were the articles from the OP epidemiology studies peer reviewed before publication in academic journals, but EPA also convened the FIFRA SAP to review them. The SAP called the studies the "best available," "carefully designed," and "well executed." 2012 SAP Report at 22. While the Trump administration had issued a rule that would have precluded use of scientific studies when the raw date cannot be made public for privacy reasons, a court vacated that rule earlier this year. *See* 86

[76] EPA OPP, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides (Dec. 28, 2016) at 15, https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.

[77] EPA, Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment at 9-10 (2012), https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf; EPA, Plan to Increase Access to Results of EPA-Funded Scientific Research at 11 (2016); EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA at 21 (2002).

Fed. Reg. 469 (Jan. 6, 2021), vacated by *Env't Def. Fund v. EPA*, 2021 WL 402824 (D. Mont. Feb. 1, 2021), and 2021 WL 270246 (D. Mont. Jan. 27, 2021).

Not surprisingly, the 9th Circuit eviscerated this reason for not revoking the chlorpyrifos tolerances. The court noted reasonable concerns for the study participants' privacy and that EPA's position as to the benefit of access to the data had flipflopped over the years, which "suggests the weakness" of the argument. 996 F.3d at 699. Ultimately, however, the 9th Circuit determined that access to the raw data, like more information about the exposures in the Columbia study, "would not change the result in this case." *Id*. The court explained:

> This is because, while . . . lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCA requires the EPA to consider the "information" that is "available" and to make a safety determination based on that information. In this case, . . . peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available – even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: speculation. Such speculation "runs counter to the evidence before the agency," so it cannot form the basis for denying the 2007 Petition.

996 F.3d at 699-700 & n. 149, citing 21 U.S.C. § 346a(d)(4)(A), and *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

E. Retaining the FQPA Tenfold Safety Factor Is Insufficient to Ensure Reasonable Certainty of No Harm to Children.

In the final chlorpyrifos tolerance revocation rule, EPA says it is "not ignoring or dismissing the extensive data concerning the potential for adverse neurodevelopmental outcomes," but "is addressing the uncertainties surrounding the potential for adverse neurodevelopmental outcomes by retaining the default 10X FQPA [Food Quality Protection Act] safety factor." 86 Fed. Reg. at 48,325. While EPA had to retain the FQPA tenfold safety factor based on the demonstrated harm to the developing brain and remaining scientific uncertainties, doing so is not sufficient to ensure reasonable certainty of no harm to children for at least three reasons.[78]

[78] In September 2020, EPA convened a FIFRA SAP to review the possibility of eliminating the FQPA 10X based on new methodologies in development that would use a suite of *in vitro* assays to assess the developmental neurotoxicity potential of individual OP pesticides, focusing on cholinesterase inhibition. The SAP issued a highly critical report finding serious data gaps and substantive problems with EPA's proposed use of the new methodologies in the OP risk assessments, and particularly for determining a safe exposure level and eliminating uncertainty factors. *See* Transmittal of Meeting Minutes and Final Report of the Federal Insecticide, Fungicide and Rodenticide Act, Scientific Advisory Panel (FIFRA SAP) Virtual Meeting held on September 15-18, 2020 (Dec. 14, 2020) ("2020 NAM Report"), https://www.regulations.gov/document?D=EPA-HQ-OPP-2020-0263-0054.

First, 10% RBC AChE inhibition is not the most sensitive endpoint. As explained above, EPA policy requires identifying a point of departure based on the most sensitive endpoint *and then* applying appropriate safety factors to account for uncertainties including, for example, children's increased susceptibility to pesticide exposure in the pre- and post-natal periods.

Second and related, because neurodevelopmental harm occurs below these low exposure levels, 10% RBC AChE inhibition is not a "no observable adverse effects level" or "NOAEL." Instead, it is a "low observable adverse effects level" or "LOAEL." Under EPA policy, which the final rule acknowledges at 86 Fed. Reg. at 48,323, the use of a LOAEL, instead of NOAEL, requires an additional uncertainty factor of 10X, but EPA did not include one.[79]

Third, EPA has not determined that retaining the FQPA tenfold safety factor, while still using 10% RBC AChE inhibition as the critical effect, would be sufficient to prevent neurodevelopmental harm to children. Indeed, when EPA has conducted a dose-response assessment for an OP pesticide based on neurodevelopmental toxicity, it derived an acceptable level that was orders of magnitude lower than acceptable levels based on 10% RBC AChE inhibition. A dose-response assessment by the California Department of Pesticide Regulation (CDPR) reached similar results. These dose-response assessments are discussed below.

EPA's 2016 Human Health Risk Assessment for Chlorpyrifos

In 2016, EPA's risk assessment for chlorpyrifos found that acceptable levels of exposure to this OP pesticide based on harm to children's brain development were dramatically lower than acceptable levels based on 10% RBC AChE inhibition, which was the critical effect used in EPA's 2014 and 2020 risk assessments for chlorpyrifos. For the 2014 risk assessment, the agency derived population adjusted doses — the acceptable levels of exposure — for steady-state exposure to chlorpyrifos residues on food of 0.78 to 2.6 mcg/kg/day (Table 1). 2014 Chlorpyrifos HHRA at 76. In 2016, when EPA assessed risks from chlorpyrifos based on neurodevelopmental toxicity, the population adjusted doses were 0.0012 to 0.002 mcg/kg/day — *more than three orders of magnitude* lower than when the acceptable level was based on 10% RBC AChE inhibition (Table 6). 2016 Chlorpyrifos HHRA at 23.

Table 6: Steady-state Population Adjusted Doses (mcg/kg/day) for Food Exposure to Chlorpyrifos

	AChE Inhibition (2014/2020)	Neurodevelopment (2016)
Infants	2.6	0.002
Children	2.5	0.0017
Youths	2.2	0.0012
Adults	0.78	0.0012

[79] EPA, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment at 9 (2002), https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf; EPA, A Review of the Reference Dose and Reference Concentration Processes at 4-44 (2002), https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.

The stark contrast in population adjusted doses, or acceptable levels, for 10% RBC AChE inhibition and neurodevelopmental toxicity in EPA's risk assessments indicate that continuing to base risk assessments for chlorpyrifos on the former endpoint is under-protective — even when the FQPA tenfold safety factor is retained. If the point of departure and thus the population adjusted dose for the neurodevelopmental toxicity of chlorpyrifos could be more than 1,000X lower than what EPA has derived for AChE inhibition, relying only on the FQPA safety factor of 10X to protect children from neurodevelopmental harm is plainly inadequate.

EPA's final chlorpyrifos tolerance revocation rule reverted to using 10% RBC AChE as the regulatory endpoint without addressing the extensive comments showing this endpoint is under-protective and without providing any rational explanation as to why that endpoint could be safe in light of the 2016 risk assessment. Specifically, after describing the 2016 assessment, EPA wrote:

> Despite that effort, EPA's position is that the shortcomings of the data with regard to the dose-response relationship and lack of exposure information discussed above, continue to raise issues that make quantitative use of the CCCEH data in risk assessment not scientifically sound.[80]

This statement was a non-sequitur. The 2016 assessment does *not* "make quantitative use of the CCCEH data." Rather, EPA used a physiologic-based pharmacokinetic model developed by the registrant and its own exposure models to conduct this assessment. Indeed, in 2016, EPA said an advantage of this approach was that it "does not directly rely on quantitative measures of chlorpyrifos in cord blood obtained from the CCCEH."[81] EPA's decision in the tolerance revocation rule revert to using 10% RBC AChE as the critical effect was entirely unsupported by the agency. The 2016 dose-response assessment cannot be ignored: it continues to demonstrate that OPs may harm children's brain development at levels hundreds of times lower than levels that cause AChE inhibition.

California's 2018 Toxic Air Contaminant Evaluation for Chlorpyrifos

CDPR also conducted a dose-response assessment for chlorpyrifos and concluded that prenatal exposure can elicit neurodevelopmental toxicity at levels of exposure that do not result in 10% RBC AChE inhibition. In 2018, when evaluating whether chlorpyrifos is a toxic air contaminant under California law, CDPR noted, "Recent in vivo animal studies provide evidence of neurotoxicity to developing organisms at chlorpyrifos doses below those causing cholinesterase inhibition."[82] The agency based its evaluation on developmental neurotoxicity rather than AChE inhibition: "These studies, along with epidemiological studies, are the impetus for CDPR considering developmental neurotoxicity as the critical endpoint for chlorpyrifos."[83]

---

[80] 86 Fed. Reg. 48315, 48325 (Aug. 30, 2021).
[81] 2016 HHRA at 14.
[82] CDPR, Final Toxic Air Contaminant Evaluation of Chlorpyrifos at 9-10 (2018), https://www.cdpr.ca.gov/docs/whs/pdf/chlorpyrifos_final_tac.pdf.
[83] *Id*.

CDPR considered five toxicological studies reporting neurodevelopmental effects at low doses that did not elicit meaningful AChE inhibition.[84] It derived reference doses from them, found chlorpyrifos unsafe, and initiated cancellation proceedings, which led to the phase out of approximately 99% of chlorpyrifos use by the end of 2020.[85] Table 7 compares CDPR's references doses for neurodevelopmental toxicity from acute oral exposure to EPA's 2014 and 2020 population adjusted doses for AChE inhibition from steady state dietary exposure. CDPR's acceptable levels are 47-150X lower than EPA's, which further suggests that EPA's approach is under-protective of children's health.[86]

Table 7: Reference Doses and Population Adjusted Doses (mcg/kg/day) for Chlorpyrifos

	CDPR (2018)	**EPA (2014/2020)**
Infants	0.1	15
Children	0.1	14
Youths	0.1	13
Adults	0.1	4.7

EPA's 2020 risk assessment concluded that one of the studies finding neurodevelopmental toxicity in the absence of AChE inhibition was "of high quality" and that it "provides strong support for the conclusion that effects on the developing brain may occur below a dose eliciting 10% AChE inhibition."[87] A memo attached to the risk assessment provided a detailed review of the five studies and indicated that this study could be used "quantitatively,"[88] which is what CDPR did. The memo further indicated that a second study likewise finding neurodevelopmental toxicity in the absence of AChE inhibition was "adequate"[89] and could be used "qualitatively."[90] Like EPA's own dose-response assessment, California's analysis indicates that relying on the FQPA tenfold safety factor alone to protect children's brain development is inadequate.

The record is replete with reliable information indicating that using 10% cholinesterase inhibition as the regulatory endpoint could lead to exposures greater than a true safe exposure level by a thousand-fold or more. Simply retaining the FQPA tenfold safety factor while using this endpoint provides an insufficient margin of safety for children. EPA *must* utilize a point of departure based on neurodevelopmental toxicity for OP risk assessments. EPA must update its

[84] EPA, Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Lifestage Exposure (2020).
[85] CDPR, Final Toxic Air Contaminant Evaluation of Chlorpyrifos at 9-10; *see also* CDPR, Agreement Reached to End Sale of Chlorpyrifos by February 2020 (Oct. 9, 2019), https://www.cdpr.ca.gov/docs/pressrls/2019/100919.htm.
[86] CDPR, Final Toxic Air Contaminant Evaluation of Chlorpyrifos at 82; 2014 HHRA at 75; 2020 HHRA at 34-35.
[87] 2020 HHRA at 88.
[88] E. Méndez, *Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Life Exposure* (Jun. 1, 2020).
[89] 2020 HHRA at 88.
[90] E. Méndez, *Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Life Exposure* (Jun. 1, 2020).

OP human health risk assessment so that they use a regulatory endpoint that will protect children from neurodevelopmental harm.

IV. EPA MUST CANCEL REGISTRATIONS FOR OP USES THAT HAVE UNREASONABLE ADVERSE EFFECTS ON WORKERS.

As with dietary and drift exposures, EPA's OP risk assessments document pervasive unacceptable risks to workers both from handling the pesticides and from entering the fields after they have been sprayed. For many OP uses, workers face unconscionably high risks from the tasks they perform in growing our food. EPA documented these risks many years ago, for some OPs as long ago as 2014. And yet, EPA has taken no actions to protect workers from this demonstrated harm. Now is the time to take such actions.

EPA should immediately cancel or modify registrations to protect workers from the egregious risks documented in the risk assessments. EPA's failure to use an endpoint to protect against neurodevelopmental harm to children exposes pregnant women to levels of chlorpyrifos that could cause serious learning disabilities and reduced IQ in their children. EPA must update the OP worker risk assessments using an appropriate endpoint that will prevent such neurodevelopmental harm. EPA will also need to conduct a cumulative risk assessment for all of the OPs. It must not, however, let these processes of updating the OP worker risk assessments delay protecting workers from the risks that are already so well-documented.

A. EPA's OP Risk Assessments Document Unacceptable Risks to Farmworkers.

1. Unacceptable Risks to Handlers

EPA's risk assessments estimate the exposures and risks workers face from performing various tasks, such as mixing and applying the pesticides in different amounts and frequencies, in different forms, such as powder or liquid, and using different application methods, such as aerial, airblast, groundboom, or backpack spraying. EPA compares exposure estimates to the levels it associates with what it identifies as unsafe exposures, which it calls risks of concern.

To determine risks of concern, EPA purports to identify a no-adverse-effect exposure level. For OPs, EPA identified 10% red-blood cell cholinesterase inhibition as an effect that would be short of what would poison the worker. As discussed above, this is not a no observable adverse effect level for neurodevelopmental harm to children, which occurs at lower exposure levels. To prevent exposures that cause 10% cholinesterase inhibition, EPA uses safety factors that it multiplies by the no-adverse-effect level. For the OPs, EPA has retained the FQPA 10X safety factor and typically includes both the inter-species 10X and intra-species 10X safety factors, which results in a margin of exposure ("MOE") of 1000.[91] If the calculated margin of exposure for a particular activity is less than 1000, it poses a risk of concern. The smaller the

[91] For some OPs, like inhalation exposures to bensulide, terbufos, and malathion, EPA has added a 3X safety factor because a particular endpoint is based on a LOAEL instead of a NOAEL, and for some, it has reduced the inter-species or inter-species safety factors because of its reliance on human studies, as it did with inhalation exposures to ethoprop and acephate.

MOE, the closer the expected exposure is to the level that causes 10% cholinesterase inhibition, an unacceptable outcome from a public health perspective.[92]

EPA's worker risk assessments typically assess the risks using the personal protective equipment (PPE), like coveralls or respirators, and engineering controls (*e.g.,* enclosed cabs or cockpits, water-soluble packaging, and closed mixing/loading systems), that are required on the current pesticide labels. Where EPA finds risks of concern, it then models what the risks would be with additional PPE or engineering controls.

Workers who handle OP pesticides face the highest risks. EPA's OP risk assessments routinely find pervasive and extremely high risks of concern for the handlers.

For example, EPA found risks of concern for **all** handler scenarios for bensulide with the label-required PPE. Bensulide HHRA at 53-56. Even with maximum PPE, **all** scenarios still pose risks of concern. *Id.* All but one crop scenario still pose risks of concern with engineering controls. Chemigation and handgun applications using liquid formulations pose alarmingly high risks.

Diazinon also poses risks of concern for **all** scenarios even with maximum PPE and engineering controls. Aerial applications on lettuce and chemigation and groundboom applications in orchards and on field crops are extremely dangerous, as is backpack spraying. Diazinon HHRA at 48-52.

And for naled, EPA found dermal and inhalation risks of concern for several scenarios "even with the use of engineering controls or maximum levels of PPE such as coveralls and half-face respirators." Naled DHHRA at 86-87. It found that most aerial applications of naled for agricultural field crops and orchards, which must already be in enclosed cockpits, pose risks of concern. *Id*. at 87-89, 91. Most scenarios involving acephate pose risks of concern with current label measures, and 1/3 still pose risks of concern with additional PPE and engineering controls. Acephate HHRA at 59-61.

All of the OPs pose risks of concern to occupational handlers as shown in the table below:

[92] EPA sometimes uses the term Level of Concern (LOC) instead of or in addition to MOE in assessing worker risks. EPA determines the LOC by multiplying a NOAEL level by the safety factors. For example, if EPA applies a 10X safety factor for interspecies variability (extrapolating from a rodent study to human risk), and another 10X for intraspecies variability (differences between individual people across a diverse population), multiplying the two produces a total LOC of 100. When a 10X to protect children is added, the LOC becomes 1000X. The MOE is calculated as the point of departure divided by the actual or projected environmental exposure of interest. If the MOE is less than the LOC, EPA finds a risk of concern.

Table 8: Occupational Risk from Exposure to OPs for Occupational Handlers

	Occupational Handler Risk	
Pesticide Name	**Main Use Scenarios of Concern Under Current Labels**	**Magnitude of Risk**
Acephate	• **Aerial** (Mixing, Loading) • **Airblast** (Mixing, Loading, Applying) • **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading) • Tractor-Drawn Spreader (Mixing, Loading, Applying)	Most use scenarios pose severe risk to workers
Bensulide	• **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading) • **Tractor-Drawn Spreader** (Mixing, Loading, Applying)	All use scenarios pose severe risk to workers
Chlorethoxyfos	• Tractor-Drawn Spreader (Loading, Applying)	No use scenarios pose severe risk to workers.
Chlorpyrifos-methyl	• **Hand Application** (Mixing, Loading, Applying)	All use scenarios pose severe risk to workers
Diazinon	• **Aerial** (Mixing, Loading, Applying) • Airblast (Mixing, Loading, Applying) • **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading)	Most use scenarios pose severe risk to workers
Dichlorvos	• **Hand Application** (Mixing, Loading, Applying)	All use scenarios pose severe risk to workers
Dicrotophos	• **Aerial** (Mixing, Loading, Applying) • Groundbloom (Mixing, Loading, Applying)	Some use scenarios pose severe risk to workers
Dimethoate	• **Aerial** (Mixing, Loading, Applying) • **Airblast** (Mixing, Loading, Applying) • **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading)	All use scenarios pose severe risk to workers
Ethoprop	• **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Loading, Applying) • **Chemigation** (Mixing, Loading) • **Tractor-Drawn Spreader** (Loading, Applying)	All use scenarios pose severe risk to workers

	Occupational Handler Risk	
Pesticide Name	**Main Use Scenarios of Concern Under Current Labels**	**Magnitude of Risk**
Malathion	• **Aerial** (Mixing, Loading, Applying) • **Airblast** (Mixing, Loading, Applying) • **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading) • **Tractor-Mounted Fogger** (Mixing, Loading, Applying)	All use scenarios pose severe risk to workers
Naled	• **Aerial** (Mixing, Loading, Applying) • Groundbloom (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • Tractor-Mounted Fogger (Mixing, Loading, Applying)	Some use scenarios pose severe risk to workers
Phorate	• **Aerial** (Applying) • **Ground-Based Equipment** (Loading, Applying)	All use scenarios pose severe risk to workers
Phosmet	• **Aerial** (Mixing, Loading, Applying) • **Airblast** (Mixing, Loading, Applying) • **Groundbloom** (Mixing, Loading, Applying) • **Hand Application** (Mixing, Loading, Applying) • **Chemigation** (Mixing, Loading)	All use scenarios pose severe risk to workers
Terbufos	• **Ground-Based Tractor** (Loading, Applying)	All use scenarios pose severe risk to workers
Tribufos	• Aerial (Mixing, Loading, Applying) • Groundbloom (Mixing, Loading, Applying)	*

Note: Occupational handlers are workers involved in the pesticide application process. Occupational handlers can experience varying exposures to pesticides due to the distinct job functions or tasks related to pesticide application, which include mixing pesticide formulations, loading pesticide application apparatuses, and applying liquid or granular pesticides to fields. EPA typically evaluates exposures to occupational handlers from dermal absorption of pesticide residues and/or inhalation of pesticides during the application process.

All use scenarios in the above table indicate dermal and/or inhalation risks of concern to occupational handlers. Additionally, for all pesticides indicated above, one or more use scenarios still pose risks of concern to handlers even if additional PPE or engineering controls are applied. In **bold** are use scenarios that have one or more application methods (mixing/loading/applying) associated with **severe risk**, which we have defined as having a dermal and/or inhalation exposure that is one or more order(s) of magnitude greater than the risk level of concern.

* = EPA provided insufficient information in the human health risk assessment to identify the severity of occupational handler risk associated with this pesticide.

EPA's risk assessments found risks an order of magnitude more severe than its risk of concern level for some application methods. For example, tribufos poses alarmingly high dermal risks of concern from all scenarios even with coveralls, long pants and long-sleeve shirts, chemical resistant footwear, socks, and aprons, and protective eyewear. The risks remain grave even with additional PPE and engineering controls. Tribufos HHRA at 42-44. Similarly, for terbufos, the risks for loaders and applicators are within 2-8X and <1-3X, respectively, the exposures correlated with 10% cholinesterase inhibition. Terbufos Occupational and Residential Exposure Assessment at 14-20. And for ethoprop, workers applying ethoprop face risks of concern from all mixing, loading, and application tasks. The risks are 1-2 orders of magnitude greater than EPA's risks of concern level for almost all application tasks. Ethoprop HHRA at 55-59.

While use of PPE can reduce risks from loading and mixing pesticides, it often fails to do so. As a general example, although the WPS permits the use of safety glasses to satisfy the requirements for eye protections, a Washington State study found that safety glasses "were not effective in protecting against splashes or wind-blown spray mist.[93] "Black light and fluorescent tracers dramatically demonstrate the extent to which pesticide exposure may occur, even with the use of PPE."[94] Additionally, it is well recognized that a full set of protective clothing is "cumbersome and can be very uncomfortable in hot weather, causing workers to shed their protective gear."[95] Indeed, an analysis performed by EPA scientists concluded that wearing a full body Tyvek coverall over a shirt and pants would likely produce an internal body temperature of 38.3 degrees centigrade (or 100.94 degrees Fahrenheit), at the cusp of the body temperature that is considered a sign of heat stress.[96] Thus, if pesticide handlers wore full PPE while mixing and loading pesticides, there would be a real risk that heat stress symptoms would reduce their alertness, creating a potential hazard.[97]

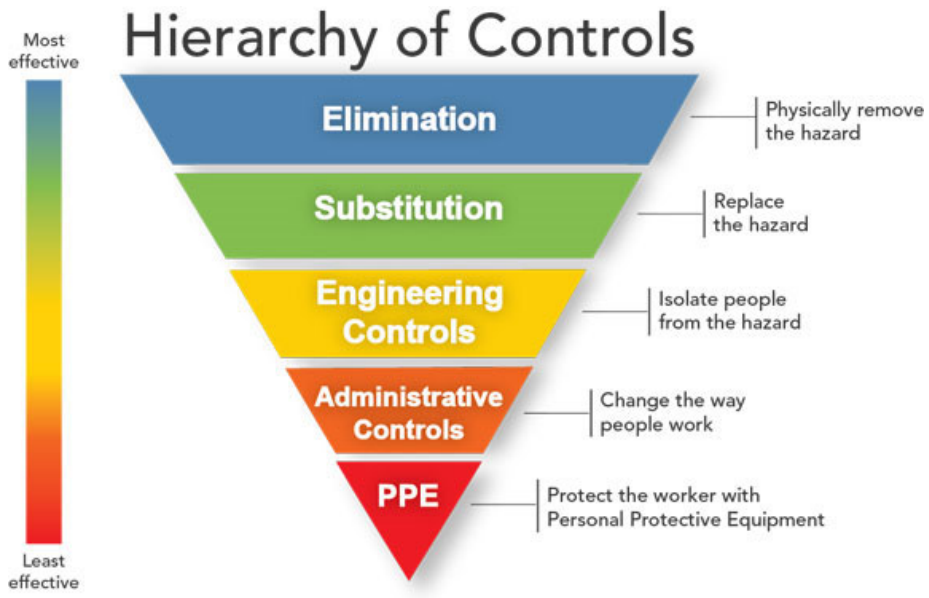
That is why it is standard practice to follow the hierarchy of controls, which prioritizes eliminating the risk by ending the harmful practice over having the worker wear PPE, which placing the burdens on the worker and fails to account for the chance the PPE will fail to afford the needed protection. The American National Standards Institute/American Industrial Hygiene Association Z10 2005 standard[98] provides that employers shall implement and maintain a process for feasible risk reduction based on the following preferred hierarchy of controls:

---

[93] Wash. State Dep't of Health, *Pesticide Incident Reporting & Tracking Panel*, 2000-2001 Annual Report (2002), http://www.doh.wa.gov/Portals/1/Documents/Pubs/334-293.pdf; *see also* Wash. State Dep't of Health, *Pesticide Incident Reporting & Tracking Panel*, 2009, Annual Report 61-64 (2009).
[94] Frederick M. Fishel, *Exposing Pesticide Exposure Using Fluorescent Tracer Dyes* (2014), http://edis.ifas.ufl.edu/pdffiles/PI/PI19900.pdf.
[95] W.W. Jacobs (1982). *Closed Mixing and Loading Systems and Pesticide Containers,* in Pesticide Tank Mix Applications: First Conference 58, 61 (John F. Wright, et al. eds., 1982); Rutz, R. 1987. *Closed System Acceptance and Use in California*, in Pesticide Formulations and Application Systems Vol. 7, at 28-34 (G.B. Beestman & D.I.B. Vander Hooven eds., 1987).
[96] C. Lunchick, et al., *Engineering Controls and Protective Clothing in the Reduction of Pesticide Exposure to Tractor Drivers*, Performance of Protective Clothing: Second Symposium 605, 608 (Seymour Zack Mansdorf, et al. eds., 1988).
[97] *Id*.
[98] Fred A. Manuele, ANSI/AIHA Z10-2005: *The New Benchmark for Safety Management Systems*, Pub. Safety (Feb. 2006) at 25.

1. Elimination
2. Substitution of less hazardous materials
3. Engineering controls
4. Administrative controls; and
5. Personal protective equipment.

NIOSH depicts the hierarchy of controls with this graphic, which shows the significantly increased effectiveness of controls other than PPE:[99]



The hierarchy of controls prioritizes hazard elimination and substitution over less protective controls, like engineering controls, and PPE "is always considered a last resort and should only be used as a method of exposure control when all other controls have been implemented and have not sufficiently reduced the hazard."[100]

OSHA regulations adopt a hierarchy of controls to prevent employee inhalation, ingestion, skin absorption or contact with harmful amounts of toxic substances:

> [A]dministrative or engineering controls must first be implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used to keep the exposure of employees to air contaminants within the limits prescribed in this section.

[99] Hierarchy of Controls, NIOSH (last updated July 18, 2016), https://www.cdc.gov/niosh/topics/hierarchy/.
[100] Justine L. Weinberg et al., *Application of Industrial Hygiene Hierarchy of Controls to Prioritize and Promote Safer Methods of Pest Controls: A Case Study*, 124 Pub. Health Rep. 53-62 (2009).

29 C.F.R. § 1926.55(b); *see also id*. § 1910.134(a)(1) (prioritizing engineering controls over respirators to reduce toxic air exposures); 43 Fed. Reg. 52,952 (Nov. 14, 1978) (preamble to lead standard finding repeatedly that respirators are ineffective because they do not eliminate the exposure, they provide inadequate protection, and they create additional hazards by interfering with vision and mobility).

What EPA has done to protect workers from risks of concern from OPs is nothing. It documented the risks and mitigation options and sat on the risk assessments, some for more than six years. Failing to protect workers from such extreme risks is indefensible.

2. Unacceptable Risks to Field Workers

EPA's OP risk assessments also document pervasive risks of concern to field workers who enter the fields to perform various tasks. To protect field workers, EPA establishes prohibitions on entering the fields during a re-entry interval (REI) after the pesticide application. EPA's OP risk assessments document risks of concern from re-entering fields after spraying to perform various activities, like weeding, irrigating, scouting, and harvesting. EPA then identifies the number of days needed before a worker can enter the field safely to perform the specific task.

By way of example, in response to past litigation, EPA extended some restricted re-entry intervals for phosmet, but it succumbed to grower pressure by shortening re-entry periods for appeals in the eastern U.S., allowing continued aerial applications on apples and pears, and retaining pick-your-own uses. Most field workers face unacceptable risks for more than 30 days after spraying, although some activities could be performed at 12 and 28 days after spraying. Current labels restrict re-entry for 1-14 days after spraying.

For malathion, the post-application exposure data shows that current REIs of 12 hours to 48 hours are often under protective. EPA found that REIs of 12 hours to nine days, with one scenario as high as 13 days (grapes), would be necessary to reach acceptable MOEs. Malathion HHRA at 73.

For dimethoate, field workers face risks of concern for many activities, like harvesting, irrigating, and weeding, without longer REIs than the 2-24 days currently required. The risk assessment includes recommendations to lengthen the REIs required for 20 crop activities and for 8 of these activities to 26-30 days. *Id*. at 7, 60-71. In addition to dimethoate and phosmet, a 30-day REI would be necessary to address risks of concern from acephate on some crops and for all mechanical activities for crops on which tribufos is sprayed.

Table 9: Occupational Risk from Exposure to OPs for Occupational Field Workers[101]

	Occupational Post-Application Risk	
Pesticide Name	**Risk Levels of Concern**	**Magnitude of Risk (Maximum Days Post- Application)**
Acephate	●	>30 days
Bensulide	●	5 days
Chlorethoxyfos	N/A	N/A
Chlorpyrifos-methyl	N/A	N/A
Diazinon	●	8 days
Dichlorvos	N/A	N/A
Dicrotophos	●	3 days
Dimethoate	●	30 days
Ethoprop	N/A	N/A
Malathion	●	13 days
Naled	●	8 days
Phosmet	●	>30 days
Terbufos	N/A	N/A
Tribufos	●	30 days

Note: Occupational field workers, also sometimes referred to as "post-application" workers, perform post-application activities in previously treated fields but do not directly apply pesticides themselves. EPA typically evaluates exposures to occupational field workers from dermal absorption of pesticide residues and/or inhalation of volatilized pesticides or resuspended dusts/particulates that occur in fields where pesticides were used and it determines the number of days the workers must remain out of the fields to avoid harmful exposures, called “re-entry interval.” This table does not reflect occupational post-application risk from phorate exposure because EPA has not conducted a human health risk assessment for phorate since 1999.

N/A = occupational post-application exposure is not expected for this pesticide based on typical application methods

Despite documenting these risks to field workers as long as six years ago, EPA has taken no steps to lengthen the interval that field workers must stay out of the fields after spraying. Its delays have put workers in harm’s way again and again.

[101] Some OPs, like bensulide, chlorethoxyfos, ethoprop, and terbufos, do not pose risks of concern to field workers because they are applied pre-plant.

CONCLUSION

EPA has a hard statutory deadline of October 1, 2022, to complete registration review of the OP pesticides. Due to the stalling tactics of the prior administration, EPA will not be able to fully meet that deadline. It must, however, take action expeditiously to address the documented risks of concern from the OPs. As soon as possible and no later than October 1, 2022, EPA must revoke all tolerances and cancel associated registrations for food uses of OPs EPA cannot find safe. For any OP uses that remain, including nonfood uses, EPA must cancel registrations for uses that cause unreasonable adverse effects to workers. To make legally and scientifically defensible decisions on the OPs, EPA must update its risk assessment to use a regulatory endpoint that protects children from neurodevelopmental harm.

EPA must take these actions for each OP individually, even though it cannot fully complete registration review of the OPs by the statutory deadline. EPA remains legally obligated to conduct a cumulative risk assessment and take necessary regulatory actions for OPs as a class, to ensure the OP registrations comply with the ESA, and to complete endocrine disruption screening of the OPs. The fact that it cannot complete these reviews by the statutory deadline provides no excuse to delay tolerance revocations and registration cancellations for the individual OPs based on their individual risk assessments.

Submitted on November 18, 2021 by:

Teresa Romero, President
Giev Kashkooli, Legislative and Political Director
United Farm Workers
29700 Woodford-Tehachapi Road
P.O. Box 62
Keene, CA 93531
(661) 823-6105

Diana Tellefson Torres, Executive Director
Andrea Delgado, Government Affairs Director
Eriberto Fernández, Deputy Director for Government Affairs
United Farmworkers Foundation
P.O. Box 23400
Los Angeles, CA 90023
1-877-881-8281

Patti A. Goldman, Senior Attorney
Rashmi Joglekar, Staff Scientist
Tyler Smith, Consultant
Earthjustice
810 Third Avenue, Suite 610
Seattle, WA 98104
(206) 578-5868

Anne Katten, Director, Pesticide & Worker Safety Project
California Rural Legal Assistance Foundation
2210 K St., Suite 201
Sacramento, CA 95816
(916) 446-7904

Jeannie Economos, Coordinator, Pesticide Safety and Environmental Health Program
Farmworker Association of Florida
1264 Apopka Blvd.
Apopka, FL 32703
(407) 886-5151

Iris Figueroa, Director of Economic and Environmental Justice
Farmworker Justice
1126 16th St NW, Suite LL-101
Washington, DC, 20036
(202) 293-5420

Mark Magaña, President
GreenLatinos
PO Box 60217
Washington, D.C. 20039
(202) 230-2070

Jose Vargas, Executive Director
Labor Council for Latin American Advancement
815 Black Lives Matter Plz NW
Washington, DC 20006
(202) 508-6919

Sindy Benavides, CEO
William Moreno, Director of Policy and Legislation
Cintia Ortiz, Fellow, Environmental Justice
League of United Latin American Citizens
1133 19th Street, NW, Suite 1000
Washington, DC 20036
(202) 833-6130

Tracy Gregoire, Director, Healthy Children Project
Learning Disabilities Association of America
4068 Mount Royal Boulevard, Suite 224B,
Allison Park, PA 15101
(412) 341-1515

Margaret Reeves, Senior Scientist
Pesticide Action Network North America
2000 Allston Way
P.O. Box 521
Berkeley, CA 94704
(510) 788-9020

Reyna Lopez, Executive Director
Pineros y Campesinos Unidos del Noroeste
300 Young St.
Woodburn, OR 97071
(503) 902-0367

LIST OF EXHIBITS

NO.	TITLE
1.	Deborah Bennett et al., *Project TENDR: Targeting Environmental Neuro-Developmental Risks. The TENDR Consensus Statement*, Env't Health Persp. (July 2016).
2.	Maryse F. Bouchard et al., *Prenatal Exposure to Organophosphate Pesticide and IQ in 7-Year-Old Children*, Env't Health Persp. (Aug. 2011).
3.	California Department of Pesticide Regulation, Coachella Valley High School Pesticide Episode Investigation Report (Oct. 1, 2015).
4.	California Department of Pesticide Regulation, *Final Toxic Air Contaminant Evaluation of Chlorpyriphos. Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders* (Jul. 2018).
5.	Presentation, California Environmental Health Tracking Program, *Agricultural Pesticide Use Near Public Schools in California* (Apr. 2014).
6.	Press Release, California Environmental Protection Agency. Agreement Reached to End Sale of Chlorpyrifos in California by February 2020 (Oct. 9, 2019).
7.	Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States*, 1998-2005, 51 Am. J. Indus. Med. 883, 890 (2008).
8.	Presentation, Daniel Carroll et al., *Changing Characteristics of U.S. Farmworkers: 21 Years of Findings from the National Agricultural Workers Survey* (May 12, 2011).
9.	Rosemary Castorina et al., *Comparison of Current-Use Pesticide and Other Toxicant Urinary Metabolite Levels among Pregnant Women in the CHAMACOS Cohort and NHANES*, Env't Health Persp. (June 2010).
10.	Stephanie M. Engel et al., *Prenatal Organophosphate Metabolite and Organochlorine Levels and Performance on the Brazelton Neonatal Behavioral Assessment Scale in a Multiethnic Pregnancy Cohort*, AM. J. of Epidemiology (2007).
11.	Stephanie M. Engel et al., *Prenatal Exposure to Organophosphates, Paraoxonase 1, and Cognitive Development in Childhood*, Env't Health Persp. (Aug. 2011).
12.	Stephanie M. Engel et al., *Prenatal Organophosphorus Pesticide Exposure and Child Neurodevelopment at 24 Months: An Analysis of Four Birth Cohorts*, Env't Health Persp. (June 2016).

NO.	TITLE
13.	Environmental Working Group, *Every Breath You Take – Airborne Pesticides in the San Joaquin Valley* (Jan. 2001).
14.	EPA Memorandum from Ashlee Aldridge, et al. to Yu-Ting Guilaran, Updated Literature Review on Neurodevelopmental Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides (Dec. 29, 2016).
15.	EPA Memorandum from Elizabeth Méndez to Michael Metzger, Chlorpyrifos: Review of 5 Open Literature Studies Investigating Potential Developmental Neurotoxicity Following Early Lifestage Exposure (June 1, 2020).
16.	Letter from EPA Unions to Stephen L. Johnson, EPA Administrator (May 24, 2006).
17.	Brenda Eskenazi et al., *Organophosphate Pesticide Exposure and Neurodevelopment in Young Mexican-American Children*, Env't Health Persp. (May 2007).
18.	Rafter Ferguson, Kristina Dahl, and Marcia DeLonge, *Farmworkers at Risk: The Growing Dangers of Pesticides and Heat*, Union of Concerned Scientists (Dec. 2019).
19.	Frederick M. Fishel, *Exposing Pesticide Exposure Using Fluorescent Tracer Dyes*, PI-162, Univ. of Fla. IFAS Extension (revised Apr. 2014).
20.	Melissa A. Furlong et al., *Prenatal Exposure to Organophosphate Pesticides and Reciprocal Social Behavior in Childhood*, Env't Int'l (June 2014).
21.	Gen. Accounting Office, Report to the Chairman, *Pesticides on Farms: Limited Capability Exists to Monitor Occupational Illnesses and Injuries* (Dec. 1993).
22.	Philippe Grandjean et al., *Pesticide Exposure and Stunting as Independent Predictors of Neurobehavioral Deficits in Ecuadorian School Children*, Pediatrics (Mar. 2006).
23.	Alexis J. Handal et al., *Occupational Exposure to Pesticides During Pregnancy and Neurobehavioral Development of Infants and Toddlers*, Epidemiology (2008).
24.	Jerrold J. Heindel et al., *Developmental Origins of Health and Disease: Integrating Environmental Influences*, Endocrinology (2016).
25.	Irva Hertz-Picciotto et al., *Organophosphate Exposures During Pregnancy and Child Neurodevelopment: Recommendations for Essential Policy Reforms*, PLoS Med. (Oct. 24, 2018).
26.	W. W. Jacobs, *Closed Mixing and Loading Systems and Pesticide Containers*, Am. Soc'y for Testing and Materials (1982).

NO.	TITLE
27.	Alice C. Larson, *Migrant and Seasonal Farmworker Enumeration Profiles Study: California* (Sept. 2000).
28.	Curt Lunchick et al., *Engineering Controls and Protective Clothing in the Reduction of Pesticide Exposure to Tractor Drivers*, Am. Soc'y for Testing and Materials (1988).
29.	Fred A. Manuele, *ANSI/AIHA Z10-2005 The New Benchmark for Safety Management Systems*, Pro. Safety (Feb. 2006).
30.	Amy R. Marks et al., *Organophosphate Pesticide Exposure and Attention in Young Mexican-American Children: The CHAMACOS Study*, Env't Health Persp. (2010).
31.	María Teresa Muñoz-Quezada et al., *Neurodevelopmental Effects in Children Associated with Organophosphate Pesticides: A Systematic Review*, NeuroToxicology (2013).
32.	Joanne Bonnar Prado et al., *Acute Pesticide-Related Illness Among Farmworkers: Barriers to Reporting to Public Health Authorities*, 22(4) J. Agromedicine 395 (2017).
33.	Virginia A. Rauh et al., *Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First 3 Years of Life Among Inner-City Children*, Pediatrics (Dec. 2006).
34.	Virginia A. Rauh et al., *Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide*, Env't Health Persp. (2011).
35.	Virginia A. Rauh et al., *Brain Anomalies in Children Exposed Prenatally to a Common Organophosphate Pesticide*, PNAS (Mar. 2012).
36.	Virginia A. Rauh et al., *Prenatal Exposure to the Organophosphate Pesticide Chlorpyrifos and Childhood Tremor*, NeuroToxicology (July 2015).
37.	Roy Rutz, *Closed System Acceptance and Use in California*, Am. Soc'y for Testing and Materials (1987).
38.	Wash. State Dep't of Health Pesticide Incident Reporting and Tracking Review Panel, *2000-2001 Annual Report* (Apr. 2002).
39.	Wash. State Dep't of Health Pesticide Incident Reporting and Tracking Review Panel, *2009 Annual Report* (Apr. 2010).
40.	Wash. State Dep't of Health, *Learning from Listening: Results of Yakima Farmworker Focus Groups About Pesticides and Health Care* (June 2004).

NO.	TITLE
41.	Justine Lew Weinberg et al., *Application of the Industrial Hygiene Hierarchy of Controls to Prioritize and Promote Safer Methods of Pest Control: A Case Study*, Public Health Reports (2009).
42.	R.M. Whyatt et al., *Biomarkers in Assessing Residential Insecticide Exposures During Pregnancy and Effects on Fetal Growth*, Toxicology and Applied Pharmacology (Apr. 2005).
43.	Jessica G. Young et al., *Association Between In Utero Organophosphate Pesticide Exposure and Abnormal Reflexes in Neonates*, NeuroToxicology (Jan. 2005).

LIST OF ABBREVIATIONS

AChE RBC AChE	Acetylcholinesterase Red blood cell acetylcholinesterase
CDPR	California Department of Pesticide Regulation
CRLAF	California Rural Legal Assistance Foundation
DOL	Department of Labor
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FJ	Farmworker Justice
FQPA	Food Quality Protection Act
FWAF	Farmworker Association of Florida
HHRA	Human health risk assessment
LCLAA	Labor Council for Latin American Advancement
LDA	Learning Disabilities Association of America
LOAEL	Low-observed-adverse effect level
LOC	Level of Concern
LULAC	League of United Latin American Citizens
MOE	Margin of exposure
MRI	Magnetic resonance imaging
NAS	National Academy of Sciences
NAWS	National Agricultural Workers Survey
NOAEL	No-observed-adverse effect level
OP	Organophosphate pesticide

PANNA	Pesticide Action Network North America
PCUN	Pineros y Campesinos Unidos del Noroeste
PoD	Point of departure
PPE	Personal protective equipment
REI	Re-entry interval
SAP	Scientific Advisory Panel
USDA	U.S. Department of Agriculture
USGS	U.S. Geological Survey
UFW	United Farm Workers