

Objections to March 29, 2017 Order Denying PAN/NRDC Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos

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Docket No. EPA-HQ-OPP-2007-1005

Submitted by:

Earthjustice

Objectors:

Pesticide Action Network

Natural Resources Defense Council

United Farm Workers

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

National Hispanic Medical Association

Pineros y Campesinos Unidos del Noroeste

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OBJECTIONS TO MARCH 29, 2017 ORDER DENYING PAN/NRDC PETITION TO REVOKE ALL TOLERANCES AND CANCEL ALL REGISTRATIONS FOR THE PESTICIDE CHLORPYRIFOS

INTRODUCTION AND SUMMARY

These objections seek: (1) reversal of the Environmental Protection Agency's ("EPA's") March 29, 2017 Order denying a 2007 petition to revoke all food tolerances for chlorpyrifos, a neurotoxic pesticide; and (2) an immediate final order revoking all chlorpyrifos tolerances. These objections are filed on behalf of Pesticide Action Network ("PAN"), Natural Resources Defense Council ("NRDC"), United Farm Workers, 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, National Hispanic Medical Association, and Pineros y Campesinos Unidos del Noroeste, by Earthjustice (collectively "Objectors").

PAN and NRDC filed the petition in 2007 asking EPA to revoke chlorpyrifos food tolerances and cancel all food uses of the pesticide. Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos (Sept. 12, 2017) ("2007 Petition") (EPA-HQ-OPP-2007-1005-0005). The 2007 Petition sought action by EPA on two critical issues left unaddressed when EPA re-registered chlorpyrifos in 2001 and 2006: (1) the growing scientific evidence that chlorpyrifos causes damage to children's brains from prenatal and early childhood exposures and that it does so at lower exposure levels than what EPA used in re-registering chlorpyrifos; and (2) harmful exposures to chlorpyrifos from pesticide drift and volatilization, which EPA never addressed in re-registering chlorpyrifos, despite numerous reported pesticide poisonings from chlorpyrifos every year and air monitoring detecting chlorpyrifos in school yards and residential neighborhoods in harmful amounts.

PAN and NRDC filed the 2007 Petition under the Federal Food, Drug and Cosmetic Act ("FFDCA"), which prescribes the required procedural and substantive outcomes. Procedurally, EPA may issue a proposed or final rule revoking the tolerances or an order denying the petition. 21 U.S.C. § 346a(d)(4)(A). Substantively, the FFDCA makes food safety the highest priority and constrains EPA's discretion accordingly. EPA may leave a tolerance in effect for a pesticide "only if the Administrator determines the tolerance is safe." *Id.* § 346a(b)(2)(A)(i). Conversely, the Administrator "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* The Act further constrains EPA by defining "safe" to mean that "the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure" to the pesticide. *Id.* § 346a(b)(2)(A)(ii).

As early as 2000, EPA noted that laboratory studies consistently showed that the developing brain can be harmed by low-level exposures to chlorpyrifos.¹ When EPA began to review the studies correlating chlorpyrifos exposures with damage to children's brains in response to the 2007 Petition, it found such a correlation. It submitted its analysis to EPA's

¹ EPA, Human Health Risk Assessment: Chlorpyrifos (June 8, 2000) at 131 ("Results of multiple studies have consistently shown that the developing brain is susceptible to chlorpyrifos treatment.").

Scientific Advisory Panel (“SAP”) on multiple occasions beginning in 2008, and each time, the SAP confirmed EPA’s conclusion that early life exposures to chlorpyrifos pose a risk of long-lasting, adverse cognitive, behavioral, and motor impairments. And both EPA and the SAP found that the exposures associated with serious damage to children’s brains were far below the regulatory endpoint used by EPA in its 2001 and 2006 re-registration determinations and in establishing the chlorpyrifos tolerances currently in effect. *See infra* at 14-16.

These reviews culminated in EPA’s official finding in its revised human health risk assessment, released in 2014, that chlorpyrifos causes long-lasting damage to children’s brains at exposures lower than EPA’s regulatory endpoint. *See infra* at 16-17. The 2014 risk assessment also documented unsafe chlorpyrifos exposures from drinking water contamination. In 2015, EPA proposed to revoke all chlorpyrifos tolerances based on these findings. 80 Fed. Reg. 69,080 (Nov. 6, 2015). In the proposed revocation rule, EPA explicitly and repeatedly found chlorpyrifos unsafe. *Id.* at 69,081-083, 69,097, 69,103, 69,105-106.

At the same time, the proposed revocation rule noted that EPA’s 2014 risk assessment was under-protective in a fundamental way. EPA had not changed its regulatory endpoint, which continued to be based on poisoning risks, even though lower chlorpyrifos exposures caused brain impairments. EPA recognized that its 2014 risk assessment and 2015 proposed tolerance revocation did not address the greatest risks and most sensitive endpoint, as EPA policy requires.

EPA, therefore, continued to explore ways to establish an exposure limit that would protect children from neurodevelopmental harm. Each method it explored revealed more serious risks from chlorpyrifos than the 2014 risk assessment. In November 2016, EPA released its second revised human health risk assessment using a regulatory endpoint designed to guard against damage to children’s brains. That risk assessment found unsafe exposures from every way that people come into contact with chlorpyrifos —on food, in drinking water, through pesticide drift, and from applying the pesticide or working in fields that had recently been sprayed.² EPA indicated it had found no chlorpyrifos uses that meet the FFDCA safety standard and all chlorpyrifos tolerances would need to be revoked. 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016).

While the FFDCA does not establish a timeline for resolving petitions to revoke tolerances, EPA, like all federal agencies, must respond to administrative petitions “within a reasonable time.” 5 U.S.C. § 555(b). EPA fell far short of this obligation with respect to the 2007 Petition to ban all food uses of chlorpyrifos. In 2015, the Ninth Circuit Court of Appeals found EPA guilty of “egregious” unreasonable delay and issued a writ of mandamus setting deadlines for EPA to take action. *In re PANNA v. EPA*, 798 F.3d 809, 811 (9th Cir. 2015). When EPA found that chlorpyrifos poses such serious risks that a nationwide ban was warranted, the court became persuaded that the time for study had passed and the time for action had arrived. *Id.* at 814. The court gave EPA a March 31, 2017 deadline to take final action on the 2007 Petition.

Something changed as that deadline approached, but it was neither the science, nor the legal mandates. A newly inaugurated President appointed a new EPA Administrator, Mr. Scott

² Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Nov. 3, 2016) (EPA-HQ-OPP-2015-0653-0454).

Pruitt, and it fell to him to meet the court-ordered March 31, 2017 deadline. Administrator Pruitt chose not to finalize the revocation order, even though he could not make the safety findings required to keep chlorpyrifos in place. He decided to put off regulatory action. He issued an order on March 29, 2017, denominated “Chlorpyrifos: Order denying PANNA and NRDC’s petition to revoke tolerances.” 82 Fed. Reg. 16,581 (Apr. 5, 2017) (“Pruitt Order”). That Order, however, did not determine that the 2007 Petition should or could be denied on its merits. Nor did it make the safety findings required by law to take that course of action. Instead, the Pruitt Order postpones taking final action on the proposed tolerance revocation rule until some unspecified future time that could be five or more years off.

Such a postponement violates the FFDCA’s substantive mandates. It leaves chlorpyrifos tolerances in place, but EPA has the authority to do so *only if* it finds chlorpyrifos safe. EPA has, however, repeatedly found chlorpyrifos to be unsafe. Under the FFDCA, EPA must revoke tolerances if it determines the tolerances unsafe. Revoking all chlorpyrifos tolerances is the only legally and scientifically defensible course of action. These objections ask EPA to rule on these objections within 60 days and revoke all chlorpyrifos on an expeditious basis.

PRELIMINARY MATTERS

I. NO FEE REQUIRED

Counsel for Objectors spoke with EPA’s Office of General Counsel on June 1, 2017, and was informed that the fee described in 40 CFR 178.25(a)(5) is not required because EPA is prohibited from collecting such fees at this time. *See* 21 U.S.C. § 346a(m)(3) (“PROHIBITION. During the period beginning on October 1, 2007, and ending on September 30, 2017, the Administrator shall not collect any tolerance fees under paragraph (1).”). Therefore, no fee accompanies these objections.

II. THE ADMINISTRATIVE RECORD

Since completing re-registration of chlorpyrifos in 2006, EPA has engaged in extensive reviews and a rulemaking process regarding chlorpyrifos registrations and tolerances and has established three related dockets. The first docket, EPA-HQ-OPP-2007-1005, was opened in response to the 2007 Petition. The second docket, EPA-HQ-OPP-2008-0850, was opened when EPA began the registration review process for chlorpyrifos. The third docket, EPA-HQ-OPP-2015-0653, was opened when EPA initiated the tolerance revocation process after determining that chlorpyrifos was unsafe. EPA cites all three dockets as being relevant to its denial decision. 82 Fed. Reg. 16,581, 16,582 (Mar. 29, 2017). As such, all three dockets must be considered part of the administrative record for reviewing these objections to EPA’s denial of the 2007 Petition.

In September 2016, many of the Objectors filed a Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Pose Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos. After EPA released a revised human health risk assessment in November 2016 finding all food uses of chlorpyrifos unsafe, these groups withdrew the portion of the petition seeking an immediate suspension of chlorpyrifos uses that pose unacceptable risks to workers because revocation of chlorpyrifos food tolerances seemed inevitable and would end the uses and the associated harm to workers. The portion of the petition seeking cancellation of chlorpyrifos uses remains before EPA. EPA never opened a docket for the suspension and

cancellation petition, but the petition and supporting declaration and exhibits were submitted through comments to docket EPA-HQ-OPP-2015-0653 and are part of the record.³

Additionally, the administrative record must include all communications regarding chlorpyrifos between EPA (including the post-2016 election transition and beachhead teams) and Dow Agrosiences, CropLife America, the U.S. Department of Agriculture, and any other entity or agency that communicated with EPA outside of the public comment process.⁴ *See, e.g., Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993) (“The complete administrative record consists of all documents and materials directly or indirectly considered by the agency”).

III. NO EVIDENTIARY HEARING IS NEEDED IN LIGHT OF THE PURLEY SCIENTIFIC ISSUES RAISED IN THESE OBJECTIONS

The Objectors do not seek an evidentiary hearing because these objections present purely legal issues, namely whether EPA can leave chlorpyrifos tolerances in place when it has found chlorpyrifos unsafe. The FFDCA requires EPA to revoke chlorpyrifos tolerances in these circumstances and no evidentiary hearing is needed to do so.

BACKGROUND

I. THE LEGAL FRAMEWORK REQUIRES PROTECTION, PARTICULARLY OF CHILDREN, FROM HARMFUL PESTICIDES

A. 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).

The Food Quality Protection Act (“FQPA”), passed unanimously in 1996, amended the FFDCA to require that EPA “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).

³ Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0661). The Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Pose Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos and the Declaration of Philip J. Landrigan, M.D., M.Sc. in Support of Petition to Suspend and Cancel Chlorpyrifos Uses were submitted as attachments to these comments.

⁴ Earthjustice, on behalf of PAN, submitted a Freedom of Information Act (“FOIA”) request to EPA for these documents on March 15, 2017. EPA failed to substantively respond to that request within the statutory timeline, and to date has not released any documents related to PAN’s FOIA request. On May 10, 2017, PAN filed a FOIA lawsuit against EPA seeking production of the requested records. *Pesticide Action Network of North America v. U.S. Environmental Protection Agency*, 3:17-cv-02706-SK (N.D. Cal. filed May 10, 2017).

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.⁵ It documented the ways that children are not “little adults” but have unique exposures from the foods they eat, their play, and their metabolism. 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 chemicals on their development. Chemical exposures can damage the developing brain at exposures less than those that affect adults.

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. 21 U.S.C. § 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-

⁵ 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>.

natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” 21 U.S.C. § 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.*

In addition, 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 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).

B. Pesticide Use on Food Crops Is Regulated Under Overlapping Provisions of the Federal Insecticide, Rodenticide and Fungicide Act

EPA regulates use of pesticides in the United States under the Federal Insecticide, Rodenticide and Fungicide Act (“FIFRA”). Under FIFRA, EPA must establish a registration before a pesticide may generally be sold or used in the United States. 7 U.S.C. § 136a(a). To register or re-register a pesticide, EPA must determine that its use “will not generally cause unreasonable adverse effects on the environment,” which includes risks to human health. *Id.* § 136a(c)(5)(D); *see id.* § 136(bb) (definition of “unreasonable adverse effects”). EPA has the authority to cancel a pesticide registration if the pesticide use “causes unreasonable adverse effects on the environment.” *Id.* § 136d(b).

The two statutes’ safety standards are intertwined through FIFRA’s definition of “unreasonable adverse effects,” which includes “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard.” 7 U.S.C. § 136(bb)(2). In other words, a pesticide may not be registered for a food use unless a food tolerance is in place, and whenever a food tolerance is revoked, the registration for use of the pesticide on that food crop must be cancelled. Because of this interdependence, the FQPA directs EPA to coordinate FQPA actions to revoke tolerances with any related, necessary FIFRA action. 21 U.S.C. § 346a(1).

Congress gave EPA a ten-year deadline, which ended in August 2006, to bring all food-use pesticides into compliance with these protective mandates. 21 U.S.C. § 346a(q)(1). The August 2006 deadline applied to both tolerances established under the FFDCA, as amended by the FQPA, and re-registration decisions under FIFRA.

To ensure that pesticides in use in the United States continue to meet the FQPA and FIFRA standards in light of the development of scientific methodologies and available scientific information on health effects and exposures, Congress required periodic review of pesticides every 15 years, but provided: “Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide . . .” 7 U.S.C. § 136a(g) and § 136a(g)(1)(C). The first round of registration reviews of older pesticides, which includes chlorpyrifos, must be completed by October 1, 2022. *Id.* § 136a(g)(1)(A)(iii)(I).

II. EPA’S RE-REGISTRATION OF CHLORPYRIFOS

A. Chlorpyrifos

Chlorpyrifos is a widely used organophosphate pesticide first registered by EPA in 1965. It is used on an extensive variety of crops, including fruit and nut trees, vegetables, wheat, alfalfa, and corn. In 2006-2012, chlorpyrifos was applied to more than half of the country’s apple and broccoli crops, 45% of onion, 46% of walnut, and 41% of cauliflower crops.⁶ Five to eight million pounds are used annually in agriculture, including one million pounds on both corn and soybeans.⁷

Organophosphate chemicals were developed as nerve agents in World War II and adapted for use as insecticides after the war. They have deleterious effects on people who come into contact with them when they are used as insecticides.

Chlorpyrifos is acutely toxic and causes a significant number of acute pesticide poisoning incidents every year. Chlorpyrifos and other organophosphate pesticides do this by suppressing the activity of an enzyme called acetylcholinesterase, which regulates nerve impulses throughout the body. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, abdominal cramps, dizziness, difficulty breathing, vomiting, diarrhea, tremors, muscle spasms, seizures, skin rashes, and sometimes convulsions, respiratory paralysis, comas, and even death in extreme cases.

Widespread use of chlorpyrifos has exposed people through the air, in drinking water, and through the foods they eat. Monitoring by the California Department of Pesticide Regulation showed chlorpyrifos as having one of the highest number of detections in its 2011-2015 air monitoring, and water monitoring detected chlorpyrifos in 17.7% of samples, with 9.9%

⁶ 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).

⁷ *Id.*

exceeding the state's concentration limit.⁸ In 2015, 61% of the air samples taken at a high school detected chlorpyrifos.⁹

In addition to poisonings, a growing body of published scientific research from both animal and epidemiology studies links exposure to chlorpyrifos with causing neurodevelopmental harm to children's brains. Children's brains are particularly vulnerable to damage from low-dose exposures because the placenta is not a barrier to passage of many toxic chemicals, including chlorpyrifos, from the mother to the fetus. An extensive body of published animal studies reveals cognitive, motor control, and social behavior impacts from chlorpyrifos exposures.

Additional evidence of neurodevelopmental harm from chlorpyrifos has come from three population cohorts that were studied by university research teams as part of the NIH-funded network of Centers for Children's Environmental Health. A research team at University of California-Berkeley followed a cohort of children born to farmworkers in Salinas Valley in California. A Mount Sinai School of Medicine study observed a New York City Hispanic population. A research team at Columbia University followed African American and Dominican children in New York City. The three studies each enrolled pregnant women and conducted long-term birth-cohort studies. Even though the studies were conducted in different parts of the country on different populations with different types of exposures, they produced strongly convergent results. All found that prenatal exposures to pesticides were statistically significantly correlated with cognitive impairments that persist into the school years, and the Columbia study was specific to chlorpyrifos. Prenatal exposures correlate with lasting functional harm to children's brains in the form of reduced IQ, loss of working memory, attention deficit disorders, and delayed motor development. Chlorpyrifos also has been found to cause physical changes in brain structure that may have long-lasting effects. Children living near agricultural fields suffer disproportionately from these effects. The Declaration of Philip J. Landrigan, M.D., M.Sc., who led the 1993 study that produced the NAS Report, describes the lines of evidence documenting damage to children's developing brains from chlorpyrifos and the other organophosphates (attached as Exhibit 1).

B. EPA's Re-registration Determinations for Chlorpyrifos

EPA used a two-part process for re-registering chlorpyrifos and the other organophosphate pesticides. First, it conducted risk assessments and made interim re-registration determinations for the individual organophosphates, which it did in 2001 for chlorpyrifos. Second, it conducted a cumulative risk assessment of all the organophosphates,

⁸ Vidrio, E., Wofford, P., Segawa, R., Schreider, J. March 2013. Air Monitoring Network Results for 2011. Vol. 1. California Environmental Protection Agency, Department of Pesticide Regulation, http://www.cdpr.ca.gov/docs/emon/airinit/amn_vol1_final.pdf; and Zhang X., Starner K., Spurlock F. 2012. Analysis of Chlorpyrifos Agricultural Use in Regions of Frequent Surface Water Detections in California, USA . California Department of Pesticide Regulation, Environmental Monitoring Branch, Surface Water Protection Program. http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/zhang_chlorpyrifos_report.pdf.

⁹ http://www.cdpr.ca.gov/docs/emon/airinit/amn_2015_report_final.pdf (Shafter High School).

which it completed in 2006. The cumulative risk assessment did not result in changes in the interim re-registration and tolerance determinations for chlorpyrifos.

In its risk assessment for chlorpyrifos (as with the other organophosphates), EPA identified a level of 10% cholinesterase inhibition in red blood cells as the endpoint it would use in determining whether chlorpyrifos exposures violate the regulatory standards. In assessing risks from aggregate exposures to chlorpyrifos, EPA determined that home uses had to be cancelled. Children crawling on treated carpets and hugging pets after flea treatments faced unsafe exposures. Seeing the writing on the wall, the chemical makers agreed to cancel homeowner uses of chlorpyrifos in 2000.

EPA, however, never assessed the extent to which children in agricultural communities are exposed to chlorpyrifos through drift from agricultural sites to schools, day cares, playfields, and homes, or through residues their parents take home on their clothes. The failure to assess risks to and protect children in farmworker communities, who are primarily Latino and low-income, evinced a double standard that raises serious environmental justice concerns.

Nor did EPA protect the fetus and young children from neurodevelopmental harm, despite acknowledging in its 2000 human health risk assessment for chlorpyrifos that the fetus and young children are more sensitive to chlorpyrifos and that multiple studies consistently showed that the developing brain can be harmed by chlorpyrifos exposures.¹⁰

PAN, NRDC, and others commented on EPA's 2001 interim re-registration determination for chlorpyrifos, urging EPA to address pesticide drift and the mounting evidence of neuro-developmental impacts to children at low doses. The New York Attorney General also submitted comments emphasizing that the interim re-registration determination underestimated the risks of chlorpyrifos, particularly to children, and failed to make a finding that the pesticide is "safe" and complied with the FQPA.¹¹ The comments cited studies that suggested "that there is *no* level of exposure to chlorpyrifos that is without adverse effects on developmental neurotoxicity in the young..."¹² In 2006, after releasing its cumulative organophosphate risk assessment, EPA finalized its re-registration of chlorpyrifos without protecting children from drift or neurodevelopmental harm from chlorpyrifos and without addressing the public comments.

III. ADVOCACY TO CONVINCING EPA TO PROTECT CHILDREN FROM DRIFT AND NEURODEVELOPMENTAL HARM FROM CHLORPYRIFOS EXPOSURES

Farmworker and health advocates pursued three legal avenues to rectify EPA's failure to

¹⁰ See NRDC Comments on Chlorpyrifos Interim Reregistration Decision (Jan. 14, 2002) (Docket ID No. OPP-34203G), attached Exhibit 2, (citing Human Health Risk Assessment - Chlorpyrifos (June 8, 2000), available at https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf).

¹¹ Attorney General of the State of New York, comments on Chlorpyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision pursuant to 66 Fed. Reg. 57,073-074 (Nov. 14, 2001) at 2, attached Exhibit 3.

¹² *Id.* at 19.

protect children from the hazards posed by chlorpyrifos. First, UFW, PAN, PCUN, and others, represented by Earthjustice and Farmworker Justice filed a federal district court challenge to the 2001 chlorpyrifos interim re-registration decision, in part, for failing to protect children and other bystanders from pesticide drift and failing to cancel uses that expose workers to admittedly excessive poisoning risks.¹³ The parties negotiated principles on which the case could be settled with an EPA commitment to make a new regulatory decision for chlorpyrifos by 2010 that would address drift exposures to children and other bystanders. However, after the Ninth Circuit ruled in a case of first impression that challenges to FIFRA registration determinations must be brought in the courts of appeals within 60 days of the decision, the settlement fell apart.¹⁴

Second, PAN, UFW, PCUN, California Rural Legal Assistance Foundation, and others, represented by Earthjustice, and Farmworker Justice, petitioned EPA to address pesticide drift as mandated by the FQPA.¹⁵ The Kids' Petition highlighted EPA's violation of its legal duty to protect children from all aggregate exposures to each pesticide in tolerance and re-registration determinations and asked EPA to expedite adoption of mitigation for airborne routes of exposure to organophosphates and n-methyl carbamates, another pesticide that suppresses cholinesterase, because of the heightened poisoning risks posed by these classes of pesticides. In March 2014, EPA responded to the petition, acknowledging its legal obligation to address pesticide drift under the FQPA and FIFRA. However, EPA indicated it would not protect children from drift until it reviewed pesticide registrations and tolerance decisions individually in registration review, and it refused to impose interim protections.¹⁶ The petitioners filed administrative objections, which have not been resolved.¹⁷

Third, on September 12, 2007, PAN and NRDC submitted a petition asking EPA to ban chlorpyrifos based on the mounting evidence of risks from chlorpyrifos that were left unaddressed in EPA's 2001 and 2006 regulatory decisions. At its heart, the 2007 Petition raised two issues:

1. The 2007 Petition (at 17-21) challenged EPA's failure to account for risks to children and bystanders from chlorpyrifos drift and volatilization, as required by the FQPA. In support of this obligation, the petition presented the California Air Resources Board's air monitoring reports and data, which documented concentrations above EPA's levels of

¹³ *UFW v. Administrator, EPA*, No. 07-3950-JF (N.D. Cal. filed Aug. 1, 2007).

¹⁴ *UFW v. Administrator*, Stipulation of Voluntary Dismissal, Dkt. 98, No. 07-3950-JF (N.D. Cal. filed April 27, 2010); see *UFW v. Administrator, EPA*, 592 F.3d 1080 (9th Cir. 2010) (challenges to registration decisions must be brought in courts of appeals within 60 days, rather than in district court under a six-year statute of limitations as had previously been the case).

¹⁵ See *Pesticides In The Air – Kids At Risk: Petition to EPA to Protect Children From Pesticide Drift* (October 13, 2009) (the "Kids' Petition") (EPA-HQ-OPP-2009-0825-0002).

¹⁶ *Agency Response to Pesticides In The Air – Kids At Risk: Petition to EPA to Protect Children From Pesticide Drift* (March 31, 2014) at 2, 32-33 ("Agency Response to Kids' Petition") (EPA-HQ-OPP-2009-0825-0084).

¹⁷ *UFW, et al.*, Written Objections to EPA's Response to Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children From Pesticide Drift (May 28, 2014). A court challenge to the decision not to impose interim protection was rejected. *PAN v. U.S.E.P.A.*, No. 14-71514 (9th Cir.).

concern near fields and in schoolyards, and community air monitoring, which showed widespread contamination in multiple locations and over a period of years, including in schoolyards.¹⁸

2. The 2007 Petition (at 6-9, 11-16) compiled the mounting evidence documenting serious cognitive and behavioral effects from low-dose chlorpyrifos exposures, including peer-reviewed scientific studies showing that children and infants exposed to chlorpyrifos exhibit long-lasting, and possibly permanent, impaired cognitive and behavioral development from early life exposure. The Petition cited concerns raised by members of EPA's Scientific Advisory Panel that EPA had failed to account for scientific evidence showing brain impacts from early life exposures to chlorpyrifos at lower doses than those used by EPA in its regulatory decisions. *Id.* at 13, 22-23.

IV. EPA'S ACTIONS IN RESPONSE TO THE 2007 PETITION

EPA has long recognized that organophosphates generally, and chlorpyrifos in particular, raise significant health issues. For this reason and because it would be reviewing the novel, complex scientific issues raised in the 2007 Petition and developing new scientific methodologies to do so, EPA decided to move up the registration review of chlorpyrifos in order to complete it several years in advance of the 2022 deadline.¹⁹ EPA initiated the chlorpyrifos registration review and projected it would result in proposed regulatory decisions in 2014 and final ones in 2015. Chlorpyrifos Final Work Plan: Registration Review (Sept. 2009). PAN objected to the lengthy timetable, stating that uncertainties with respect to aspects of chlorpyrifos toxicity do not justify delaying action to protect children.²⁰

As described above, the 2007 Petition sought a ban on use of chlorpyrifos on food based primarily on the need to protect children: (1) from exposure to chlorpyrifos from drift and volatilization; and (2) from exposures that could harm the developing brain. The petition raised other issues as well, which EPA separated from the two core issues. When faced with unreasonable delay litigation (*see infra*), EPA issued partial denials on various secondary issues, such as delays in completing endocrine disruption studies, cancer risks, that over-reliance on industry studies, and exporting chlorpyrifos to other countries.²¹

¹⁸ Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos at 17-21 (September 12, 2007), EPA-HQ-OPP-2007-1005.

¹⁹ Declaration of Jack Housenger, Director of Health Effects Division of EPA's Office of Pesticide Programs ¶ 13, in *In re PANNA*, No. 12-71125 (9th Cir. July 23, 2012).

²⁰ Pesticide Action Network Comments (May 18, 2009) (EPA-HQ-OPP-2008-0850-0010).

²¹ EPA's Partial Response to Chlorpyrifos Petition by NRDC & PANNA, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 16, 2012) (EPA-HQ-OPP-2007-1005-0095); Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014) (EPA-HQ-OPP-2007-1005-0098).

As to the heart of the petition, EPA engaged in several rounds of scientific review, solicited input from its Scientific Advisory Panel on numerous occasions, and developed methodologies to analyze, quantify, and for drift, to mitigate the risks.

A. Inhalation Exposures through Pesticide Drift and Volatilization

EPA's 2001 re-registration determination for chlorpyrifos ignored exposures through pesticide drift and volatilization on the theory that such exposures were exempted from the FQPA as occupational exposures. In responding to the Kids' Petition and in its preliminary human health risk assessment released in 2011, EPA acknowledged its legal obligation to assess and protect against drift and volatilization as aggregate exposures. Agency Response to Kids' Petition at 2, 32-34; 2011 PHHRA at 71-75. EPA committed to address such exposures in responding to the 2007 Petition and its registration review of chlorpyrifos and other pesticides.

1. EPA Has Appropriately Taken Steps to Reduce Exposures From Spray Drift, But These Steps Fail to Protect Children From Unsafe Exposures to Chlorpyrifos Through Drift

EPA has developed a standard methodology for assessing a pesticide's propensity to drift from the point of application offsite to schools, homes, day cares, playfields, and other places people gather and will be exposed. EPA models inhalation exposures from aerial applications, but for groundboom and airblast applications, it focuses only on dermal exposures when people come into contact with residues deposited on the ground. EPA justifies this omission because current pesticide labels prohibit applying pesticides in a manner that will allow drift to contact people. Public comments objected to this approach because of the extensive evidence that drift is reaching people and causing poisonings, thereby demonstrating that the label prohibition is not preventing harmful spray drift.²²

EPA applied its standard methodology in assessing chlorpyrifos and found that chlorpyrifos can drift in harmful amounts. To protect children and other bystanders, EPA convinced the registrants to change chlorpyrifos labels by December 2012 to reduce application rates for aerial spraying, change nozzle types and droplet sizes, and impose no-spray buffers around sensitive sites frequented by non-occupational bystanders, especially children. Such sites include "residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or commercial purposes. Sensitive sites include homes, farmworker housing, or other residential buildings, schools, day care centers, nursing homes, and hospitals."²³ The buffers are 10 feet for groundboom spraying, 10 feet for airblast applications, enlarged to 25-50 feet for large volume, medium or coarse droplet applications, and 10-100 feet for aerial spraying.

²² Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Apr. 30, 2015) at 47 ("2015 Farmworker Comments") (EPA-HQ-OPP-2008-0850-0848) (citing Centers for Disease Control and Prevention investigation of pesticide drift causing poisonings of 20 workers between 30-350 feet from the application site).

²³ EPA, Chlorpyrifos – Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures (July 13, 2012) at 3.

In an interim response to the 2007 Petition, EPA stated that it was partially granting the Petition with respect to inhalation exposure risks and was reducing risks from primary spray drift by limiting application rates and imposing buffer zones around sensitive sites adjacent to agricultural applications.²⁴

2. EPA Initially Found Harmful Exposures From Volatilization, But Reversed Course Based on Dow Studies That Have Been Heavily Criticized

EPA assessed risks from volatilization in its 2011 Preliminary Human Health Risk Assessment (“2011 PHHRA”) based on ambient and application site monitoring. EPA’s assessment showed that one-quarter of the acute ambient air concentrations resulted in risks of concern to residential bystanders, as did over half of the acute application site concentrations and most of the short- and intermediate-term application site concentrations.²⁵

In 2013, drawing on methods used to assess bystander inhalation risks from fumigant pesticides and recommendations from a December 2009 Scientific Advisory Panel meeting, EPA conducted an assessment of volatilization risks from chlorpyrifos. EPA found that chlorpyrifos applied to fields can volatilize and harm people nearly a mile away (and likely farther): “Given the current available information and the state of the science concerning the volatilization of pesticides, this preliminary risk assessment indicates risks of concern are exceeded for bystanders.”²⁶ EPA identified buffer zones that would be required to reduce off-site concentrations to safe levels. For example, for oranges, the average application rate is so high (greater than 2 pounds of active ingredient/acre) that the maximum buffers would need to be between 1,476 and 4,724 feet and whole field buffers would need to range from 623-2,838 feet, so large that continued use of chlorpyrifos would be infeasible.²⁷

EPA subsequently reversed course based on two studies conducted by Dow AgroSciences, which purport to show that people will not experience adverse effects from volatilization exposures. Without submitting the studies to its Scientific Advisory Panel or obtaining other peer review, EPA accepted the studies and found that chlorpyrifos poses no risk of cholinesterase inhibition from volatilization. On July 15, 2014, EPA provided a partial response indicating that EPA will deny the volatilization component of the petition based on the

²⁴ Chlorpyrifos Petition – December 2012 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Dec. 18, 2012) (EPA-HQ-OPP-2007-1005-0096).

²⁵ Chlorpyrifos Preliminary Human Health Assessment for Registration Review (June 30, 2011) at 55 (EPA-HQ-OPP-2008-0850-0025).

²⁶ Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization (Jan. 31, 2013) at 55 (assessment based on a study that measured the effects of aerosolized chlorpyrifos – the form chlorpyrifos takes when applied as a spray – and not the vapor form it takes after volatilization) (EPA-HQ-OPP-2008-0850-0114).

²⁷ *Id.* at 32-46.

Dow studies on chlorpyrifos vapors, as opposed to aerosols, which could have produced the monitoring concerns noted in 2011 and the risks of concern in the 2013 assessment.²⁸

Public comments objected to EPA's use of the Dow studies without subjecting them to peer review. 2015 Farmworker Comments at 32-33. Comments explained that the Dow studies ignored the effects of temperature, soil moisture, and individual variation and submitted biomonitoring and incident reports showing poisoning incidents at distances as far away as one-half mile from the application site. *Id.* at 50-58. Comments also pointed out the lack of controls in the Dow study that demonstrated that the experiment was capable of successfully producing or detecting cholinesterase inhibition. Without such controls, the study results cannot be interpreted or used to claim that chlorpyrifos volatilization does not produce cholinesterase inhibition.²⁹

B. EPA Found that Chlorpyrifos Exposures are Correlated with Harm to the Developing Brain at Exposures Far Below EPA's Regulatory Endpoint

As long ago as 2000, EPA noted that animal studies reveal that the developing fetus and young animals are more susceptible to chlorpyrifos than adults. Since that time, the scientific evidence of harm to children's brains from chlorpyrifos exposures has grown, with dozens of peer-reviewed scientific articles documenting statistically significant correlations between early life exposures and neurodevelopmental harm.

To respond to the 2007 Petition, EPA conducted a series of transparent and iterative reviews of the extensive scientific literature, including both animal and epidemiology studies, regarding neurodevelopmental harm from chlorpyrifos. It convened its Scientific Advisory Panel ("SAP") several times to review its assessments.

In 2008, EPA convened its SAP to review the significant new data since EPA's 2000 risk assessment. The SAP found that laboratory studies show that "gestational or early postnatal exposures can lead to neurochemical and behavioral alterations that persist into adulthood," including long-term neurobehavioral changes in motor and cognitive behaviors. 2008 SAP Report at 11-12.³⁰ The Panel found that "chlorpyrifos likely played a role in the birth and neurodevelopmental outcomes noted in the three cohort studies," and found the Columbia study the most sound and appropriate for use in assessing developmental toxicity of chlorpyrifos. *Id.* at 12, 37; *see also id.* at 43 ("chlorpyrifos is likely associated with adverse neurodevelopmental outcomes."). Finally, Panel members noted that the exposures in the Columbia study were below EPA's regulatory endpoint and of concern in light of evidence demonstrating that low levels of exposure to toxicants like lead, mercury, and PCBs are now known to produce significant adverse effects when they were previously thought to be harmful only at high levels.

²⁸ Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014).

²⁹ 2015 Farmworker Comments at 51; Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) at 21-22.

³⁰ FIFRA SAP Meeting Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the EPA Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos (Sept. 2008), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0274-0064>.

Id. at 43.

In 2010, EPA convened its SAP to address how to incorporate epidemiology and incident data into risk assessments. EPA had developed a draft framework for incorporating epidemiology and human incident data into human health risk assessment. The Panel reviewed the draft and provided factors to be used to evaluate the quality of epidemiology studies, and identified ways such studies could be used in risk assessment.³¹

In July 2011, EPA released its Preliminary Human Health Risk Assessment, which confirmed, as the 2007 Petition claimed was legally required, the need to address drift, volatilization, and health impacts to children at low doses.³² The assessment expressed concern that current tolerances may not afford sufficient protection to children from drinking water and drift exposures, particularly infants. Reader's Guide at 2-3; 2011 PHHRA at 17. As to the mounting evidence of neurodevelopmental impacts, EPA concluded that "chlorpyrifos likely played a role in long term neurological effects from early exposures that were evaluated in the epidemiology studies." Reader's Guide at 2-3. Despite these statements, EPA proposed to reduce the FQPA 10X safety factor to 1X, *i.e.*, to eliminate it. Numerous comments opposed eliminating the FQPA 10X safety factor, including comments submitted by the California Department of Pesticide Regulation observing that developmental neurotoxicity may be a more sensitive endpoint than cholinesterase inhibition and "[p]rotection against brain cholinesterase inhibition alone may be insufficient to protect against such effects."³³

In 2012, EPA convened its SAP to review EPA's more comprehensive analysis of the neurotoxicity of chlorpyrifos. In its report, the SAP noted significant, long-term adverse effects on neurobehavioral development from chlorpyrifos in laboratory animal studies. It found that the epidemiology "studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age." 2012 SAP at 17.³⁴ The Panel concurred with EPA and the 2008 SAP that "chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies," *id.* at 18, and it noted that "multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition." *Id.* at 19. Because the mode of action has not been identified, the SAP believed the cohort studies do not readily lend themselves as the basis for establishing the point of departure. However, the Panel expressed concern over EPA's focus on 10% cholinesterase inhibition because there is no

³¹ FIFRA SAP Meeting Minutes No. 2010-03, A Set of Scientific Issues Being Considered by the EPA Regarding: Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment (Feb. 2010), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0851-0059>.

³² EPA, Reader's Guide to the Preliminary Human Health Risk Assessment for Chlorpyrifos at 1-3 (July 1, 2011) ("Reader's Guide") (EPA-HQ-OPP-2008-0850-0027).

³³ Comment submitted by California Department of Pesticide Regulation to EPA (Sept. 30, 2011) at 3 (EPA-HQ-OPP-2008-0850-0099).

³⁴ FIFRA SAP Meeting Minutes No. 2012-04, A Set of Scientific Issues Being Considered by the EPA Regarding: Chlorpyrifos Health Effects (Apr. 2012), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0040-0029>.

mechanism whereby a 10% AChE activity reduction in pregnant women would be responsible for a cognitive defect or developmental delay in their offspring.” *Id.* at 25. The Panel advised EPA to explore ways to use the Columbia study to inform dose-response relationships. *Id.* at 19.

In December 2014, EPA released its Revised Human Health Risk Assessment for Chlorpyrifos (“2014 RHHRA”)³⁵ and acknowledged the strong convergence in the findings from the animal studies and the three mother-child cohort studies. It found that the laboratory animal studies indicated “that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood.” 2014 RHHRA at 25; *see id.* at 26 (“upon review of the published literature a pattern of neurodevelopmental adverse outcomes emerges.”). It called the cohort studies “strong studies which support a conclusion that chlorpyrifos likely played a role in these outcomes.” *Id.* at 33. More specifically, the studies:

consistently identified associations with neurodevelopmental outcomes in relation to chlorpyrifos exposure. There is evidence of delays in mental development in infants (24-36 months), attention problems and pervasive developmental disorder in early childhood, and intelligence decrements in school age children who were exposed to chlorpyrifos or OP during gestation. Investigators reported strong measures of statistical association across several of these evaluations (odds ratios 2-4 fold increased in some instances) and observed evidence of exposure-response trends in some instances, e.g., intelligence measures.

Id. at 42. EPA concluded “that these lines of evidence together support a conclusion that exposure to chlorpyrifos results in adverse neurodevelopmental outcomes in humans, at least under some conditions.” *Id.* at 49. EPA also concluded that the range of exposures in the epidemiology studies were too low to result in cholinesterase inhibition. *Id.*; *see id.* at 47 (“it is unlikely that [cholinesterase] would have been inhibited by any meaningful or measureable amount, if at all” in the studies). EPA noted that the mode of action by which chlorpyrifos causes long-lasting damage to children’s brains is uncertain, as is the particular exposure level at which such effects occur (apart from knowing it is lower than EPA’s regulatory endpoint based on cholinesterase inhibition). Based on these uncertainties, EPA retained the FQPA 10X safety factor for infants, children, youth, and women of child-bearing years. *Id.* at 49.

EPA continued to use cholinesterase inhibition as its regulatory endpoint in its 2014 risk assessment, despite acknowledging that the harm to children’s brains occurred at lower exposures and is therefore the most sensitive endpoint. EPA then used a model developed by Dow Agrosiences (called a physiologically based pharmacokinetic or PBPK model) to estimate doses in people associated with cholinesterase inhibition. Because the model uses human data, at least in part, EPA decided it could eliminate the traditional 10X safety factor that accounts for uncertainty in extrapolating from animal tests to human impacts (inter-species safety factor). It also reduced by half or more the other traditional 10X safety factor designed to account for variability and sensitivity within human populations (intra-species factor), believing that the human data and the model incorporate such human variability.

³⁵ Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Dec. 29, 2014) (EPA-HQ-OPP-2008-0850-0195).

Public comments objected to the reduction of these traditional safety factors because the Dow model estimates exposures associated with the cholinesterase inhibition endpoint, and neurodevelopmental harm occurred from prenatal exposures far below those that would result in 10% cholinesterase inhibition.³⁶ In addition, EPA's Scientific Advisory Panel had found serious problems with the Dow model in 2011, yet EPA never submitted the model, as subsequently modified, for further review by the Panel, nor did EPA explain how the modifications corrected the problems identified by the 2011 SAP. 2011 SAP at 11, 13-17.³⁷ The model uses data from two studies that deliberately dosed people, and EPA cannot rely on such deliberate human testing without ensuring the tests meet rigorous ethical and scientific standards. 40 C.F.R. §§ 26.1701-.1706. Comments objected to EPA's use of the Dow model because EPA did not obtain review of the studies under current legal standards by its Human Studies Review Board and because of ethical flaws in using Dow employees in one study and in its misleading informed consent, as well as scientific deficiencies. 2015 Farmworker Comments at 36-42.

Even though the 2014 RHHRA used an endpoint that fails to protect children from neurodevelopmental harm and shrunk the traditional safety factors, it found that a substantial number of chlorpyrifos uses will result in exposures that exceed EPA's drinking water levels of concern. 80 Fed. Reg. at 69,083. EPA determined that the drinking water exceedances were likely to be conservative because its modeling is validated by empirical water monitoring data and its modeling is based on a single application.³⁸

V. THE UNREASONABLE DELAY LITIGATION

It took a series of unreasonable delay lawsuits to obtain EPA action on the 2007 Petition. Shortly after PAN filed the 2007 Petition, EPA found that the petition met the legal requirements for FFDCA petitions and published a notice in the Federal Register requesting public comments. 72 Fed. Reg. 58,845 (Oct. 17, 2007). After three years passed without a response to the 2007 Petition, PAN and NRDC filed an unreasonable delay lawsuit, which they settled based on EPA's commitment to respond to the Petition by the end of November 2011. *NRDC v. EPA*, No. 10-05590-CM, Dkt. No. 17, at 2-3 (S.D.N.Y. Dec. 21, 2010) (Stipulation).

After EPA missed the 2011 deadline, PAN and NRDC brought a second delay lawsuit. EPA issued a partial response to the 2007 Petition, promising a complete final response in

³⁶ 2015 Farmworker Comments at 28-32. *See also*, Comment submitted by Elaine M. Faustman, Ph.D. DABT, on behalf of the Institute of Risk Analysis and Risk Communication and the Center for Child Environmental Health Risks Research at the University of Washington (EPA-HQ-OPP-2008-0850-0829); Comment submitted by Robin M. Whyatt, Professor, Columbia University, Dale Hattis, Research Professor, Clark University and Theodore Slotkin, Duke University School of Medicine (EPA-HQ-OPP-2008-0850-0510).

³⁷ FIFRA SAP Meeting Minutes No. 2011-03, A Set of Scientific Issues Being Considered by the EPA Regarding Chlorpyrifos Physiologically Based Pharmacokinetic and Pharmacodynamics (PBPK/PD) Modeling Linked to Cumulative and Aggregate Risk Evaluation System (CARES) (Feb. 2011), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0588-0038>.

³⁸ Chlorpyrifos: Updated Drinking Water Assessment for Registration Review (Dec. 23, 2014) (EPA-HQ-OPP-2008-0850-0198).

December 2012.³⁹ While EPA's first interim response addressed six points made in the 2007 Petition, it did not determine whether EPA would ban chlorpyrifos. *See id.* The only practical effect of EPA's July 2012 partial decision consisted of EPA's announcement that the chlorpyrifos registrants had agreed to a spray drift mitigation package that calls for small no-spray buffers (most were only ten feet) around school grounds, homes, residential lawns, athletic fields, nursing homes, hospitals, sidewalks, and other places frequented by bystanders.⁴⁰ EPA then missed the December 2012 deadline for issuing a response to the 2007 Petition, but it promised a final response by February 2014.⁴¹

In 2013, the Ninth Circuit Court of Appeals decided not to order EPA to respond to the 2007 Petition because the agency had "set forth a concrete timeline for final agency action that would resolve the 2007 Petition by February 2014." *In re PANNA*, 532 F. App'x 649, 651 (9th Cir. 2013).

EPA missed its February 2014 deadline. In July 2014, EPA issued another partial response and reversed its earlier preliminary determination that chlorpyrifos volatilization presents risks that warrant large, no-spray buffers (in some instances many thousands of feet) around schools, homes, and other places frequented by people. EPA based this reversal on two new studies conducted by Dow AgroSciences LLC, the primary chlorpyrifos registrant.⁴² In that partial response, EPA indicated that it planned to release a revised human health risk assessment for public comment in December 2014, along with either a proposed rule revoking tolerances for chlorpyrifos or a proposed order denying the 2007 Petition, and that it would issue any final denial of the 2007 Petition by the summer of 2015.

After EPA missed its February 2014 deadline, PAN and NRDC filed a third unreasonable delay case seeking a writ of mandamus from the Ninth Circuit directing EPA to act. When the case was argued on June 4, 2015, EPA told the court that it would complete its preliminary review of the public comments on the 2014 risk assessment by June 30, 2015 and determine whether it would deny or grant the 2007 Petition, in whole or in part. On June 10, 2015, the court ordered EPA to file a status report by June 30, 2015 informing the court which path it would take and proposing a timeline for final resolution of the 2007 Petition. *In re PANNA*, 790 F.3d 875 (9th Cir. 2015). EPA's June 30, 2015 status report revealed that EPA had become convinced that revocation of all chlorpyrifos food tolerances was warranted because of drinking

³⁹ EPA's Partial Response to Chlorpyrifos Petition by NRDC & PANNA, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 16, 2012).

⁴⁰ *Id.* (citing Chlorpyrifos – Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures (July 13, 2012) at 3).

⁴¹ *See* Chlorpyrifos Petition – December 2012 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Dec. 18, 2012) (EPA-HQ-OPP-2007-1005-0096); Chlorpyrifos Petition – January 2013 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Jan. 25, 2013) (EPA-HQ-OPP-2007-1005-0097); EPA Response to Petition for Writ of Mandamus, in *In re PANNA*, No. 12-71125 (9th Cir. July 24, 2012).

⁴² Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014) at 2-5.

water contamination. Because it offered no definitive timetable for initiating and completing such a revocation rule, PAN and NRDC asked the Court to do so.

In August 2015, the Ninth Circuit issued a writ of mandamus setting deadlines for EPA action. The decision began as follows:

Although filibustering may be a venerable tradition in the United States Senate, it is frowned upon in administrative agencies tasked with protecting human health. Pesticide Action Network North America and the Natural Resources Defense Council have been waiting for years for the United States Environmental Protection Agency to respond to their administrative petition requesting a ban on the pesticide chlorpyrifos. Instead, they've received a litany of partial status reports, missed deadlines, and vague promises of future action. We recognize the scientific complexity inherent in evaluating the safety of pesticides and the competing interests that the agency must juggle. However, EPA's ambiguous plan to possibly issue a proposed rule nearly nine years after receiving the administrative petition is too little, too late. This delay is egregious and warrants mandamus relief. We order EPA to issue a full and final response to the petition no later than October 31, 2015.

In re PANNA, 798 F.3d 809, 811 (9th Cir. 2015); *see id.* at 813 (“Issuing a writ of mandamus is necessary to end this cycle of incomplete responses, missed deadlines, and unreasonable delay.”).

The court explained that the circumstances had changed in two significant respects since the court rejected the earlier request in 2013. First, in 2006, after residential uses had ended, EPA had found the remaining chlorpyrifos uses to be safe and it had not overturned those findings in its 2011 preliminary human health risk assessment. That changed in 2014 when EPA found agricultural uses of chlorpyrifos unsafe due to drinking water contamination and also noted serious risks to farmworkers who apply chlorpyrifos or who enter fields after chlorpyrifos has been sprayed. The court found that “EPA offers no acceptable justification for the considerable human health interests prejudiced by the delay. In view of EPA’s own assessment of the dangers to human health posed by this pesticide, we have little difficulty concluding it should be compelled to act quickly to resolve the administrative petition.” *Id.* at 814.

Second, EPA told the court that complex regulatory proceedings may be needed to effectuate a chlorpyrifos ban. While it indicated it would try to negotiate a settlement with the registrants, if voluntary action did not eliminate unsafe exposures, EPA would need to take regulatory action to revoke chlorpyrifos food tolerances. Yet EPA offered the court no concrete timeline for proposing, let alone finalizing, a tolerance revocation rule. Calling this approach “a roadmap for further delay,” the court concluded that EPA had “stretched the ‘rule of reason’ beyond its limits.” *Id.*

The court ordered EPA either to initiate a tolerance revocation rulemaking or deny the 2007 Petition by October 31, 2015, and if it proposed to revoke tolerances, to provide a timeline for finalizing that proposed rule. *Id.* at 815. After EPA proposed to revoke all chlorpyrifos tolerances, the court directed EPA to take final action on that proposal by December 30, 2016. *In re PANNA*, No. 14-72794, Order (9th Cir. Dec. 10, 2015). The court also directed EPA to file

a status report on June 30, 2016, detailing the steps taken to meet the final deadline and indicating that the court would extend the deadline only if EPA showed that extraordinary circumstances made compliance impracticable. *Id.*

EPA sought an additional six months to conduct further scientific review, referring to its efforts to quantify the exposures associated with damage to children's brains for use in a quantitative risk assessment and to continue its assessment of drinking water risks. The court denied the request, calling it "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action' that has been repeated for the past nine years." *In re PANNA*, No. 14-72794, Order (9th Cir. Aug. 12, 2016). The court found no justification for further delay in responding "to the pressing health concerns presented by chlorpyrifos." *Id.*; *see id.* ("a claim of premature rulemaking has come and gone."). The court nonetheless gave EPA until March 31, 2017 to take final action and stated: "This is the final extension, and the court will not grant any further extensions." *Id.*

VI. EPA PROPOSED TO REVOKE ALL TOLERANCES BECAUSE IT FOUND CHLORPYRIFOS UNSAFE

In October 2015, EPA proposed to revoke all chlorpyrifos tolerances because of drinking water contamination. 80 Fed. Reg. 69,080 (Nov. 6, 2015). EPA concluded that it "is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA)." *Id.*; *see also id.* at 69,081 ("EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all non-occupational exposures for which there is reliable information, are safe."). "Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances in response to a Petition from PANNA and the Natural Resources Defense Council (NRDC) to revoke all chlorpyrifos tolerances...." *Id.* at 69,081.

Drinking water contamination proved to be the impetus for the proposed revocation. EPA relied on its 2014 risk assessment, which it called "a highly sophisticated assessment of hazard and exposure to chlorpyrifos and its oxon." *Id.* at 69,082. Based on that assessment, EPA determined that multiple chlorpyrifos uses exceed EPA's drinking water level of concern with considerable frequency and present a risk of concern with infants most at risk. *Id.* at 69,082-83. EPA found all chlorpyrifos uses under current labels to be unsafe. *Id.* at 69,083. The proposed rule held open the possibility that registrants and growers might be able to submit additional information and propose label modifications to prevent some watersheds from being at risk from certain chlorpyrifos uses. *Id.* at 69,080.

The proposed rule also acknowledged that the 2014 risk assessment was under-protective of children because it was based on cholinesterase inhibition and the harm to children's brains is associated with lower exposures. EPA indicated that it would continue to review the evidence of long-lasting neurodevelopmental harm to children from low-level exposures and to try to incorporate that evidence into its risk assessment and regulatory determination.

In public comments to EPA, farmworker and health advocates submitted recently published scientific articles that continued to strengthen the correlation between low-level

chlorpyrifos exposures and damage to children's brains, and also found lung damage in 11-year olds and tremors that could impair their ability to draw and write.⁴³ The comments continued to urge EPA to develop an endpoint or restore the traditional safety factors to protect children from this harm, and conducted calculations based on the 2014 risk assessment to add such protection, which showed that exposures are unsafe from food alone, all drinking water, and from drift at distances greater than those covered by the spray drift buffers put in place in 2012. The comments cited evidence that chlorpyrifos travels further, including a Washington incident when workers were sickened by chlorpyrifos being applied about a mile from their worksite.⁴⁴

VII. EPA FOUND SERIOUS HARM, PARTICULARLY TO CHILDREN, AT LOWER EXPOSURES IN ITS MOST RECENT ASSESSMENTS

To protect against damage to children's brains from low-level exposures and to ensure that its regulatory actions are based on the most sensitive endpoint, consistent with longstanding EPA policy, EPA sought to identify a regulatory endpoint from the Columbia study that correlated chlorpyrifos exposures with serious harm to children's brains.⁴⁵ In 2016, EPA used measurements of chlorpyrifos in cord blood from the Columbia study to derive a more protective endpoint that would protect against adverse brain impacts, heeding a recommendation of the 2012 SAP. EPA submitted its analysis to the SAP for review. Even though the SAP did not support EPA's particular methodology for deriving such an endpoint, the SAP concurred with EPA's conclusion in the 2014 risk assessment that the 10% cholinesterase inhibition endpoint is not protective because damage to children's brains occurred at lower doses and EPA should take steps to protect against this harm. 2016 SAP at 18, 52-53.⁴⁶

In November 2016, EPA released its 2016 Chlorpyrifos Revised Human Health Risk Assessment ("2016 RHHRA").⁴⁷ EPA derived a regulatory endpoint based on neurodevelopmental effects because the Agency had determined that neurodevelopmental harm to fetuses occurred when pregnant mothers were exposed to far lower doses of chlorpyrifos than what produces 10% cholinesterase inhibition. 2016 RHHRA at 13. EPA considered all lines of

⁴³ Earthjustice, et al Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 5, 2016) at 7 (EPA-HQ-OPP-2015-0653-0390).

⁴⁴ *Id.* at 21 (citing Washington State Department of Health Comments (May 8, 2015) (EPA-HQ-OPP-2008-0850-0842)).

⁴⁵ Also, as EPA continued to review the scientific evidence correlating low-level exposures to chlorpyrifos and other organophosphates with damage to children's brains, it reiterated and expanded its findings substantiating this harm to all organophosphates, given that they share a common mechanism of toxicity, and extensive scientific evidence correlates organophosphates with adverse neurodevelopmental effects. *See* Literature Review on Neurodevelopment Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides (Sept. 2015), *available at* <https://www.regulations.gov/%23!documentDetail;D=EPA-HQ-OPP-2008-0440-0039>.

⁴⁶ FIFRA Scientific Advisory Panel Minutes No. 2016-01, A Set of Scientific Issues Being Considered by the EPA Regarding Chlorpyrifos: Analysis of Biomonitoring Data (Apr. 2016), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0062-0140>.

⁴⁷ Chlorpyrifos Revised Human Health Risk Assessment (Nov. 3, 2016) (EPA-HQ-OPP-2015-0653-0454).

evidence, including human epidemiological and animal toxicological studies in making its determination to change its endpoint. 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (agreeing with Scientific Advisory Panel that existing point of departure based on 10% cholinesterase inhibition is “not sufficiently health protective”). EPA also retained the FQPA 10X safety factor to account for uncertainty in using a lowest-observable adverse effect level in the absence of a no-observable adverse effect level. 2016 RHHRA at 22.⁴⁸

In establishing an updated regulatory endpoint, EPA used the physiologically based pharmacokinetic (“PBPK”) model developed by Dow AgroSciences as a tool to analyze exposure estimates. EPA followed the recommendation of the 2016 Scientific Advisory Panel and used the PBPK model to predict a time-weighted average blood concentration for women in the Columbia cohort. 2016 RHHRA at 16-17. EPA applied the average blood concentration to females, infants, and young children, which was supported by data from animal studies showing that both the pre- and post-natal periods are windows of susceptibility.⁴⁹

Using this more appropriate endpoint, EPA found that chlorpyrifos presents unacceptable safety risks through exposures from food, drinking water, spray drift, and occupational activities. Food-only exposures for chlorpyrifos were found to be unsafe for all population subgroups analyzed, with young children having the highest risks of concern. 2016 RHHRA at 23. While the adult subgroup had an alarming risk estimate at 62 times the safe level of exposure, the risk estimate for children ages 1-2 was more than double that of adults at 140 times safe levels. *Id.* Additionally, EPA’s revised assessment did not result in any changes to its finding that “the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures.” 81 Fed. Reg. at 81,050. Regarding spray drift, EPA found unsafe levels of chlorpyrifos from the field’s edge to distances of more than 300 feet from where the pesticide is sprayed and unsafe levels in the ambient air recorded in air monitoring performed in agricultural communities in California and Washington. 2016 RHHRA at 31. EPA also found unacceptable risks to all farmworkers who mix and apply chlorpyrifos, even with maximum levels of personal protective equipment or engineering controls. 2016 RHHRA at 36-37. Moreover, even though current labels allow workers to re-enter the fields within 1-5 days after pesticide spraying to weed, irrigate, and pick crops, EPA found that, on average, re-entry intervals of at least 18 days were needed to protect workers from risks of concern. *Id.* at 38.

After releasing the 2016 RHHRA, EPA reopened the comment period for its proposal to revoke chlorpyrifos food tolerances, noting that:

⁴⁸ EPA’s longstanding risk assessment methods apply an additional uncertainty or safety factor when the scientific studies do not identify a no-observable adverse effect level. EPA then uses and extrapolates from the lowest-observable adverse effects level, and adds a safety factor to guard against exposing people to the observed adverse effects. EPA Office of Pesticide Programs, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment* at 9 (Feb. 28, 2002) (<https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf>).

⁴⁹ EPA reviewed animal studies and found at in its 2014 Revised Human Health Risk Assessment for Chlorpyrifos that, “There is a considerable and growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals (rats and mice) indicating that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood. These data provide support for the susceptibility of the developing mammalian brain to chlorpyrifos exposure.” 2014 RHHRA at 25-26.

EPA's revised analyses do not result in a change to the EPA's proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP. The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the "reasonable certainty of no harm" safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures. Accordingly, based on current labeled uses, the agency's analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard. EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe. EPA has not identified a set of currently registered uses that meets the FFDCA safety standard because it is likely only a limited number of food uses alone, and in combination with predicted drinking water exposures, would meet the standard. Further, EPA has not received any proposals for mitigation that registrants may be willing to undertake that would allow the EPA to retain any of the tolerances subject to this rulemaking.

81 Fed. Reg. at 81,050.

This was the state of the record as the March 31, 2017 court-ordered deadline approached. EPA had found chlorpyrifos unsafe due to drinking water contamination in 2014, leading to the 2015 proposal to revoke all tolerances. No mitigation or further analysis lessened the risks. To the contrary, as EPA conducted further assessment to determine what action is necessary to guard against damage to children's developing brains, it found unsafe exposures every way people come into contact with chlorpyrifos whether in food, in drinking water, or in the air. And young children are most at risk. The fate of chlorpyrifos had been all but sealed.

VIII. THE ORDER DENYING THE 2007 PETITION

Instead of finalizing the proposed revocation order based on its findings that chlorpyrifos is unsafe, on March 29, 2017, the new EPA Administrator, Scott Pruitt, issued an order on March 29, 2017, entitled "Chlorpyrifos: Order Denying PANNA and NRDC Petition to Revoke Tolerances" ("Pruitt Order"), 82 Fed. Reg. 16,581, 16,583 (Apr. 5, 2017). The Pruitt Order finalized the interim responses EPA had previously provided addressing spray drift, volatilization, endocrine disruption screening, cancer risks, export hazards, and other issues. The Pruitt Order reiterated the interim responses, even where subsequent EPA action had reversed or severely undermined the rationale for the earlier partial response based on further analysis or new scientific evidence. For example, EPA defended dispensing with the FQPA 10X safety factor for chlorpyrifos, even though it decided in 2014 that the FQPA safety factor had to be retained in full. *Id.* at 16,588-89. EPA also repeated its earlier justification for not considering genetic vulnerability to chlorpyrifos, even though the Dow model used in EPA's 2014 and 2016 risk assessments incorporated such genetic variability into its metrics. *Id.* at 16,585-86. And EPA adhered to its incomplete assessment and mitigation for spray drift and volatilization,

without ever acknowledging, let alone addressing, the public comments criticizing EPA's approach as legally and scientifically flawed.

With the exception of the FIFRA export claim not at issue here, EPA had indicated that it would not make its interim, partial responses final, unless PAN and NRDC requested that it do so. *See id.* at 16,583, 16,585. PAN and NRDC did not ask EPA to make the partial responses final because the heart of the 2007 Petition — neurodevelopmental harm to children from chlorpyrifos at low doses — remains unresolved. Resolution of that issue in a manner that protects children would lead to revocation of chlorpyrifos tolerances and eliminate the need for objections and further proceedings. Moreover, EPA had not addressed the comments submitted by PAN, NRDC, and others, criticizing the spray drift mitigation and interim volatilization determination because they were based on poisoning risks and not damage to children's brains at lower doses. Nor had EPA yet addressed comments making the case that EPA: (1) had illegally ignored direct drift and inhalation exposures in its spray drift assessment and mitigation; and (2) had backtracked from its volatilization assessment documenting unsafe exposures far from the application site based on two scientifically flawed Dow studies.

PAN and NRDC believed that EPA would follow the law and science, and revoke all chlorpyrifos tolerances once it developed a regulatory endpoint and risk assessments that would protect children from neurodevelopmental harm, and once it addressed the public comments revealing serious flaws in its approach to spray drift and volatilization. While EPA did revise its human health risk assessment in 2016 based on a regulatory endpoint designed to prevent low-level exposures associated with brain damage to children, the Pruitt Order made no final decisions and took no final action based on that assessment or any other approach that would protect children's brains. Nor did the Pruitt Order address the public comments revealing flaws that made its treatment of spray drift and volatilization to date under-protective, particularly of children.

As to the one issue EPA had not previously resolved — neurodevelopmental harm from chlorpyrifos — the Pruitt Order made no substantive determination. Despite EPA's repeated findings that chlorpyrifos is unsafe, the Pruitt Order did not finalize the tolerance revocation rule. Instead, the Pruitt Order postponed such action based on the Administrator's preference to engage in further study of the harm to children's brains from chlorpyrifos before finalizing the October 2015 proposed revocation rule or taking an alternative regulatory path. *Id.* at 16,590. Without any elaboration, the Pruitt Order asserted vaguely that comments received in response to the October 2015 proposed rule and its November 2016 risk assessment suggest some stakeholders believe uncertainty persists about the use of epidemiological data in risk assessments. *Id.*

EPA framed its delay in deciding whether to revoke chlorpyrifos food tolerances as a reprioritization of the chlorpyrifos registration review schedule developed by earlier administrations. *Id.* EPA asserts that, while the Ninth Circuit's order compelled a response to the 2007 Petition, the court "cannot compel EPA to complete the registration review of chlorpyrifos in advance of the October 1, 2022 deadline" for registration review of all older pesticides. *Id.*

Acknowledging that it is not legally a relevant factor, the Pruitt Order nonetheless stated: "it is important to note that for many decades chlorpyrifos has been and remains one of the most

widely used pesticides in the United States” and that a decision to remove the pesticide from the market would be a “significant policy choice.” *Id.* Citing the significance of the decision and uncertainty regarding the correlation between chlorpyrifos and adverse neurodevelopmental effects, the Pruitt Order expressed the Administrator’s preference to engage in further study before finalizing any regulatory action. *Id.*

Within a week of EPA’s Pruitt Order, PAN and NRDC filed a motion with the Ninth Circuit seeking further mandamus relief because EPA had essentially given itself an open-ended extension of time to make chlorpyrifos tolerance decisions, rather than take action on the 2007 Petition and EPA’s findings that chlorpyrifos is unsafe. Specifically, PAN and NRDC asked the Ninth Circuit to give EPA a 30-day deadline to take final regulatory action by either: (1) revoking chlorpyrifos tolerances based on its findings that chlorpyrifos is unsafe; or (2) denying the 2007 Petition if EPA could find chlorpyrifos safe. The motion also asked the court to establish a deadline for EPA to resolve any objections filed contesting its final tolerance action. The motion was fully briefed on May 5, 2017. If the Ninth Circuit fully grants the motion, it will moot these objections.

OBJECTIONS

The EPA Administrator’s decision to leave chlorpyrifos tolerances in place cannot stand for two reasons. First, the decision violates the law, which allows the Administrator to leave tolerances in place only if he finds the pesticide safe. EPA has repeatedly found chlorpyrifos unsafe. The Administrator therefore lacks the legal authority to retain tolerances for this harmful pesticide. Second, the Administrator’s rationale for putting off regulatory action on chlorpyrifos is indefensible under both the law, given EPA’s findings chlorpyrifos is unsafe, which flow from the solid and extensive scientific evidence before the agency. The Pruitt Order should be reversed, and EPA should issue a final revocation rule on an expeditious basis. It should take EPA no longer than 60 days to rule on these objections because they present purely legal issues, and EPA has an obligation to resolve objections “as soon as practicable”. *See* 21 U.S.C. § 346a(g)(2)(c) (EPA Administrator must issue an order on objections “as soon as practicable”).

I. EPA’S DENIAL OF THE 2007 PETITION IS ILLEGAL BECAUSE EPA CANNOT MAINTAIN TOLERANCES IN THE FACE OF ITS FINDINGS THAT CHLORPYRIFOS IS UNSAFE

EPA’s decision to leave chlorpyrifos tolerances in place violates the law and exceeds the Administrator’s legal authority. Under the FFDCA, the EPA Administrator “may establish or leave in effect a tolerance for a pesticide chemical residue in or on food *only if* the Administrator determines that the tolerance is safe.” 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). “Safe” means the Administrator has determined that there is a reasonable certainty of no harm from aggregate exposures to the pesticide chemical residue. *Id.* § 346a(b)(2)(A)(ii). The law spells out the consequences of an inability to make the required safety finding in a way that leaves no discretion: “The Administrator *shall* modify or revoke a tolerance if the Administrator determines it is not safe.” *Id.* § 346a(b)(2)(A)(i) (emphasis added). Because EPA has repeatedly found chlorpyrifos to be unsafe, the Administrator must revoke all food tolerances for chlorpyrifos.

EPA first found unsafe drinking water exposures and proposed to revoke all chlorpyrifos tolerances on this basis, which is addressed in A below. When EPA took steps to protect children from neurodevelopmental harm, it found chlorpyrifos unsafe every way people are exposed to it, which is addressed in B below.

A. EPA Found Unsafe Drinking Water Contamination from Chlorpyrifos Using Poisoning Risks as the Regulatory Endpoint

After years of study and several rounds of review by its Scientific Advisory Panel, EPA has made an unbroken series of findings that chlorpyrifos harms children's brains at lower exposures than those used by EPA in its previous risk assessments and regulatory decision. EPA's analysis of the scientific evidence and several SAP reviews culminated in the 2014 risk assessment, which found that chlorpyrifos causes harm to children's brains from prenatal exposures and that this harm occurs at exposures far lower than EPA's regulatory endpoint, 10% red-blood cell cholinesterase inhibition. This finding, coupled with uncertainties about the precise low-level exposures that damage children's developing brains, led EPA to retain the FQPA tenfold margin of safety to protect children from neurodevelopmental harm. The 2014 risk assessment documented drinking water contamination from chlorpyrifos that exposed children to unsafe levels of the pesticide. 2014 RHHRA at 48-49, 95-96.

In October 2015, EPA proposed to revoke all tolerances because it could not "determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe." 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015). EPA explained:

Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), authorizes EPA to revoke tolerances in response to administrative petitions submitted by any person. Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances in response to a Petition from PANNA and the Natural Resources Defense Council (NRDC) to revoke all chlorpyrifos tolerances . . . This proposal also implements the agency findings made during the registration review process required by section 3(g) of FIFRA (7 U.S.C. 136(a)(g)) which EPA is conducting in parallel with its petition response.

Id. EPA's proposal to revoke chlorpyrifos tolerances is replete with findings that chlorpyrifos is unsafe:

EPA cannot determine that current dietary exposures to chlorpyrifos are safe within the meaning of FFDCA section 408(b)(2)(A). [*Id.* at 69,106.]

EPA cannot find that any current tolerances are safe and is therefore proposing to revoke all chlorpyrifos tolerances. [*Id.*]

[F]ood exposures, when aggregated with residential exposures and potentially more significant drinking water exposures do present a significant risk concern and support revocation of all chlorpyrifos tolerances. [*Id.* at 69,097.]

[W]e cannot make a safety finding based on drinking water exposure. [*Id.* at 69,106.]

See also Declaration of Richard P. Keigwin, Jr., EPA Office of Pesticide Programs, ¶ 5, in *In re PANNA*, No. 14-72794, Dkt. No. 25-2 (9th Cir. Oct. 29, 2015) (proposed rule is “based on EPA’s conclusion that it could not make the ‘reasonable certainty of harm’ finding”).

B. EPA Found All Exposures to Chlorpyrifos to be Unsafe When it Sought to Protect Against Damage to Children’s Developing Brains

EPA’s findings that chlorpyrifos is unsafe flow from the 2014 risk assessment, which uses 10% red blood cell cholinesterase inhibition as the regulatory endpoint. That risk assessment, however, contained a pivotal, and troubling, finding: the damage to children’s brains in the mother-child cohort studies occurred from exposures that were too low to produce cholinesterase inhibition. 2014 RHHRA at 47, 49. In its proposal to revoke chlorpyrifos tolerances, EPA indicated it would heed the SAP’s advice and try to reconstruct the exposures correlated with adverse brain impacts in the Columbia study or find some other method to protect against this type of harm. This attempt to identify exposures linked to damage to the developing brain is consistent with EPA’s policy to ensure that its risk assessments are designed to identify and protect the most sensitive endpoint. While the 2016 SAP did not agree with EPA’s first effort to reconstruct the exposure levels based on cord blood samples from the Columbia study, it agreed with EPA that the harmful brain impacts occurred at exposures far below EPA’s regulatory endpoint based on cholinesterase inhibition and that EPA should be more protective to guard against such impacts. 2016 SAP at 18, 52-53.

EPA’s second effort, released in November 2016, was based in large part on Dow’s PBPK model and showed that people will be at risk of harm from virtually every use and every way that people are exposed to chlorpyrifos, with children, and particularly 1 to 2- year olds, most at risk. 2016 RHHRA at 23. With the lower endpoint, the 2016 risk assessment revealed even higher and more pervasive risks from chlorpyrifos:

All food exposures exceed safe levels, with the most exposed population - children 1-2 years of age - exposed to 140 times what EPA deems to be safe.

Use of chlorpyrifos contaminates drinking water.

Drift of pesticides from the fields expose children to unsafe levels of chlorpyrifos within 300 or more feet of the fields where the pesticide is sprayed. Children could be exposed to harmful drift at schools, day cares, in their homes, and at playgrounds.

For children between 1 to 2- years old, all 11 acute ambient air concentrations assessed resulted in risks of concern. For adults, all but one of the 11 steady state ambient air concentrations assessed resulted in risks of concern.

All workers who mix and apply chlorpyrifos pesticides are exposed to levels greater than what EPA deems to be safe.

Field workers are currently allowed to re-enter fields within 1-5 days after pesticide spraying, but unsafe exposures continue on average for 18 days after applications.

Id. at 23-24, 30-33.

Not surprisingly, EPA found based on the 2016 risk assessment:

The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the ‘reasonable certainty of no harm’ safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures. Accordingly, based on current labeled uses, the agency’s analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard. EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe. EPA has not identified a set of currently registered uses that meets the FFDCA safety standardFurther, EPA has not received any proposals for mitigation that registrants may be willing to undertake that would allow the EPA to retain any of the tolerances subject to this rulemaking.

81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (citing 2016 RHHRA).

C. EPA’s Findings that Chlorpyrifos is Unsafe Compel the Administrator to Revoke All Chlorpyrifos Food Tolerances

In the face of these findings, which build upon the 2014 risk assessment and 2015 tolerance revocation proposal, the EPA Administrator has a legal obligation to revoke all chlorpyrifos tolerances. This is the only legally defensible course of action under the law, which allows the Administrator to leave a tolerance in place “only if the Administrator determines that the tolerance is safe.” 21 U.S.C. § 346a(b)(2)(A)(i). Beginning in 2014, EPA has repeatedly stated that it cannot find chlorpyrifos safe and it has since found chlorpyrifos unsafe every way that people are exposed to it. In the face of these findings, the law is clear: “the Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.” *Id.*

This mandatory obligation is reinforced by the FFDCA’s provisions laying out the “actions” the Administrator is authorized and directed to take on a petition to revoke tolerances. The FFDCA provides that the Administrator “shall” take one of three permissible actions:

- (i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue . . . (which final regulation shall be issued without further notice and without further period for public comment);

- (ii) issue a proposed regulation under subsection (e) of this section and thereafter issue a final regulation under such subsection; or
- (iii) issue an order denying the petition.

Id. § 346a(d)(4)(A).

These actions are stated in the alternative, meaning they are mutually exclusive paths the Administrator may take on a petition or specific part of a petition. The second option starts with a proposed regulation and proceeds to a final regulation after notice and public comment. Here, in contrast, EPA proposed to revoke chlorpyrifos tolerances, but did not finalize that regulation. He left the proposed revocation rule intact, awaiting further final action. Administrator Pruitt then issued an order purporting to deny the 2007 Petition, but without withdrawing the proposed regulation because he did not resolve the merits of the 2007 Petition. The FFDCA does not allow the Administrator to take these two mutually exclusive actions on the same issue concurrently. For this reason as well, the Administrator acted in blatant violation of the law by denying the 2007 Petition and leaving chlorpyrifos tolerances in place.

II. EPA'S RATIONALE FOR LEAVING CHLORPYRIFOS TOLERANCES IN PLACE IS LEGALLY AND SCIENTIFICALLY INDEFENSIBLE

The Pruitt Order offers several reasons for delaying action on chlorpyrifos tolerances for many years, possibly until October 1, 2022. None can legally justify defying the clear legal mandate to revoke tolerances because EPA cannot find chlorpyrifos safe.

A. EPA Cannot Rely on Its 2006 Safety Finding When It Has Since Determined Based on Mounting Scientific Evidence that Chlorpyrifos Damages Children's Brains and is Unsafe

The 2007 Petition sought to compel EPA to address and act on scientific evidence and routes of exposure disregarded in its old risk assessments used in re-registering chlorpyrifos in 2001 and 2006. Oddly, the Pruitt Order defends the 2006 cumulative risk assessment based on the science then available as if time stood still. *See, e.g.*, 82 Fed. Reg. at 16,589 (“the Agency is confident that its assessment for chlorpyrifos in 2006 was reasonably based on the best available science *at the time of the assessment*”) (emphasis added). To state the obvious, it is no longer 2006. EPA must address the extensive and ever-growing evidence of serious brain damage to children from chlorpyrifos, developed over the past 11 years. *See* 21 U.S.C. § 346a(d)(4) (EPA must assess available information); *id.* § 346a(b)(2)(C)-(D) (EPA must consider available information concerning such factors as toxicity, population sensitivities, and children's exposures).

The Pruitt Order also depicts much of the 2007 Petition as a challenge to the 2006 re-registration determination when the heart of the Petition sought action on issues EPA had sidestepped in 2006, namely drift, volatilization, and damage to the developing brain. *See* 82 Fed. Reg. at 16,590. At one point, the Pruitt Order defends eliminating the FQPA 10X safety factor, even though EPA decided in 2014 that it must retain that safety factor due to gaps in information needed to protect infants and children. *Id.* at 16,588. The Pruitt Order asserts that PAN and NRDC failed to show that using a FQPA 10X safety factor would show chlorpyrifos is unsafe. *Id.* That statement is mind-boggling in light of EPA's findings in its 2014 and 2016 risk

assessments (that retain a FQPA 10X safety factor) that chlorpyrifos is unsafe, which compels revocation of all chlorpyrifos tolerances.

EPA cannot continue to rely on its 2006 safety finding in light of the Agency's and multiple SAP's subsequent findings that chlorpyrifos fails to meet the FQPA safety standard based on an extensive body of peer-reviewed toxicological and epidemiological studies correlating neurodevelopmental harm to fetuses and children with chlorpyrifos exposure. As the Ninth Circuit Court of Appeals noted, EPA "has backtracked significantly from" its 2006 pronouncement of safety when it found chlorpyrifos unsafe in its 2014 risk assessment and determined its tolerances needed to be revoked. *In re PANNA v. EPA*, 798 F.3d at 814. The FQPA gives EPA only two options: the Agency must find that chlorpyrifos is safe based on the evidence currently before it in order to retain chlorpyrifos tolerances, which it cannot do, or it must revoke tolerances based on its findings that chlorpyrifos is unsafe. Hiding behind stale 2006 findings that have since been reversed based on numerous, definitive studies and EPA and SAP findings is not an option.

B. Scientific Uncertainty is Not a Legally Permissible Reason to Leave Chlorpyrifos Tolerances in Place

The primary justification offered in the Pruitt Order for failing to revoke chlorpyrifos tolerances in the face of its prior findings that chlorpyrifos exposures are unsafe is that the Administrator prefers to engage in further study. 82 Fed. Reg. at 16,590 ("EPA's preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional peer review of EPA's risk assessment prior to finalizing any regulatory action in the course of registration review."). The Pruitt Order states that:

EPA has concluded that, despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution of those issues.

82 Fed. Reg. at 16,583; *see also id.* at 16,590 ("the science on this question is not resolved and would likely benefit from further inquiry.").

1. The Science Underlying EPA's Findings that Chlorpyrifos is Unsafe is Well-Settled

In putting off action on the 2007 Petition and its proposal to revoke chlorpyrifos tolerances, the Pruitt Order alludes generally to scientific uncertainties, ignoring how much progress has been made in assessing the mounting scientific evidence of neurodevelopmental harm from chlorpyrifos exposures and the weight of the scientific evidence. EPA and the SAP have consistently found that chlorpyrifos causes damage to children's developing brains and that this damage has resulted from exposures that are far lower than EPA's regulatory endpoint. The

chlorpyrifos tolerances currently in place do not protect against these adverse brain impacts. On this point, assertions of scientific uncertainty ring hollow given the overwhelming scientific evidence and the unbroken EPA and SAP findings.

When EPA convened its SAP in 2008 to review post-re-registration science, the SAP found that prenatal and early postnatal chlorpyrifos exposures can produce long-lasting cognitive and motor impairments. 2008 SAP Report at 11-12. The SAP also found that the exposures associated with this serious harm were below EPA's regulatory endpoint. *Id.* at 43-44. In 2012, the SAP again found, based on more extensive scientific review, that chlorpyrifos is associated with abnormal reflexes, mental deficiencies, and attention and behavioral problems from exposures lower than those associated with cholinesterase inhibition, EPA's regulatory endpoint. 2012 SAP at 17, 19. Even the 2016 SAP, which disagreed with EPA's first attempt to quantify exposures correlated with such brain damage, agreed that chlorpyrifos harms children's brains at exposures far below EPA's regulatory endpoint and that EPA needs to be more protective than its 2014 risk assessment. 2016 SAP 18, 52-53.

EPA's risk assessments have, since 2011, similarly found correlations between low-level chlorpyrifos exposures and long-lasting harm to children's brains. The 2011 PHHRA found that chlorpyrifos played a role in causing such neurodevelopmental harm. 2011 PHHRA at 8. The 2014 RHHRA made even stronger findings from multiple lines of evidence that chlorpyrifos results in neurodevelopmental harms to children, such as reduced IQ, delays in mental development, and attention disorders, and that the exposures associated with these brain impairments were too low to produce cholinesterase inhibition. 2014 RHHRA at 41-43, 46.

There may be scientific uncertainty on other issues, but not as to these uncontestable findings. And these findings alone revealed in the 2014 RHHRA that chlorpyrifos is unsafe due to drinking water contamination. *Id.* at 48-49, 95-96.

Scientific uncertainty remains as to the mode of action by which chlorpyrifos damages children's brains and the exact dose at which such effects occur. EPA does not need to know the precise mode of action to know that harm is occurring and that the statutory safety standard is being violated. *See id.* at 48. Nor does EPA need to know the precise dose at which neurodevelopmental harm occurs, given that such harm is occurring at exposures so far below the regulatory endpoint supporting the current chlorpyrifos tolerances that EPA cannot identify a safe exposure level. As explained below, Congress has prescribed how EPA must deal with such uncertainties in protecting the safety of our food supply and preventing harm to children.

2. Congress Directed EPA to Revoke Tolerances if Scientific Uncertainty Precludes Finding the Pesticide Safe.

Congress has established a statutory standard that precludes delaying protection, particularly to children, due to scientific uncertainty when there is evidence of harm. This direction manifests itself in three ways.

First, 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." 21 U.S.C. § 346a(b)(2)(A)(i). An affirmative finding of safety is a prerequisite to establishing or retaining a tolerance. And if EPA determines a pesticide is not safe, "[t]he Administrator *shall* modify or revoke a tolerance."

Id. (emphasis added). EPA acknowledged the statutory mandates in its proposed revocation rule, stating: “It is important to stress, however, that because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe.” 80 Fed. Reg. 69,080 (Nov. 6, 2015). Explicitly requiring a safety finding to retain a tolerance reinforces longstanding precedent that places the burden of proof on EPA and industry registrants seeking to retain food tolerances to prove safety. *See Env’tl. Def. Fund, Inc. v. U.S. Dep’t of Health, Ed. & Welfare*, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970) (following petition for revocation, burden of establishing the safety of any tolerance is on those seeking to permit a residue).⁵⁰ EPA is mistaken in asserting in the Pruitt Order that petitioners bear the burden of proving that chlorpyrifos is unsafe. 82 Fed. Reg. at 16,587-88.⁵¹ When EPA adhered to the regulatory safety standard and burdens, it proposed to revoke all chlorpyrifos tolerances.

Second, “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). Not only must EPA make a safety finding to retain a tolerance, it must find a reasonable certainty of no harm. The fact that chlorpyrifos is associated with serious brain damage at low doses makes it impossible for EPA to find a reasonable certainty of no harm from exposures allowed under the current tolerances.

Third, other FQPA provisions further specify how EPA must deal with scientific uncertainty. The FQPA directs EPA to act on the basis of available information on the special susceptibility of infants and children, including neurological differences between adults and infants and children, and EPA must apply an additional tenfold margin of safety to account for gaps in data or evidence of pre- or post-natal toxicity to children. 21 U.S.C. § 346a(b)(2)(C).

⁵⁰ The court’s reasoning (*id.*) applies with even greater force to the FFDCA standard, as amended by the FQPA.

Section 408 of the FDCA authorizes the Secretary of HEW to establish tolerances for pesticide residues on or in raw agricultural commodities ‘to the extent necessary to protect the public health.’ The section also authorizes the setting of a zero tolerance (no residue) level ‘if the scientific data before the Secretary does not justify the establishment of a greater tolerance.’ We need not pause to plumb the obvious ambiguities in this language since both Senate and House Committee Reports make the intended meaning of this section indisputably clear:

‘Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.’

⁵¹ The Pruitt Order states that EPA proposed to revoke all chlorpyrifos tolerances based in part on uncertainty surrounding the correlation between chlorpyrifos exposures and longlasting neurodevelopmental harm. 82 Fed. Reg. at 16,583, 16,590. However, EPA proposed to revoke chlorpyrifos tolerances because it could not find chlorpyrifos safe. To the extent the Pruitt Order is referring to the requirement that EPA be able to find safety in order to retain tolerances, that is what Congress has mandated.

Congress specifically directed EPA to act to protect children where scientific evidence shows they are at risk of harm and it will take time to fill in gaps in the data.

In 2014, EPA retained the FQPA tenfold safety factor because of gaps in scientific information on the mode of action and exposure levels by which chlorpyrifos causes damage to children's brains. It recognized, however, that the 2014 risk assessment was under-protective because it continued to use cholinesterase inhibition as the regulatory endpoint, and that brain damage to children has resulted from lower exposure levels. In the face of this evidence, EPA also recognized that it needed to lower its regulatory endpoint or have additional safety factors to protect children's brains, and the 2016 SAP concurred. 2016 RHHRA at 13-14; 2016 SAP at 18-19.

The uncertainties go to the precise exposure level to use or additional safety factors to include in establishing a brain-protective regulatory endpoint. That uncertainty offers no reason to retain tolerances, however. In 2014, even using a poisoning regulatory endpoint that is not protective of children's brains, EPA found chlorpyrifos unsafe due to drinking water contamination. When it developed a regulatory endpoint that would protect children's brains, it found chlorpyrifos unsafe every way people are exposed to it with young children exposed to 140 times safe levels in food.⁵² More study will simply confirm how hazardous and devastating this pesticide can be. Congress decided not to expose children to such risks by precluding EPA from maintaining tolerances when it cannot find a reasonable certainty of no harm from the pesticide.

3. The Pruitt Order Fails to Address Significant Concerns Raised in Comments that EPA's 2014 Risk Assessment and Proposed Revocation Fail to Protect Children.

The Pruitt Order indicates that EPA decided that the science regarding neurodevelopmental harm from chlorpyrifos remains unresolved and warrants further study before final regulatory action “[f]ollowing a review of comments” on the proposed revocation and 2016 risk assessment. 82 Fed. Reg. at 16,583. While it is typical for EPA to prepare a response to comments as part of a rulemaking, no response to comments document is in the administrative records for the chlorpyrifos registration review or the proposed revocation.

Agencies need to “consider and respond to significant comments received during the period for public comment” on proposed rules. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015); *see also* 5 U.S.C. § 553(c) (agency must give consideration to relevant matter, including data and arguments submitted during the comment period on proposed rules). Of particular relevance to this proceeding, when resolving a petition to revoke tolerances and deciding to leave a tolerance in effect, EPA must consider “information available to the Administrator” and specifically information relevant to such statutorily mandated considerations as pre- and post-natal neurotoxicity, children's exposures, population sensitivities, and gaps in

⁵² If scientific uncertainties prevent EPA from identifying an acceptable exposure level that will prevent damage to children's brains, EPA must use additional safety factors due to pre-natal and post-natal neurotoxicity from chlorpyrifos. See Earthjustice, et al., Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) at 2-11; 2016 SAP 18-19.

information. 21 U.S.C. § 346a(b)(2)(C)-(D) and § 346a(d)(4)(A); *see also* Dichlorvos (DDVP); Order Denying NRDC's Objections and Requests for Hearing, 73 Fed. Reg. 42683, 42696 (July 23, 2008) (EPA recognizes its obligation to provide a reasoned explanation for its treatment of significant comments when acting on petitions to revoke tolerances).

While EPA has apparently heeded some unspecified and vaguely referenced comments from Dow Agrosiences and others who want to retain chlorpyrifos tolerances, it is silent as to the multiple and extensive comments offering scientific reasons why the 2014 risk assessment and proposed revocation do not protect children and violate governing legal standards.

Particularly formidable are the numerous, well-supported comments from scientists, health professionals, and farmworker and health advocates making the case that EPA is failing to protect against the most sensitive health effect — harm to children's developing brains — because the 2014 risk assessment and proposed revocation use 10% cholinesterase inhibition as the regulatory endpoint.⁵³ If EPA had either lowered its regulatory endpoint or used the traditional and FQPA safety factors to guard against such brain impairments, it would have, as it did in 2016, found unsafe exposures in food, from drift 300 feet or more from the application site, and in drinking water nationwide. 2016 RHHRA at 23-24, 30-33.⁵⁴

In denying the 2007 Petition, EPA did not disavow its prior findings that chlorpyrifos is unsafe. Nor could it credibly do so in light of the overwhelming scientific evidence correlating low-level chlorpyrifos exposures with damage to children's developing brains. If EPA were to modify the particular brain-protective endpoint used in the 2016 risk assessment, it would need to ensure that the endpoint selected, possibly coupled with additional safety factors, would produce a risk assessment that protects children from permanent brain damage from chlorpyrifos exposures. The only way EPA can ensure there is reasonable certainty of no harm from chlorpyrifos exposures is to account for the evidence of such harm from exposures far below the regulatory endpoint underpinning the current tolerances.

⁵³ *See, e.g.*, 2015 Farmworker Comments; Comments to EPA from Environmental Health Scientists and Healthcare Professionals in support of EPA's 2016 Revised Human Health Risk Assessment and the 2015 proposed tolerance revocation for chlorpyrifos (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0587); Comments to EPA submitted on behalf of University of California, Davis scientists with the UC Davis Environmental Health Sciences Center and the UC Davis Center for Children's Environmental Health in support of EPA's 2016 Revised Human Health Risk Assessment in conjunction with the 2015 proposed rulemaking to revoke tolerances for chlorpyrifos (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0640); Comments to EPA from Environmental Health Scientists and Healthcare Professionals in support of EPA's Proposal to Revoke Chlorpyrifos Food Residue Tolerances (Jan. 5, 2016) (EPA-HQ-OPP-2015-0653-0374); Comment submitted by Harry Wang, Vice-President, Physicians for Social Responsibility/Sacramento (Apr. 30, 2015) (EPA-HQ-OPP-2008-0850-0834).

⁵⁴ *See also* Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 5, 2016) at 8-10 (If EPA had used a 1000X safety factor, it would have found risks of concern to all children from food, even without using an endpoint that reflects the harm to the developing brain, with children 1-2 years old facing the highest risks, more than 2 times EPA's level of concern.).

Public comments raised several other significant issues that EPA would need to address if it persists in leaving chlorpyrifos tolerances in place in response to the 2007 Petition.⁵⁵ First, the farmworker and health advocate comments disputed EPA's legal authority to ignore inhalation exposures from chlorpyrifos spraying, which EPA tried to justify because the labels prohibit allowing a pesticide to drift onto people. Chlorpyrifos drift poisons people every year, documenting that the label prohibition is ineffective and greater safeguards are needed to provide reasonable certainty of no harm. 2015 Farmworker Comments at 43-49.

Second, while EPA recognized in its 2011 preliminary risk assessment that chlorpyrifos has a propensity to volatilize after application and move large distances as vapor, and that buffers as large as 4000 feet may be necessary to prevent harm from exposures to chlorpyrifos vapors, it ultimately disregarded volatilization exposures based on two rat studies submitted by Dow Agrosciences that purport to show that it is impossible to inhale enough chlorpyrifos to produce an adverse effect. Public comments pointed out that the Dow studies suffer from significant flaws because they fail to address temperature and soil moisture impacts on volatilization, individual variation, a lack of controls to ensure the experiment could detect cholinesterase inhibition, and biomonitoring and incident data showing harmful exposures at distances as large as one-half mile from application sites. 2015 Farmworker Comments at 50-58.

Third, the comments submitted California incident data documenting poisonings from chlorpyrifos at far greater distances than the spray drift buffers put in place by the registrants in 2012. These real-life impacts show that reasonable certainty of harm persists. This year on Cinco de Mayo, roughly one dozen farmworkers in Kern County, California, were poisoned and a total of 50 put at risk from spray drift of what has been reported to be chlorpyrifos.⁵⁶ Local news described how "twelve people reported symptoms of vomiting [and] nausea and one person fainted." *Id.* The farmworkers were harvesting cabbage at a farm that does not use chlorpyrifos when drift from a nearby field led workers to complain of "a bad odor, nausea and vomiting."⁵⁷ Following the incident, the Kern County Department of Agriculture and Measurement Standards stated that testing was still underway, but confirmed that they are investigating a ground application of chlorpyrifos that took place one-half mile from where the poisoning occurred.

Fourth, not only did EPA continue to use poisoning as its regulatory endpoint, it used a model developed by Dow AgroSciences to try to pinpoint the exposures that will produce 10% cholinesterase inhibition in people. Public comments objected to use of the model because, in February 2011, EPA's Scientific Advisory Panel found numerous flaws in the model, using terms like "very problematic," "cursory," "overstated," "inadequate," "inaccurate," "imprecise,"

⁵⁵ Objectors incorporate by reference all comments submitted by Objectors under docket numbers EPA-HQ-OPP-2007-1005, EPA-HQ-OPP-2008-0850, and EPA-HQ-OPP-2015-0653.

⁵⁶ Tom Philpott, *Trump's EPA Greenlights a Nasty Chemical. A Month Later, It Poisons a Bunch of Farmworkers.*, Mother Jones (May 15, 2017, 6:00 AM) <http://www.motherjones.com/environment/2017/05/california-farm-workers-just-got-poisoned-nasty-pesticide-greenlighted-trump>.

⁵⁷ Oliver Milman, *Pesticide that Trump's EPA refused to ban blamed for sickening farm workers*, The Guardian (May 17, 2017, 7:00 AM), <https://www.theguardian.com/environment/2017/may/17/pesticide-trump-ban-california-farm-workers-sick>.

and “incomplete.”⁵⁸ Dow made some changes in the model, but EPA did not obtain another review by its Scientific Advisory Panel.

In addition, the model is based on ethically and scientifically deficient studies. Congress has required that human testing must meet minimal ethical and scientific standards before EPA can rely on such tests. An EPA ethics advisor found that the key Dow human study fell short of meeting informed consent requirements, and EPA’s Human Studies Review Board found the study scientifically deficient in two respects that have not been corrected. EPA has since strengthened its regulatory standards governing use of intentional human dosing studies, yet EPA failed to resubmit the study to the Human Studies Review Board. EPA has provided no credible basis for relying on human testing without subjecting it to such scrutiny and without confronting the earlier findings of ethical and scientific shortcomings. 2015 Farmworker Comments at 36-42.

Based on the Dow model, EPA eliminated the inter-species safety factor altogether, and it shrank the intra-species safety factor from 10X to 4X-5X for children, although it retained a 10X for women of childbearing age since the Dow model lacks data reflecting how a pregnant woman’s body processes chlorpyrifos. The result — under the 2014 risk assessment — EPA will allow chlorpyrifos exposures to be an order of magnitude higher for pregnant women and even higher still for children than would be allowed if traditional safety factors had been retained. Comments argued that EPA cannot use Dow’s model to eliminate or reduce the safety factors in light of the neurodevelopmental effects that occur at lower doses than those used in the model. 2015 Farmworker Comments at 28-32. If EPA had heeded these comments and had retained the traditional safety factors, it would have found in 2014 that chlorpyrifos is unsafe on food as well as in drinking water, and that children are at even greater risk from chlorpyrifos drift and workers from handling the pesticide or re-entering fields shortly after chlorpyrifos spraying.

C. Widespread Use of Chlorpyrifos in Agriculture is Legally Irrelevant Because Congress Made Protecting Food Safety and Preventing Neurodevelopmental Harm to Children Paramount.

The Pruitt Order states:

Although not a legal consideration, it is important to recognize that for many decades chlorpyrifos has been and remains one of the most widely used pesticides in the United States, making any decision to retain or remove this pesticide from the market an extremely significant policy choice.

82 Fed. Reg. at 16,590; *see also id.* at 16,584 (“chlorpyrifos is currently the only cost-effective choice for control of certain insect pests.”). The Pruitt Order then cites the significance of the decision as a reason for further study of the risks before taking final regulatory action. *Id.*

EPA issued a press release on the Pruitt Order noting that chlorpyrifos is “one of the most widely used pesticides in the world” and quoting EPA Administrator Scott Pruitt as saying, “We need to provide regulatory certainty to the thousands of American farms that rely on

⁵⁸ Meeting minutes, report, and background material is available in Docket EPA-HQ-OPP-2010-0588 and on the SAP meetings website at: <http://www.epa.gov/scipoly/sap/meetings/2011/021511meeting.html>.

chlorpyrifos.” The EPA press release included a statement from Sheryl Kunickis, director of the Office of Pest Management Policy at the U.S. Department of Agriculture (“USDA”), endorsing the Pruitt Order because it “frees American farmers from significant trade disruptions that could have been caused by an unnecessary, unilateral revocation of chlorpyrifos tolerances in the United States.”⁵⁹ EPA released another press statement on April 5, 2017, compiling statements from USDA and various agricultural associations praising EPA’s decision not to ban chlorpyrifos.⁶⁰

As the Pruitt Order acknowledges, however, EPA must make food tolerance decisions based on safety and in particular whether EPA can find that there is a reasonable certainty of no harm from the pesticide. Congress decided long ago that the safety of our food cannot be sacrificed, and in 1996, it expanded that mandate to aggregate exposures to a pesticide in food, drinking water, and pesticide drift. EPA cannot leave tolerances in place in the absence of a finding of safety, no matter how widely used the pesticide is.⁶¹ Indeed, widespread use of chlorpyrifos cuts the other way because its use exposes children and communities throughout the country to poisoning and brain damage risks, making the Administrator’s decision to delay protections even more egregious.

D. The Deadline for Completing Registration Review for All Older Pesticides is Not A License to Maintain Tolerances for Pesticides That are Unsafe

As a final reason for denying the 2007 Petition and leaving chlorpyrifos tolerances in place, EPA claims the right to re-order the priorities that had been set by previous administrations. It asserts that it can put off deciding whether to revoke chlorpyrifos tolerances for years as long as it does so before October 1, 2022, the deadline for completing registration review of all older pesticides. 82 Fed. Reg. 16,581, 16,590 (April 5, 2017); *see* 7 U.S.C. § 136a(g)(1)(A)(iii)(I) (registration review deadline). This position is indefensible because it ignores other legal mandates and the scientific evidence that precludes the safety finding that is necessary to leave chlorpyrifos tolerances in place.

⁵⁹ Press Release, U.S. EPA, EPA Administrator Pruitt Denies Petition to Ban Widely Used Pesticide (Mar. 29, 2017), <https://www.epa.gov/newsreleases/epa-administrator-pruitt-denies-petition-ban-widely-used-pesticide-0>.

⁶⁰ Press Release, U.S. EPA, Agriculture Community Reacts to Recent EPA Action (Apr. 5, 2017), <https://www.epa.gov/newsreleases/agriculture-community-reacts-recent-epa-action>.

⁶¹ Chlorpyrifos usage has declined over time, as many farmers have shifted to less toxic alternatives, even before EPA’s proposal to revoke chlorpyrifos tolerances. Annual agricultural pesticide use data compiled by the U.S. Geological Survey’s Pesticide National Synthesis Project show that, since the mid-1990s, chlorpyrifos use has declined. https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2014&map=CHLORPYRIFOS&hilo=L&disp=Chlorpyrifos. Additionally, in California, the combined use of chlorpyrifos in alfalfa, almonds, citrus, and cotton decreased from 2006 -2012. While overall use increased in 2013 and 2014, it remained below the amount used in 2006. “Identifying and Managing Critical Uses of Chlorpyrifos Against Key Pests of Alfalfa, Almonds, Citrus and Cotton” (UC IPM report for CA DPR), August 31, 2016 at 3.

Under the FFDCA, any person may file a petition to revoke tolerances. 21 U.S.C. § 346a(d)(1). The Administrator must give the petition due consideration and issue either a proposed or final regulation to revoke the tolerances or an order denying the petition. *Id.* § 346a(d)(4)(A). While the FFDCA does not establish a specific deadline for acting on petitions to revoke tolerances, the Administrative Procedure Act requires that federal agencies respond to petitions “within a reasonable time.” 5 U.S.C. § 555(b). In 2015, the Ninth Circuit held that EPA’s delay in responding to the 2007 Petition was unreasonable and “egregious” and set a timeline for EPA to respond. *In re Pesticide Action Network North America v. EPA*, 798 F.3d 809, 811 (9th Cir. 2015). In 2016, the court reiterated its concerns over any further delay, stating that any “claim of premature rulemaking has come and gone.” *In re PANNA*, No. 14-72794, Order (9th Cir. Aug. 12, 2016).

The fact that Congress established an October 1, 2022, deadline for EPA to complete registration review of all older pesticides is no license for EPA to continue to exacerbate its unreasonable delay in acting on the 2007 Petition seeking revocation of chlorpyrifos tolerances. First, the registration review provision states that: “Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide . . .” 7 U.S.C. § 136a(g)(1)(C). This clause prohibits EPA from relying on the registration review deadline to forestall other legally required or scientifically compelled regulatory action.

Second, it is FIFRA, not the FFDCA, that establishes the registration review process. While registration review will include an assessment of food and drinking water risks and determine whether food tolerances may be retained or must be revoked, registration review is far broader in scope than the issues arising under the FFDCA. It will examine all uses of a pesticide, not only food uses, and risks to wildlife, waterbodies, and workers in addition to food and drinking water. In addition, FFDCA tolerance determinations must be made solely on the basis of safety, while nonfood use decisions under FIFRA are based on a balancing of risks and benefits. *Compare* 21 U.S.C. § 346a(b)(2)(A)(i) & (ii) (FFDCA standard and determination of safety), *with* 7 U.S.C. § 136(bb) (FIFRA definition of “unreasonable adverse effects on the environment”). Even where EPA accelerates food safety determinations, as it had done for chlorpyrifos, other FIFRA assessments and decisions lie ahead and remain subject to the 2022 registration review deadline.

EPA’s review of chlorpyrifos has proceeded to a point of no return. The agency developed methods for addressing spray drift, volatilization, and epidemiology studies, and released human health risk assessments that document unsafe exposures from chlorpyrifos. EPA made findings that chlorpyrifos is unsafe in 2014 directed at drinking water contamination, *see, e.g.*, 80 Fed. Reg. 69,080, and expanded those findings in November 2016 to every way people are exposed to chlorpyrifos. 81 Fed. Reg. at 81,050. The law is clear. EPA can leave food tolerances in place only if it can find the pesticide safe. Because EPA has found chlorpyrifos to be unsafe, it lacks the authority to retain the food tolerances. It cannot lawfully issue an order denying the 2007 Petition, but instead must comply with the FFDCA mandate to revoke tolerances for this unsafe pesticide.

In claiming the authority to postpone revoking chlorpyrifos tolerances despite its own scientific findings, EPA cites the prerogative of a new presidential administration to make policy choices that differ from its predecessor, citing *Fed. Comm’n Comm’n v. Fox Television*

Stations, 556 U.S. 502 (2009). 82 Fed. Reg. at 16,589. *Fox Television*, however, requires agencies to provide a reasoned explanation that comports with *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 43 (1983), and to address prior factual findings and circumstances that underlay the earlier agency decision. 556 U.S. at 515-16. EPA provided no such explanation, and it has not disavowed its previous findings that chlorpyrifos is unsafe. Nor could it given the extensive scientific record documenting the damage chlorpyrifos causes to children's brains at low-level exposures. Whatever leeway a new administration has to make its own policy choices does not extend to factual determinations, like EPA's findings that chlorpyrifos is unsafe. Nor does that latitude allow the new administration to break the law by leaving tolerances in place in the face of findings of such serious harm to children.

CONCLUSION

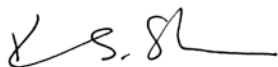
For these reasons, EPA must reverse the Pruitt Order and revoke all chlorpyrifos tolerances. This misguided Order and the delay it has spurred threaten to expose countless children and communities to chlorpyrifos well into the future. People will needlessly suffer from poisonings from chlorpyrifos drift. Parents will watch their children struggle with attention disorders and impaired brain functioning that hinders their ability to learn and play, and the children will experience lifelong deficits that make it harder for them to achieve their full potential and dreams. Prolonging revocation of chlorpyrifos tolerances, as required by the law and science, is not only unlawful, but also callous and heartless. EPA should rule on these objections within 60 days and expedite revocation of all chlorpyrifos tolerance.

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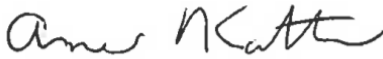
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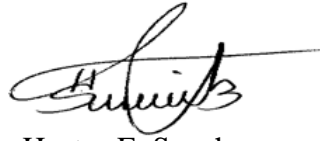
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