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

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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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. 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

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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 Agrosciences, 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).

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\(^3\) Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chloryrifos 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.

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. 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-

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nata, 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).


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(l).

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%...
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,

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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 CONVINCE 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

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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. 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.

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. 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. The petitioners filed administrative objections, which have not been resolved.

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

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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).


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).


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.


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


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.  

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. 

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.  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).


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

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

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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. 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. 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. 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. 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. 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 Resarch 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).


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. 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.

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. 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.

In November 2016, EPA released its 2016 Chlorpyrifos Revised Human Health Risk Assessment ("2016 RHHRA"). 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

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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.
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 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 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.


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.


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.”

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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 Envtl. 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). 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. 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 Agrosciences 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.


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. 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. 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.” 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,”

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and “incomplete.” 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.”

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.

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. 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.

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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. Commc’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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Exhibit 1
DECLARATION OF PHILIP J. LANDRIGAN, M.D., M.SC. IN SUPPORT OF PETITION TO SUSPEND AND CANCEL CHLORPYRIFOS USES

I, Philip J. Landrigan, M.D., M.Sc., hereby declare and state as follows:

1. I submit this declaration in support of the petition to cancel and suspend chlorpyrifos uses that is being submitted by Earthjustice on behalf of United Farm Workers and other farmworker advocates.

PROFESSIONAL BACKGROUND AND EXPERTISE

2. I am a pediatrician and epidemiologist, and I am board certified in occupational medicine, general preventive medicine and pediatrics. I have been a member of the faculty of the Icahn School of Medicine at Mount Sinai since 1985 and am currently a professor of preventive medicine and a professor of pediatrics. I am also the Dean for Global Health, a position I have held since 2010.

3. I obtained my medical degree from Harvard Medical School in 1967. I completed an internship at Cleveland Metropolitan General Hospital and a residency in pediatrics at Boston Children's Hospital. In 1977, I received a Diploma of Industrial Health from the University of London and a Master of Science degree in Occupational Medicine from the London School of Hygiene and Tropical Medicine. My CV is attached as Exhibit 1.

4. I served for 15 years as an Epidemic Intelligence Service Officer and medical epidemiologist at the Centers for Disease Control and Prevention (CDC) and the National Institute for Occupational Safety and Health (NIOSH). I directed the national program in occupational epidemiology for NIOSH from 1979-1985. I have been awarded numerous honors throughout my career, including the Meritorious Service Medal of the U.S. Public Health Service in 1985.
5. From 2000 to 2002, I served on the Armed Forces Epidemiological Board, and from 1996 to 2005, in the Medical Corps of the U.S. Naval Reserve. I retired from the United States Navy in 2005 at the rank of Captain (O-6) and continue to serve as Surgeon General of the New York Naval Militia, the naval component of the New York National Guard.

6. I was elected a member of the Institute of Medicine of the National Academy of Sciences in 1987. I have chaired committees at the National Academy of Sciences (NAS) on Environmental Neurotoxicology and on Pesticides in the Diets of Infants and Children. From 1997 to 1998, I served as Senior Advisor on Children's Health to the Administrator of the U.S. Environmental Protection Agency (EPA) and was instrumental in helping to establish a new Office of Children's Health Protection at EPA.

7. I am editor in chief of the Annals of Global Health, deputy editor of the American Journal of Industrial Medicine, and an associate editor of Environmental Health Perspectives.

8. I have studied the impacts of toxic chemicals, including pesticides, on children’s health for over thirty years. I have published more than 500 scientific papers and five books, on subjects including epidemiology, occupational health, environmental neurotoxicity, and children’s health. I have extensive knowledge and expertise in environmental and occupational medicine, epidemiology, environmental neurotoxicity, and the effects of pesticides and other chemicals on children through my education, training, professional experience, involvement in applicable peer-reviewed research, and my ongoing review of the pertinent medical and scientific literature.

CHILDREN’S VULNERABILITY TO PESTICIDES

9. A key policy breakthrough occurred over the past three decades with the discovery that children are far more sensitive than adults to toxic chemicals in the environment.
This finding led to the recognition that chemical exposures early in life are significant yet preventable causes of disease in children and adults.

10. In the 1970s, my research showed that 60% of children living within one mile of ASARCO's El Paso smelting plant had elevated blood lead levels and that even small amounts of lead exposure lowered a child's IQ. My research showed that lead can cause brain damage to children at levels too low to clinically detect signs and symptoms. This phenomenon is now called “subclinical toxicity.” These studies contributed importantly to the U.S. federal government’s decision to phase out lead components from gasoline and regulate the lead content of paint in the 1970s.

11. I led a five-year study as chair of the NAS Committee that published *Pesticides in the Diets of Infants and Children* in 1993. This pivotal study showed that infants and children, including infants in the womb, are much more sensitive to pesticides and other toxic chemicals than adults and documented four differences between children and adults that contribute to children’s heightened susceptibility to chemicals in the environment. The following description of this work is taken from an article that I co-authored with Dr. Lynn R. Goldman, “Children’s Vulnerability to Toxic Chemicals: A Challenge and Opportunity to Strengthen Health and Environmental Policy,” *Health Affairs* 30, no.5 (2011): 842-850 (Exhibit 2):

First, children have greater exposures to toxic chemicals for their body weight than adults. A six-month-old infant drinks seven times more water per pound than an adult, and children take in three to four times more calories per pound than adults. The air intake per pound of an infant is twice that of an adult. These differences result in children being disproportionately exposed to toxic chemicals in air, food, and water. Children’s hand-to-mouth behavior and play on the ground further magnify their exposures.

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Second, children’s metabolic pathways are immature, and a child’s ability to metabolize toxic chemicals is different from an adult’s. In some instances, infants are at lower risk than adults because they cannot convert chemicals to their toxic forms. More commonly, however, children are more vulnerable because they lack the enzymes needed to break down and remove toxic chemicals from the body.

Third, children’s early developmental processes are easily disrupted. Rapid, complex, and highly choreographed development takes place in prenatal life and in the first years after birth, continuing more slowly throughout childhood into puberty. In the brain, for example, billions of cells must form, move to their assigned positions, and establish trillions of precise interconnections. Likewise, development of the reproductive organs is guided by a complex and precisely timed sequence of chemical messages and is shaped by maternal and fetal hormones.

Recent research in pediatrics and developmental toxicology has elaborated the concept of “windows of vulnerability.” These are critical periods in early development when exposures to even minute doses of toxic chemicals—levels that would have no adverse effect on an adult—can disrupt organ formation and cause lifelong functional impairments. . . . These windows of vulnerability have no equivalent in adult life.

Fourth, children have more time than adults to develop chronic diseases. Many diseases triggered by toxic chemicals, such as cancer and neurodegenerative diseases, are now understood to evolve through multistage, multiyear processes that may be initiated by exposures in infancy.

12. Since the 1993 publication of the NAS report, peer-reviewed research continues to document the developing human brain’s unique vulnerability to toxic chemical exposures, and to confirm that major windows of developmental vulnerability occur in utero, during infancy, and in early childhood. During these sensitive life stages, exposure to pesticides and other chemicals can cause permanent brain injury at levels of exposure far below those which would have an effect in adults.

13. A fetus in the womb is at risk of exposure to pesticides and other toxic chemicals because of both exposure and vulnerabilities. In terms of exposure, the placenta does not block the passage of many toxic chemicals from the maternal to the fetal circulation. In fact, more than 200 chemicals have been detected in infants’ umbilical cord blood, meaning they have passed from the mother’s circulation to the baby’s circulation prior to birth. In terms of susceptibility,
several prenatal developmental processes have been shown to enhance the vulnerability of the fetus in the womb to toxic chemicals.

14. Prior to the publication of the NAS report, virtually all environmental policy in the United States had focused on assessment of risk to the average adult man weighing 150 pounds. Little attention was paid to the unique risks faced by infants, children, or other vulnerable groups within the population.

15. The core findings and recommendations of the NAS report were incorporated into the 1996 Food Quality Protection Act (FQPA), which revamped federal pesticide laws. The FQPA changed risk assessment by requiring the use of child-protective safety factors to account for children’s exposures and unique susceptibilities and to account also for gaps in data, and by requiring consideration of aggregate exposures to a pesticide via multiple routes, including diet, drinking water, and interaction with pesticide residues through play and other activities. It also required evaluation of cumulative effects of multiple pesticides that have the same mechanism of toxicity.

16. Implementation of the new standards led to bans on residential applications of two very widely used organophosphate insecticides: chlorpyrifos and diazinon. These bans were triggered by recognition of these compounds’ neurodevelopmental toxicity to children and documentation of their long residence time in indoor environments. FQPA implementation also led to a cumulative risk assessment for all organophosphates because they have a common mechanism of toxicity, as discussed below.

NEURODEVELOPMENTAL HARM TO CHILDREN’S BRAINS FROM CHLORPYRIFOS AND OTHER ORGANOPHOSPHATES

17. Chlorpyrifos, like other organophosphate pesticides (OPs), causes acute poisonings by inhibiting the enzyme acetylcholinesterase (AChE), which regulates nerve
impulses. When cholinesterase is inhibited, it leads rapidly to overt symptoms of cholinergic hyperstimulation. The symptoms include nausea, headaches, skin rashes, eye irritation, vomiting, dizziness, seizures, coma, and death, depending on the dose and the toxicity of the product. When EPA conducted risk assessments on the organophosphates in the 1990s through 2006, it set human exposure limits based on detection of AChE inhibition. Specifically, it uses 10% red-blood cell AChE inhibition as its regulatory endpoint, called its point of departure.

18. A growing body of scientific evidence has documented neurodevelopmental harm to the developing brain from organophosphates, including chlorpyrifos. This evidence comes both from animal and epidemiology studies. EPA has compiled and reviewed the published studies in its Revised Human Health Risk Assessment for Chlorpyrifos Registration Review (Dec. 29, 2014) (RHHRA), and in its Literature Review on Neurodevelopmental Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides (Sept. 15, 2015).

19. Numerous scientific studies have documented neurodevelopmental harm from prenatal and early postnatal exposures to chlorpyrifos. Animal studies have found disruption in neuronal development, neurotransmitter systems and synaptic function, as well as behavioral and cognitive impairments following low-dose perinatal chlorpyrifos exposure. Neurobehavioral effects include impairment on maze performance, locomotion, and balance in neonates exposed in utero or during postnatal life.

20. Direct evidence that chlorpyrifos can cause neurodevelopmental harm to children’s brains comes from three epidemiology studies conducted respectively at Columbia University, University of California-Berkeley, and Mount Sinai School of Medicine. These universities conducted this research through their Centers for Children’s Environmental Health and Disease Prevention Research.
21. These Centers are part of an NIH-funded, competitively awarded national network of such Centers established to increase scientific understanding of the impacts of toxic exposures on children. The Berkeley study studied children of farmworkers in the Salinas Valley of California, the Mount Sinai study observed a New York City Hispanic population whose exposures were primarily residential, and the Columbia study examined African-American and Dominican children in New York City, whose exposures were similarly residential.

22. These three Centers have been conducting long-term birth-cohort studies in which pregnant women are enrolled during their pregnancies. Their environmental exposures during pregnancy are recorded through objective measures like blood and urine samples, dust and air samples, and cord blood. Chlorpyrifos exposure during pregnancy was measured through analysis of chlorpyrifos’ metabolic breakdown products in maternal urine samples. Even though these three studies were conducted in distinct geographic regions of the country, on different populations, with different routes of exposure, and using different biomarkers, they produced strongly convergent results. All studies found cognitive impairments that persist into school years from OP exposures. The Columbia study was specific to chlorpyrifos. It found that prenatal exposure to chlorpyrifos resulted in the birth of babies with reduced head circumference. Reduction in head circumference at birth is a measure of delayed or reduced brain growth during pregnancy and is an effect seen also in infants exposed in the womb to Zika virus. In the Columbia study, the degree of reduction in head circumference was proportional to the degree of maternal exposure to chlorpyrifos during pregnancy. The impact of chlorpyrifos on head circumference was no longer observed after the ban on residential application of chlorpyrifos was imposed.
23. Follow-up studies of the babies in these three studies have found that prenatal exposures have persistent deleterious effects on cognitive function through 7 years of age. The brain impairments observed in these infants and children include reduction in motor function, decreases in working and visual memory, processing speed, verbal comprehension, perceptual reasoning, and diminished IQ. The studies also documented neurobehavioral problems, including increased risk of attention deficit hyperactivity disorder, pervasive developmental disorder, and behaviors typical of the autism spectrum. Certain subpopulations demonstrate greater susceptibility, including children of farmworkers and those who have reduced capacity to detoxify OPs. Some studies found elevated risks of respiratory symptoms consistent with asthma. And recently, a study using magnetic resonance imaging found that even low to moderate levels of prenatal exposure to chlorpyrifos may lead to long-term, potentially irreversible changes in the structure of the developing brain, causing thinning of the cerebral cortex.

24. These studies found damage to children’s brains from exposures to chlorpyrifos that produced no or less than 1% red-blood cell cholinesterase inhibition. In other words, the harm to the developing brain and nervous systems occurred at exposures substantially below EPA’s regulatory limit, which is based on exposures that are high enough to inhibit cholinesterase in adults. EPA acknowledged in its 2014 revised human health risk assessment on chlorpyrifos that the neurodevelopmental harm to children’s brains occurred at lower doses than its regulatory endpoint.

**EPA’S RISK ASSESSMENTS DO NOT PROTECT AGAINST BRAIN DAMAGE TO CHILDREN**

25. Even though EPA has acknowledged that neurodevelopmental harm to children occurs at exposures that produce no or only minimal cholinesterase inhibition, EPA has
continued to set its exposure limits based on cholinesterase inhibition. It continues to use 10% red-blood cell cholinesterase inhibition as the endpoint in its risk assessments, even though the mothers in the Columbia study who gave birth to infants with brain injury exhibited less than 1% cholinesterase inhibition or no inhibition at all.

26. Safety factors are used in risk assessment and standard-setting to account for uncertainties. In setting a standard or tolerance for a pesticide, EPA will begin the risk assessment by identifying an exposure level that produces no adverse effect as its endpoint. This is called the no observable adverse effect level. If some adverse effects are observed at that exposure level, EPA will add a three-fold safety factor. EPA then typically uses a tenfold safety factor to account for uncertainties in extrapolating from animal studies to people, and a second tenfold safety factor to account for differences among human populations due to such factors as genetic predisposition and other stressors. Finally, the FQPA requires EPA to use a third tenfold “child-protective” safety factor when there is either evidence that children are especially vulnerable to a chemical or when there are gaps in data concerning children’s exposures or vulnerabilities. For OPs, EPA has retained a 10X child-protective FQPA safety factor because of the published evidence that these chemicals cause neurodevelopmental harm to infants and children.

27. For chlorpyrifos, however, EPA departed from this usual practice and instead relied on the Dow Agrosciences Company’s pharmacokinetic-pharmacodynamic (PBPK) model of OP toxicity, which tries to pinpoint the exposures that will produce 10% cholinesterase inhibition. The Dow model is drawn largely from human studies that included deliberate dosing of people. Many of these studies were conducted in countries outside of the United States. Use of human studies in risk assessment poses significant ethical and scientific issues, and the Dow
human studies have been criticized for not meeting the informed consent standards that would be required in the US and also for scientific deficiencies. Because the Dow model uses human data, it obviates the need to extrapolate data from animals to humans. In relying on the Dow data, EPA therefore dispensed with the 10X inter-species safety factor for all populations except for women of child-bearing years. For women of child-bearing years, EPA retained the 10X intra-species safety factor because Dow did not have human data for this population.

EPA’S RISK ASSESSMENTS DO NOT PROTECT WORKERS OCCUPATIONALLY EXPOSED TO CHLORPYRIFOS AND DO NOT PROTECT THE CHILDREN IN THE WOMB OF PREGNANT WOMEN WORKERS

28. In their assessments of risk from occupational exposures to chlorpyrifos, EPA identified risks of concern for over half of the handler exposure scenarios. EPA states that additional engineering controls or protective gear could eliminate the risks of concern for 27 of these activities, but notes that 126 would remain of concern regardless of the level of personal protective equipment or environmental controls. EPA also found that protection of agricultural field workers against chlorpyrifos toxicity would need longer re-entry intervals to reduce risks.

29. For many of the handler exposure scenarios, EPA found Margins of Exposure (MOEs) of less than 10 and for some scenarios the MOEs were close to or even less than 1. In other words, EPA estimates that worker exposures from these activities likely would result in 10% cholinesterase inhibition. In these scenarios, the current EPA standard manifestly fails to protect worker health or to comply with the fundamental intent of the Occupational Safety & Health Act of 1970 (OSHA) which states that every worker has the “right to a safe and healthful workplace.”

30. EPA has acknowledged that its regulatory end point is underprotective. It has proposed using umbilical cord blood chlorpyrifos levels from the Columbia study to develop a more protective end point based on loss of working memory. It convened a Scientific Advisory
Panel (SAP) to review this proposal. The SAP did not support developing a point of departure based on a single study, but it did agree that EPA’s approach of using 10% cholinesterase inhibition as the regulatory endpoint was underprotective.

31. The California Department of Pesticide Regulation (DPR) prepared its own risk assessment of chlorpyrifos which was modeled on EPA’s approach and like EPA incorporated 10% cholinesterase inhibition, Dow’s PBPK model, and the reduced safety factors. California’s Office of Environmental Health Hazard Assessment (OEHHA), which routinely reviews pesticide standards proposed by DPR to ensure that they protect worker health, conducted a scientific peer review of DPR’s human health risk assessments on chlorpyrifos and released its review in June 2016. OEHHA found that the 10% cholinesterase inhibition end point and the reduced safety factors proposed by the DPR failed to adequately protect human health and therefore failed to comply with occupational safety and health legislation. OEHHA recommended using a total uncertainty factor of 1000X or 3000X to protect the health of workers occupationally exposed to chlorpyrifos.

32. Any occupational exposure standard for chlorpyrifos needs to take cognizance of the fact that the workforce may include pregnant women workers (who may not yet realize that they are pregnant) and that pregnant women workers who are occupationally exposed to chlorpyrifos will unwittingly pass any chlorpyrifos that they absorb into the bodies of their unborn children where the chlorpyrifos will cause irreversible brain damage. To prevent this sequence of events, EPA should at a minimum use safety factors that total 1000X. Moreover, an additional 3X uncertainty factor is warranted over and above the 1000X safety factor because 10% cholinesterase inhibition cannot be considered a “no observable adverse effect level” in
light of the finding that neurodevelopmental harm to the fetus can result at exposure levels below this outdated limit value.

PREVENTING BRAIN DAMAGE TO CHILDREN FROM TOXIC CHEMICAL EXPOSURES YIELDS SIGNIFICANT COST SAVINGS

33. Neurobehavioral development disorders affect 10-15% of births in the United States, and the prevalence of attention deficit hyperactivity disorder, autism and other neurodevelopmental disorders is increasing in the US and worldwide. Subclinical decrements in brain function are even more common. All of these disabilities can have serious consequences for individuals, such as diminished quality of life, reduced academic achievement, behavioral disruptions, and they also have consequences for society in the form of the diminished economic productivity of affected children and the increased risk that these children will grow up to become unemployed, underemployed and institutionalized or incarcerated adults. Environmental exposures play a role in many, if not most, of these developmental disorders as genetic factors account for only approximately 30-40% of them.

34. Preventing exposures to chemicals can yield great economic savings. While it is difficult to precisely quantify the harm from neurodevelopmental disorders and the cost savings that result from their prevention, several studies suggest that both are quite large. To estimate the contribution of environmental pollutants to the prevalence and costs of disease in American children, investigators at Mount Sinai School of Medicine examined four categories of illness: lead poisoning, asthma, cancer, and neurobehavioral disorders. Based on prevalence, the environmentally attributable fraction of each disease, and national economic data, they calculated that the total annual costs of these diseases attributable to environmental exposures is $54.9 billion (range $48.8 billion to $64.8 billion): $43.4 billion for lead poisoning, $2.0 billion for asthma, $0.3 billion for childhood cancer, and $9.2 billion for neurobehavioral disorders.
Because of the difficulties inherent in assessing the full economic consequences of neurobehavioral impairments, it is likely that these estimates are low.

35. After the phase-out of lead in gasoline from 1976 and 1990, the mean blood lead level of American children decreased by more than 90% (to below 2 micrograms per deciliter today), and the incidence of childhood lead poisoning also fell by more than 90%. A further consequence of the reduction in exposure to lead was that the mean IQ of American children has increased. Children born in the United States today are estimated to have IQ scores that, on average, are 2.2–4.7 points higher than those of children born in the early 1970s. And because each 1-point gain in population mean IQ is associated with an estimated 2% increase in productivity over a lifetime, the gain in population IQ is estimated to have produced a national economic benefit of $110–$319 billion in each annual cohort of babies born in the United States since the 1980s.

36. Dr. David Bellinger, a professor of neurology at Harvard Medical School, published a paper in 2012, which estimated that Americans have collectively forfeited 41 million IQ points as a result of exposure to lead, mercury, and OPs. He calculated a total loss of 16.9 million IQ points due to exposure to OPs.²

EPA’S APPROACH TO WORKER RISK MITIGATION IS UNDERPROTECTIVE AND AT ODDS WITH STANDARD OCCUPATIONAL HEALTH PRACTICE

37. When EPA identifies a risk of concern, it explores as a first priority whether use of personal protective equipment will eliminate the risk. If personal protective equipment is found not to be protective, EPA then asks whether engineering controls or administrative controls such as restricted re-entry intervals will eliminate the risk. Only if the risk of concern

remains after implementation of all such mitigation does EPA explore eliminating the exposure or shifting to less harmful alternative chemicals or application methods.

38. EPA’s approach is backwards and wrong. It violates standard, long-established occupational health practice. It fails to protect worker health.

39. In the field of occupational safety and health, regulators adhere to a hierarchy of controls that prioritizes prevention of exposure – not use of personal protection. Regulators start by asking whether the exposure can be eliminated altogether or whether other less toxic chemicals can be substituted. If those approaches are found not to be feasible, the regulator will look to engineering controls such as machine-guarding or administrative controls such as longer re-entry times to sprayed fields. The regulator will turn to personal protective equipment only as a last resort, because personal protective equipment has been shown repeatedly over the decades to be far less effective at worker protection than product substitution, engineering controls and administrative controls. A final reason for not relying on personal protective equipment is that such equipment degrades workers’ ability to function and increases risk of heat stress and heat stroke. Thus double-layers of clothing, gloves, and respirators likely impede mobility and contribute to heat and respiratory stress of pesticide handlers working in hot temperatures during summer growing seasons.

40. OSHA has adhered to this prioritization for decades. The lead standard is illustrative. EPA refused to rely on personal protective equipment, and on respirators in particular, because they fail to eliminate exposure, provides inadequate protection, and creates additional hazards by interfering with vision and mobility. The 1978 lead standard is replete with findings that respirators afford inadequate protection. OSHA required respirators in
addition to engineering controls to afford workers additional protection during the time it would take to fully implement the controls. 43 Fed. Reg. 52,952 (Nov. 14, 1978).

41. For decades, EPA has adopted a wrong-headed strategy for mitigating worker exposures to chlorpyrifos and other toxic pesticides that relies first and foremost on personal protective equipment. By relying on this inadequate strategy and by relying on personal protective equipment that has been shown to confer highly inadequate protection, EPA has allowed workers to be exposed to harmful levels of chlorpyrifos. By relying on this ineffective strategy, EPA has allowed pregnant women workers to be occupationally exposed to levels of chlorpyrifos that can result in fetal brain damage to infants in the womb. Sound occupational health principles require engineering or administrative controls, where effective, or elimination of the exposure, where engineering or administrative controls are not effective.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 7th day of September 2016, in New York, New York.

Philip J. Landrigan, M.D., M.S.
CURRICULUM VITAE
Philip J. Landrigan, M.D., M.Sc., D.I.H., F.A.A.P., F.A.C.P.M.

ACADEMIC APPOINTMENTS

Current:  Icahn School of Medicine at Mount Sinai, Dean for Global Health, 2010-Present
          Icahn School of Medicine at Mount Sinai, Professor, Department of Preventive Medicine, 1990-Present
          Icahn School of Medicine at Mount Sinai, Professor of Pediatrics, 1985-Present

Previous: Icahn School of Medicine at Mount Sinai, Ethel H. Wise Professor and Chairman, Department of Preventive Medicine, 1990-2015.
          Icahn School of Medicine at Mount Sinai, Director, Division of Environmental and Occupational Medicine, Department of Community and Preventive Medicine, 1985-1990.
          U.S. Environmental Protection Agency, Senior Advisor to the Administrator on Children's Health and the Environment, 1997-1998. (Sabbatical position)

Centers for Disease Control and Prevention
• Chief, Environmental Hazards Activity, Bureau of Epidemiology, 1974-1979.

Adjunct Positions:
Harvard School of Public Health, Adjunct Professor of Environmental Health, 2010-present; Visiting Lecturer on Occupational Health, 1981-2010
Harvard Medical School, Clinical Instructor in Pediatrics, 1969-1970; Visiting Lecturer on Preventive Medicine and Clinical Epidemiology, 1982-Present
University of Washington School of Public Health and Community Medicine, Auxiliary Clinical Professor of Environmental Health, 1983-2013
University of Cincinnati, Department of Environmental Health, College of Medicine, Assistant Clinical Professor of Environmental Health, 1981-1986
London School of Hygiene and Tropical Medicine, Visiting Fellow, TUC Institute of Occupational Health, 1976-1977

EDUCATION
High School: Boston Latin School, 1959
College: Boston College, A.B. (magna cum laude), 1963
Medical School: Harvard Medical School, M.D., 1967

POSTDOCTORAL TRAINING
Internship: Cleveland Metropolitan General Hospital, 1967-1968
Residency: Children's Hospital Medical Center, Boston, (Pediatrics), 1968-1970
Post Graduate: London School of Hygiene & Tropical Medicine, 1976-77
Diploma of Industrial Health (England), 1977
Master of Science in Occupational Medicine, University of London (with distinction), 1977
CERTIFICATION
American Board of Pediatrics - 1973
American Board of Preventive Medicine:
    General Preventive Medicine - 1979
    Occupational Medicine - 1983

MEDICAL LICENSURE
Massachusetts #31277, 1967 - present
New York #162034, 1985 - present

INSTITUTE OF MEDICINE
Institute of Medicine, National Academy of Sciences, Elected to membership, 1987

HONORS/AWARDS
Asbestos Disease Awareness Association – Dr. Irving Selikoff Lifetime Achievement Award, 2016
Grassroots Environmental Education, Award for Outstanding Leadership in Children’s Environmental Health, 2015
Boston College – Distinguished Alumni Research Award, 2014
Boston Latin School - Distinguished Graduate Award, 2014
University of Medicine & Dentistry of New Jersey - Senator Frank R. Lautenberg Annual Award in Public Health, 2011
Hearst Foundation, The Daily Green – The Heart of Green Award, 2010
U.S. Environmental Protection Agency, Region II – Environmental Quality Award on behalf of Mount Sinai Medical Center, 2009
Westchester County (NY). Sustainability Award for Service on Westchester County Global Warming Task Force, 2009
Student Physicians for Social Responsibility. Lifetime Achievement Award, 2009
Women’s City Club of New York. Civic Spirit Award, 2009
Boston College. Alumni Award for Professional Excellence, 2008
Collegium Ramazzini. Irving J. Selikoff Award, 2008
Healthy Schools Network, Inc. Healthy Schools Hero Award, 2008
Children’s Health Environmental Coalition. Lifetime Achievement Award, 2006
U.S. Environmental Protection Agency. Child Health Champion Award, 2006
Huntington Breast Cancer Action Coalition. Humanities Award for Children’s Health Protection, 2005
Icahn School of Medicine at Mount Sinai. J. Lester Gabrilove Award, 2005
American College of Occupational and Environmental Medicine. Health Achievement in Occupational Medicine Award, 2005
National Nutritional Foods Association. Rachel Carson Environmental Award, 2005
Federated Conservationists of Westchester County. Super Hero Award for Children’s Health, 2005
Physicians for Social Responsibility, Los Angeles Chapter. Socially Responsible Medicine Award, 2004
Organic Style Magazine. Environmental Power List, 2004
HONORS/AWARDS (cont)

Public Health Association of New York City, Haven Emerson Award, 2002
National Institute for Occupational Safety & Health, James Keogh Award, 2002
Icahn School of Medicine at Mount Sinai, Jacobi Medallion, 2002
Environmental Advocates (New York), Award for Environmental Advocacy on Behalf of Children, 2000
American Conference of Governmental Industrial Hygienists, William Steiger Memorial Award, 2000

Russian Academy of Medical Science, Elected as Foreign Member, 2000
Earth Day New York, Award for Excellence in Environmental Medicine, 1999
Mothers & Others for a Livable Planet, Award for Advocacy on Behalf of the Health of Children, 1999
American College of Preventive Medicine, Katherine Boucot Sturgis Award, 1999
International Society for Occupational and Environmental Health, Vernon Houk Award, 1998
New Jersey Environmental Federation Certificate of Recognition. Environmental Achievement Award, 1998

Physicians for Social Responsibility, Broad Street Pump Award in Environmental Health, 1996
International Association of Fire Fighters, Occupational Health and Safety Award, 1995
American Public Health Association, Herbert L. Needleman Medal and Award for Scientific Contributions and Advocacy on Behalf of Children, 1995
United Brotherhood of Carpenters, William Sidell Presidential Award, 1995
New England College of Occupational and Environmental Medicine, Harriet Hardy Award, 1993

New York Committee for Occupational Safety and Health, Annual Honoree, 1985
United States Navy
• Navy & Marine Corps Commendation Medal (3 awards), 2002, 2003 and 2005
• National Defense Service Medal, 2003
• Secretary of Defense Medal for Outstanding Public Service, 2002

U.S. Public Health Service
• Meritorious Service Medal, 1985
• Group Citation as Member of Beryllium Review Panel, 1978
• Career Development Award, 1976


HONORARY DEGREES:
Mount Sinai School of Medicine, Doctor of Science (honoris causa), 2007

OTHER PROFESSIONAL APPOINTMENTS:
American College of Preventive Medicine Fellow, 2003-present
Physicians for Social Responsibility, Board of Directors 1996-1999; Board of Sponsors, 1994-95
New York Academy of Medicine, Elected Fellow, 1991
American College of Occupational and Environmental Medicine, Fellow, 1986
Herman Biggs Society, Member, 1986-1992
International Commission on Occupational Health, Member, 1985-present
Collegium Ramazzini, Fellow, 1983-present
President, 1997-present
American College of Epidemiology, Fellow, 1983-present
Board of Directors, 1990 - 1993
American Epidemiological Society, Elected Member, 1982-present
American Public Health Association, Member, 1982-present
Occupational Health Section, Chair, 1989-90
OTHER PROFESSIONAL APPOINTMENTS: (cont)

Society for Epidemiologic Research, Member, 1978-present
Royal Society of Medicine, Elected Fellow, 1977
American Academy of Pediatrics, Fellow, 1975-present
New York Occupational Medicine Association, Member 1985-present
  Board of Directors, 1988-1990
New York Academy of Sciences, Fellow 2002-present

COMMITTEES:

The White House
  Presidential Advisory Committee on Gulf War Veterans' Illnesses, 1995-1996

American Academy of Pediatrics

National Research Council
  Institute of Medicine, Chairman, Interest Group (14) Environmental and Occupational Health and Toxicology, 2009-2011
  National Academy of Sciences, Board on Sustainable Development, 1995-1998
  National Academy of Sciences, Committee on Neurotoxicology in Risk Assessment, 1987-1989
  National Academy of Sciences, Committee on the Epidemiology of Air Pollutants, Vice-Chairman, 1984-1985
  Institute of Medicine, Committee for a Planning Study for an Ongoing Study of Costs of Environment-Related Health Effects, 1979-1980
  National Academy of Sciences, Assembly of Life Sciences. Board on Toxicology and Environmental Health Hazards, 1978-1987; Vice-Chairman, 1981-1984

National Institutes of Health/U.S. Public Health Service
  National Institutes of Health, National Institute of Environmental Health Sciences, External Clinical Advisory Council, 2009-present
  National Institute of Child Health and Human Development, Federal Advisory Committee to the National Children’s Study, 2003-2005
  National Institute of Child Health and Human Development, National Children’s Study, Executive Steering Committee, 2007-2009
  Food and Drug Administration, Ranch Hand Advisory Committee, 2000-2001
  National Institute for Occupational Safety and Health, Board of Scientific Counselors, 1995-1997
  National Institutes of Health, Study Section on Epidemiology and Disease Control, 1986-1990
  National Institute of Environmental Health Sciences, Third Task Force for Research Planning in the Environmental Health Sciences; Chairman, Subtask Force on Research Strategies for Prevention of and Intervention in Environmentally Produced Disease, 1983-1984

Department of Defense
  Armed Forces Epidemiological Board, 2000-2002
COMMITTEES: (cont)

State and Local Government

New York State, Governor’s Advisory Committee on Safety and Healthy New York Foods, 2015-2016
State of New York, Advisory Council on Children’s Environmental Health, Co-Chair 2009-present
State of New York, Advisory Council on Lead Poisoning Prevention, 2009-present
Westchester County, New York, Westchester County Global Warming Task Force, 2006-2008
State of New York, Health Research Science Board, 1997-present
State of New York, Public Health Priorities Committee, 1996
State of New York, New York State Advisory Council on Lead Poisoning Prevention, Chairman, 1993-2004
City of New York, Mayor’s Lead Paint Poisoning Advisory Committee, 1991-1993
State of New York, Asbestos Advisory Board, Chair, 1987-present
State of New Jersey, Meadowlands Cancer Advisory Board, Chair, 1987-1989
State of New York, Governor's Blue Ribbon Committee on the Love Canal, 1978-1979

Academic

Cornell University, Dean's Advisory Council in Veterinary Medicine, 1996-1997
Mickey Leland National Urban Air Toxics Research Center, National Advisory Committee, 1994-1995
New York Academy of Medicine, Working Group on Housing and Health, 1987-1989; Chairman, 1989
Association of University Programs in Occupational Health and Safety, 1985-Present; President, 1986-1988

International Organizations


Environmental Organizations

Healthy Child, Healthy World, Board of Directors, 1996-present
Children's Environmental Health Network, Board of Directors, 1995-present
Environmental Health Foundation, Board of Directors, 1993-1996
INFORM, Board of Directors, 1991-2003

Labor Unions

International Brotherhood of Teamsters, National Health and Safety Advisory Committee, 1994-2002
George Meany Center for Labor Studies, Board of Trustees, 1994-1997
COMMITTEES: (cont)

Labor Unions
United Automobile Workers (UAW) - Chrysler Corporation, Joint Scientific Advisory Committee,
Member, 1990-2006
International Association of Fire Fighters, John Redmond Foundation, Medical Advisory
Committee, 1989-present

Other Organizations
Health Insurance Plan (HIP) of Greater New York, Board of Directors, 1992-1994
American Legion, Science Panel, Chairman, 1988-2000

Editorial Boards
Editor-in-Chief: Annals of Global Health, 2013-present
Deputy Editor: American Journal of Industrial Medicine, 2007-present
Associate Editor: Environmental Health Perspectives, 2002-present
Editor-in-Chief: American Journal of Industrial Medicine, 1992-2006; Consulting Editor,
1979-1992
Editorial Board: New Solutions: A Journal of Environmental and Occupational Health Policy,
1990-present
Editor-in-Chief: Environmental Research, 1987-1994
Senior Editor: Environmental Research, 1985-1987
Consulting Editor: Archives of Environmental Health, 1982-present

National Service
United States Naval Reserve, Medical Corps, 1996-2005
United States Public Health Service, Commissioned Corps, 1970-1995. LCDR (0-4) to CAPT
(0-6).
New York Naval Militia 2000-present; CAPT (0-6); Surgeon General.

GRANT SUPPORT

ACTIVE:

Blacksmith Institute (Landrigan, PI) 01/01/12 – 12/23/17
$45,000

Assessing the Disease Burden of Hazardous Waste Sites
The purpose of this contract is to support the development of a series of scientific papers that will assess the
health burden associated with human exposure to hazardous waste sites in the developing world.
2011-N-13318 (Lucchini, PI) 07/01/11 – 12/31/16
CDC $28,422,550

World Trade Center Data and Coordination Center
This project is the coordinating center for a multicenter program providing monitoring and treatment to volunteers
who assisted in the recovery and cleanup after the 9/11 attack.
Role: Co-Investigator
Completed Research Support:

1T32HD049311 (Landrigan, PI)  05/01/07 - 07/01/13
NICHDD  $323,002

Research Training Program in Environmental Pediatrics
The goal of this interdisciplinary research training program is to train the next generation of physician-researchers and academic leaders in environmental pediatrics.

C-010124 NYS DoH Landrigan (PI)  4/1/09 – 3/31/12; Lucchini (PI) 4/1/12 – present

World Trade Center Responders Data and Coordinating Center. This program has collected, analyzed and published medical monitoring and treatment data collected clinically on 30,000 9/11 responders evaluated at five Clinical Centers in the New York metropolitan area.

NIH-HHSN27520080031C (Landrigan, PI)  09/28/08 - 09/27/13 (Monroe)

National Children’s Study Vanguard Centers
This project will recruit 1250 live births into a NICHD study of social, behavioral and environmental factors and their impact on childhood health, growth and development. The Queens Vanguard Center is one of the first six sites selected to pilot the NCS, which will follow more than 100,000 children across the United States from birth until age 21.

U10-OH08232 CDC Landrigan (PI)  6/1/04 – 3/31/12; Lucchini (PI) 4/1/12 - present

New York/New Jersey Education Research Center in Occupational Safety & Health. The goal of this multi-institutional program is to train professionals from multiple disciplines - medicine, nursing, industrial hygiene and industrial safety - to be future leaders in occupational health and safety.

Children’s Environmental Health Center - Inner City Toxicants, Child Growth and Development
Co-Principal Investigator
EPA RD831711-01  11/1/03 – 10/31/10
NIEHS P01 ES009584  11/1/98 – 10/31/10


**BOOKS**


OTHER PUBLICATIONS:
REVIEW ARTICLES, CONFERENCE PROCEEDINGS, BOOK CHAPTERS,
COMMENTARIES, EDITORIALS, LETTERS TO EDITOR, ABSTRACTS & POSTERS


OTHER PUBLICATIONS:
REVIEW ARTICLES, CONFERENCE PROCEEDINGS, BOOK CHAPTERS, COMMENTARIES,
EDITORIALS, LETTERS TO EDITOR, ABSTRACTS & POSTERS (cont)


271. Landrigan PJ: ACPM, Mount Sinai to Tackle Children's Environmental Health Issues. ACPM Newsletter, Spring 1999.


OTHER PUBLICATIONS:
REVIEW ARTICLES, CONFERENCE PROCEEDINGS, BOOK CHAPTERS, COMMENTARIES,
EDITORIALS, LETTERS TO EDITOR, ABSTRACTS & POSTERS (cont)


INVITED LECTURES/PRESENTATIONS

Visiting Professorships and Lectureships:

University of Utah, Wallace Stegner Lecturer, 2012
Harvard School of Public Health, The James L. Whittenberger Lecturer, 2009
University of Kentucky, Inaugural John P. Wyatt Lecturer in Environmental Health and Disease, 2008
University of Minnesota, School of Public Health, Richard G. Bond Memorial Lecture, 2007
James P. Keogh, MD Memorial, Lecturer in Occupational Medicine, University of Maryland School of Medicine, 2006
Royal College of Physicians (London), Faculty of Occupational Medicine, Richard Schilling Memorial Lecturer, 2000
University of Rochester, 44th Annual Paul W. Beaven Lecturer, 2000
Centers for Disease Control and Prevention, Langmuir Memorial Lecturer, 1999
Mayo Clinic, Department of Pediatrics, Amberg-Helmholtz Lecturer in Pediatrics, 1998
Duke University Medical School, Visiting Professor, NIEHS Clinical Training Program in Environmental Medicine, 1995
National University of Singapore, Visiting External Examiner in Occupational Medicine, 1994
Medical College of Pennsylvania, Catherine Boucot Sturgis Visiting Professor in Community and Preventive Medicine, March 1992
University of Cape Town Medical School, Visiting Professor, Department of Community Health, March 1992
University of Tokyo, Visiting Professor of the University, July 1990
University of Tokyo, Visiting Professor of the Faculty of Medicine, September 1989
Exhibit 2
January 14, 2002

Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Docket Number: OPP-34203G

Submitted by Email: opp-docket@epa.gov

RE: Comments on the Chlorpyrifos Interim Reregistration Eligibility Decision Document (IRE)

Federal Register: November 14, 2001; Volume 66, Number 220, Pages 57073-57074

Dear Sir or Madam:

We submit the following comments on behalf of the Natural Resources Defense Council (NRDC), the World Wildlife Fund (WWF), and the Farmworker Justice Fund, Inc. NRDC uses law, science, and the support of more than 500,000 members nationwide to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for all living things. NRDC has no direct or indirect financial or fiduciary interest in the manufacture or sale of chlorpyrifos. WWF is a non-profit organization with over 1.2 million members in the United States. WWF is dedicated to using the best available scientific knowledge to preserve the diversity and abundance of life on Earth by conserving endangered spaces, safeguarding endangered species, and addressing global threats to the planet's web of life. The Farmworker Justice Fund, Inc. is a national, nonprofit advocacy center that seeks to improve living and working conditions for migrant and seasonal farmworkers and their families. For the past two decades, it has urged the EPA to reduce or eliminate the use of hazardous pesticides.
Unless otherwise noted or referenced, all page number references in the text of these comments refer to the Interim Reregistration Eligibility Decision (IRED) for Chlorpyrifos, Case No. 0100.

SUMMARY OF COMMENTS:
ALL CHLORPYRIFOS TOLERANCES MUST BE REVOKED & CHLORPYRIFOS MUST BE CANCELLED

EPA has found that there is not a “no observable effect level” (NOEL), or even a “no observable adverse effect level” (NOAEL), for the developmental effects of chlorpyrifos on young animals, and therefore on human infants and children. In other words, EPA has no scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental harm due to chlorpyrifos exposure. Moreover, EPA has no basis to derive a Q* or to use any other quantitative risk assessment methodology that will derive a negligible risk level (i.e. 1 in 1 million lifetime risk) for chlorpyrifos’ developmental effects. Therefore, EPA simply cannot make a legal finding that any specific chlorpyrifos level on food is “safe” for infants and children, or that there is a “reasonable certainty of no harm” to infants and children, at any specific level. Thus, as a legal matter, under FFDCA §408(b)(2), EPA must revoke all tolerances and cancel all food uses, for chlorpyrifos.

Moreover, even assuming for the sake of argument that EPA may set tolerances for chlorpyrifos, notwithstanding the legal prohibition on EPA’s setting a tolerance for a substance that has no NOEL or NOAEL (and for which a Q* cannot be derived and therefore a cancer-like risk assessment is impossible), EPA has failed to adequately apply safety factors and to consider many routes of exposure in the IRED. EPA must apply not only the traditional two 10-fold safety factors for interspecies variability and for intra-species variability, but also must apply an additional safety factor of at least 10 for gaps in exposure data, assumptions, and underestimates of risk, as detailed in these comments, and an FQPA safety factor of at least 30 to account for potential pre-and post-natal toxicity to infants and children (10X) and to account for significant gaps in exposure data for infants and children and the lack of a NOEL (3X). EPA has failed to adequately consider important exposure routes for millions of infants and children, including children living on farms and who accompany their parents into farm fields (see discussion of farm children below), exposure from mosquito spraying, drift, and drinking water. Moreover, EPA has failed to consider cumulative exposure to organophosphates and carbamates that have a common mechanism of toxicity.
Finally, EPA must cancel all uses of chlorpyrifos under FIFRA. All food uses must be cancelled due to excessive risk and the cancellation of all tolerances under the FFDCA. Even if theoretically an extremely low tolerance could be set for chlorpyrifos after application of all appropriate safety factors, the chemical would have to be applied at such low rates and in such a manner that it would not be efficacious. Moreover, the food and non-food uses of chlorpyrifos result in worker exposure; non-occupational drift, air, and water exposure; other non-food human exposure; and ecological risks that pose “unreasonable adverse effects on the environment” and thus must result in cancellation of all uses of chlorpyrifos.

INTRODUCTION

Uses and Risks of Chlorpyrifos

Chlorpyrifos is an organophosphate pesticide used at approximately 21-24 million pounds active ingredient (a.i.) annually in the United States. In addition to food crops, chlorpyrifos is used as a cattle ear tag, as a treatment for lawns, turf, and ornamentals, and for pasture, woodland, and lots/farmsteads. Turf use accounts for 2.5 million pounds annually. By agreement with the registrants (June, 2000), almost all the residential uses (including household, schools, parks) of chlorpyrifos are being cancelled; public health uses such as mosquito and “childproof” ant-and-roach bait are residential uses that remain eligible for reregistration (IRED p.8). Termite control accounted for 5 million pounds annually, and is slated to be withdrawn or phased-out (prohibited Dec. 31, 2005; IRED p.7). These voluntary phase-outs are predicted to eliminate almost half the annual chlorpyrifos use in the United States (IRED p.12). Prior to these phase-outs, chlorpyrifos was the fourth most commonly used pesticide in US households, and comprised a full 25% of pesticide pounds in residential settings. However, these voluntary phase-outs and withdrawals in the US will not reduce the amount of chlorpyrifos exported annually, which has remained steady at approximately 8-9 million pounds annually since 1997.

Non-agricultural outdoor uses remaining include golf courses (rate of application reduction), road medians, food processing plants, manufacturing plants, ship holds, railbox cars, and non-structural wood treatments such as fenceposts, utility poles, landscape timber, poles, posts, and processed wood products (IRED p.10). NRDC believes that many of these remaining uses, especially wood treatments, pose significant exposure risks to children.
Chlorpyrifos is used in highest amounts on corn (5.53 million lbs a.i.), cotton (670 thousand), apples (550 thousand), alfalfa (480 thousand), oranges (460 thousand), and peanuts (316 thousand). Crops with the highest percentage of crop treated are Brussels sprouts (73%), cranberries (46%), apples (44%), broccoli (41%), and cauliflower (31%). This list includes some of the foods most consumed by children, making children’s exposure risk particularly high.iii Chlorpyrifos is applied aerially, by chemigation, groundboom, hand wand, airblast sprayer, and other methods.

The EPA risk summary speculates that dietary risk, acute and chronic, would now be below the Agency’s level of concern, presuming full compliance with risk mitigation recommendations. Prior to mitigation, EPA admits that acute exposures exceed the level of concern for infants, toddlers, children, and females. After mitigation, EPA believes that these risk groups no longer exceed the level of concern (IRED p.19).

However, there are considerable risks remaining for workers, even presuming full compliance with so-called “mitigation measures.” For mixers, loaders, and applicators some risks remain elevated, even assuming that maximum personal protection equipment (PPE) and engineering controls are used. In real life, however, maximum recommended PPE is often not used. Under many scenarios current restricted entry intervals (REIs) also are insufficient.iv The IRED notes that risks may be mitigated by a combination of additional PPE and engineering controls, and by reductions in application rates (IRED p.3). Again, past experience shows that recommended application rates, along with recommended PPE controls, are often disregarded. Post application risks, also exceeding the level of concern, may be mitigated by reducing application rates and by lengthening REIs. Again, this is unlikely to be sufficient to protect worker risk.

Furthermore, in measuring the extent of exposure and in determining aggregate exposure, EPA should acknowledge farmworker children to be a major, identifiable subgroup of consumers whose unique, increased level of exposures must be taken into account. These nearly 1,000,000 children are deserving of protection under the “reasonable certainty of no harm” health standard under the law.

Although EPA says the drinking water risk is below the level of concern, the Agency notes that there have been cases of high levels of drinking water well contamination associated with localized applications of chlorpyrifos as a subterranean termiticide. This is being addressed, EPA
says, by eliminating all termiticidal uses. However, despite EPA’s assertions that only termiticidal use leads to water contamination problems, USGS and others have found contamination of ground and surface water with chlorpyrifos and its metabolites, and EPA’s own modeling shows that it is likely that in certain areas of heavy use, chlorpyrifos (and its metabolites) present significant water risks. There is no evidence that the water risks of chlorpyrifos and its metabolites are limited to termiticidal use. This evidence of surface and groundwater contamination with chlorpyrifos is discussed below.

**Drift/Air Exposure**

In certain "sentinel" populations, such as farmworker children who live in a pesticide-rich environment, registered, non-residential, non-dietary sources may account for most of a child’s exposure to pesticides, regardless of whether there is registered indoor use. Pesticides applied aerially must be assessed for its effects on people affected by pesticide drift or sloppy application. Reports in the medical literature describe numerous preventable illnesses and deaths among children with such “take-home” exposures. NRDC’s report, *Trouble on the Farm*, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use (this report is hereby incorporated by reference). These exposures are particularly important for children given their greater potential susceptibility, hand-to-mouth behavior and other behaviors in the home.

Significant concentrations of organophosphate pesticides (of at least 1.0 ng/m$^3$, and at least 2.4 ng/m$^3$ in one site in California) have been detected in winter fog, outside of the growing season (Glotfelty and others, 1987; Seiber and others, 1993). This phenomenon may be due to volatilization or wind erosion, as is the case for other pesticides (Glotfelty and others, 1990c; Wu, 1981). Evidence suggests that photochemical reactions lead to the production of oxygen analogs (oxons) of chlorpyrifos in air during daylight, which are incorporated into the nighttime fog (Glotfelty and others, 1990a). Chlorpyrifos has been detected in rain at concentrations up to 180 ng/L, in air up to 199/ng/m$^3$, and in fog up to 14,200 ng/L. The maximum concentration found in rain frequently exceeded EPA’s water quality criteria for freshwater aquatic organisms (83 ng/L – acute; 41 ng/L - chronic). In addition, several studies have shown that drift is a significant concern. Thus, EPA must consider airborne exposure as a source in conducting its assessment of risk.

**Ecological Risks**
Ecological risks from chlorpyrifos use remain extremely worrisome; the Agency notes high risks, acute and reproductive toxicity, to birds, fish, mammals, and aquatic invertebrates. Some risk quotients exceed 1000 times the acceptable limit (IRED pp. 52-58). It is highly toxic to honeybees, which are killed if present even within 24 hours after application (IRED p. 54). Given that animals and insects, and especially honeybees, pollinate over ¾ of the staple crop plants worldwide, and have an estimated economic value to world agriculture of $200 billion annually, it is no surprise that any decline in honeybee populations is considered a serious threat to world food supplies.\textsuperscript{x} The IRED states that mitigation will require reduced application rates, increased retreatment intervals, reduced seasonal maximum allowable rates, and no-spray setback zones (IRED, p. 4). NRDC believes that these recommendations are unlikely to be adhered to, as discussed further in these comments. EPA estimates that risks to invertebrates will remain of concern, despite these mitigation efforts. Further, bioconcentration of chlorpyrifos will likely pose an acute and reproductive risk to aquatic birds and mammals, in spite of mitigation efforts.

**EPA’s Decision**

The Agency’s IRED concludes that chlorpyrifos may be reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for agricultural uses because the registrants agreed to cancel most residential uses, and because EPA intends to require some mitigation measures for the remaining agricultural uses. Under the Federal Food, Drug and Cosmetic Act (FFDCA), EPA relies on the same rationale to keep in effect those tolerances that the registrant continues to support.

The IRED states that with the addition of label restrictions and amendments detailed in the IRED, all currently registered uses of chlorpyrifos except open-pour dust formulations may continue. In the current IRED, EPA says the tolerance for tomatoes will be revoked, and tolerances for apples and grapes will be lowered to 0.01 ppm each (IRED p.18). In an effort to further mitigate elevated ecological risk, the IRED recommends some crop-specific measures, including reducing the maximal number of liquid applications per season as follows: alfalfa, from eight to four; citrus, to two; corn, to three, with a reduced application rate from 7.5 to 3 lbs a.i./A; cotton, from six to three, with a reduced application rate from 6 to 3 lbs a.i./A. Further, spray drift warnings and no-spray zones will be included on labels.

The Agency has determined that, with presumed full compliance with mitigation recommendations, a 10X FQPA factor for infants, children, and females aged 13-50 (IRED p.16),
and a 100X uncertainty factor for acute and chronic reference doses (IRED p.15) will provide a sufficient margin of safety.

**EPA CANNOT LAWFULLY ESTABLISH OR LEAVE IN EFFECT TOLERANCES FOR CHLORPYRIFOS**

EPA has found that there is no NOEL or NOAEL for the developmental effects of chlorpyrifos on human infants and children. EPA therefore has no scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental harm because of chlorpyrifos exposure. Moreover, EPA has no basis to derive a Q* or to use any other quantitative risk assessment methodology that will derive a negligible risk level (i.e. 1 in 1 million lifetime risk) for chlorpyrifos’ developmental effects. Therefore, EPA simply cannot make a legal finding that any specific chlorpyrifos level on food is “safe” for infants and children, or that there is a “reasonable certainty of no harm” to infants and children, at any specific level. Thus, as a matter of law, under FFDCA §408(b)(2), EPA must revoke all tolerances, and cancel all food uses, for chlorpyrifos.

Even assuming for the sake of argument that EPA can set tolerances for chlorpyrifos, notwithstanding the legal prohibition on EPA’s setting a tolerance for a substance that has no NOEL or NOAEL (and for which a Q* cannot be derived and therefore a cancer-like risk assessment is impossible), EPA has failed adequately to apply safety factors and to consider many routes of exposure in the IRED. EPA must apply not only the traditional two 10-fold safety factors for interspecies variability and for intra-species variability, but also must apply an additional safety factor of at least 10 for the data gaps and buried assumptions that underestimate risk, as detailed further below, and an FQPA safety factor of at least 30 to account for potential pre-and post-natal toxicity to infants and children (10X) and to account for significant gaps in exposure data for infants and children and the lack of a NOEL (3X). EPA has failed adequately to consider important exposure routes for millions of infants and children, including children living on farms and who accompany their parents into farm fields (see farm children section below), exposure from mosquito spraying, drift, and drinking water exposure. Moreover, EPA has failed to consider cumulative exposure to organophosphates and carbamates that have a common mechanism of toxicity; under FFDCA §408(b)(2), no tolerance may be established or left in place without considering such cumulative risks.
EPA must cancel all uses of chlorpyrifos under FIFRA. All food uses must be cancelled due to excessive risk and the cancellation of all tolerances under the FFDCA. Even if theoretically an extremely low tolerance could be set for chlorpyrifos after application of all appropriate safety factors, the chemical would have to be applied at such low rates as in such a manner that it would not be efficacious. Moreover, the food and non-food uses of chlorpyrifos result in worker exposure; non-occupational drift, air, and water exposure; other non-food human exposure; and ecological risks that pose “unreasonable adverse effects on the environment” and thus must result in cancellation of all uses of chlorpyrifos.

CHLORPYRIFOS TOXICITY CONSIDERATIONS

The Agency has seriously underestimated the risks posed by chlorpyrifos use, thereby undermining its conclusion that chlorpyrifos can continue to be used in a way that prevents “unreasonable adverse effects on the environment,” FIFRA § 3(c)(5), and provides “a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue,” FFDCA § 408(b)(2)(A). EPA rationalized the continued use of chlorpyrifos for agriculture applications, because EPA considers that dietary risks are not of concern, residential risks are no longer of concern due to voluntary withdrawals of household uses, and EPA considers that risks posed to workers and the environment are acceptable, although they exceed the level of concern in a number of scenarios.

While supporting the voluntary withdrawals of residential uses, schools, and parks, which is predicted to reduce by half the total pounds of chlorpyrifos used annually, NRDC takes issue with the above assumptions. Our concern about exposure to chlorpyrifos remains high, notwithstanding EPA’s intended cancellation and mitigation actions. Unfortunately, the Agency has understated the adverse health effects caused by chlorpyrifos, the amount of exposure that people endure without effect, and the amount of chlorpyrifos to which people are exposed. With chlorpyrifos and other developmental neurotoxic chemicals, risk to the fetus, infant, and child comes primarily from the timing of exposure. Even a very small dose, for even a short duration, during a developmental period of vulnerability will result in permanent neural dysfunction. There is no demonstrated reliable threshold of safety for this highly toxic chemical, as indicated in the IRED, where a no-effect level could not be determined for developmental neurotoxicity\textsuperscript{xii} (IRED p. 15-16). In addition, the Agency has overestimated the effectiveness of some mitigation recommendations. First, EPA assumes that pesticide applicators will reliably use personal protective equipment (PPE) and will always abide by specified re-entry intervals (REIs) – a
waiting time between applying the product and returning to the field – even though these mitigation measures are not enforced and are commonly ignored. Second, the Agency does not adequately account for “take-home” exposures from agriculture uses (domestic contact with pesticides tracked home on the clothes, shoes, and skin of workers) or exposures from spray drift (wind-blown pesticides from field or aerial applications that subsequently impact people). These points are described in greater detail in NRDC’s comments submitted to the Agency October 16, 2000.\textsuperscript{xiii}

There is demonstrated evidence of neuropathology and increased vulnerability of fetuses when exposed to chlorpyrifos (IRED p. 16; Makris et al.\textsuperscript{xi}). However, given that in these experiments neuropathology was seen in the neonates at the lowest dose tested, these studies were unable to identify an offspring NOAEL in the DNT (IRED p. 16). In that study, structural alterations in brain development, which would result in permanent brain dysfunction, were seen at the lowest doses tested (IRED p. 17), strongly indicating that a 10X FQPA margin of safety is insufficient to protect fetuses, neonates, and children from irreversible chlorpyrifos-induced brain damage. Furthermore, Congress was clear in stating that under the FQPA, EPA must establish tolerances based on a No Effect Level (NOEL); \textit{not} the NOAEL. If there is no NOEL, EPA cannot simply assume that there is a safe level based upon no evidence, and then apply safety factors. Whereas Congress did allow EPA to consider setting tolerances for non-threshold carcinogens at a level that poses no greater than a 1 in 1 million lifetime cancer risk, EPA has no scientific basis upon which to set a tolerance for chlorpyrifos that would pose a 1 in 1 million risk of suffering developmental problems, cannot establish a NOEL, and thus cannot set or leave in place a tolerance for chlorpyrifos.

Of additional concern, the chlorpyrifos metabolite, TCP, is more persistent than the parent compound (IRED p.20), is of greater toxic potency to fetuses than adults (IRED p.16), and exceeds chronic DWLOCs for children (IRED p.16). The toxicity of the chlorpyrifos metabolite was not considered in the chlorpyrifos dietary assessment (IRED p.17). This omission represents a very serious risk to tens of thousands of exposed vulnerable fetuses, neonates, and children.

Given these very serious concerns, NRDC believes that EPA simply cannot establish or leave in effect any tolerance for chlorpyrifos. Assuming arguendo that EPA can do so, at a minimum EPA must use an additional 30X FQPA margin of safety – in addition to the other uncertainty factors – to protect children and to account for demonstrated fetotoxicity, uncertainty in extrapolating from
effect-levels to NOAELs, and very substantial gaps in exposure and toxicity data (detailed in these comments). The current IRED recommends an uncertainty factor of 100X for the acute and chronic reference dose (IRED p. 15). NRDC believes that if the agency decides to establish tolerances notwithstanding the lack of NOELs (a decision that we believe would not be lawful), the Agency is clearly obligated to apply a 1000X UF, in addition to a 30X FQPA margin of safety, comprised of: 10X for interspecies extrapolation, 10X for intraspecies variability, and 10X to adjust for the lack of consideration of metabolite-induced toxicity, uncertainty in extrapolating from subchronic to lifetime effects, and uncertainty associated with other non-conservative assumptions detailed in these comments.\textsuperscript{xv} NRDC believes that there are no “safe” levels of chlorpyrifos for fetuses, infants, and children, as demonstrated by the Agency’s own DNT studies. Exposure to the developing nervous system to neurotoxic chemicals during periods of heightened vulnerability, even at low levels or short durations, will disrupt normal structure and function and will cause permanent disruption of neural function (see numerous papers by Abou-Donia et al, and Slotkin et al \textsuperscript{xvi}).

**DEVELOPMENTAL TOXICITY OF CHLORPYRIFOS IS UNDERESTIMATED**

The action of chlorpyrifos as a developmental neurotoxic chemical is undisputed. The EPA human health risk assessment of chlorpyrifos states:

In conclusion, the weight of the evidence raises concern for an increase in both the sensitivity and susceptibility of the fetus or young animal to adverse biochemical, morphological, or behavioral alterations from chlorpyrifos treatment during brain development. With respect to cholinesterase inhibition, an increase in sensitivity of the young compared to adults was seen all along the dose response curve, even at relatively low doses. There is a clear differential response (2- to ~5-fold) in the young compared to the adult animal after an acute treatment to a relatively low dose of chlorpyrifos. There is also increased sensitivity found after repeated dosing (up to 9-fold), but at the LD\textsuperscript{10} and MTD. It is important to point out that an uncertainty remains concerning the magnitude of the differential response, given that newborn animals (less than PND 7) have not been characterized for sensitivity. Results of multiple studies have consistently shown that the developing brain is susceptible to chlorpyrifos treatment. Effects on the developing CNS that are indicative of the unique susceptibility to the young animal include changes in macromolecular synthesis, altered cell signaling and muscarinic receptor down regulation, as well as morphological alterations in brain development. An uncertainty remains regarding the NOAELs for the susceptibility effects. The effects observed raise a
high degree of concern that the fetus or young animal is particularly susceptible to adverse outcome if exposed to chlorpyrifos.\textsuperscript{xvii}

A substantial body of scientific evidence exists demonstrating the fetotoxic, neurotoxic, and immunotoxic properties of chlorpyrifos and its oxon metabolite, with treatment in utero or perinatal resulting in permanent damage to the nervous system (see numerous papers by Abou-Donia et al, and Slotkin et al \textsuperscript{xviii}). NRDC is extremely concerned, in light of the experimentally demonstrated, permanent, effects of chlorpyrifos in the developing nervous system, that the chlorpyrifos IRED has underestimated risk, used central tendency estimates, used non-conservative assumptions, and ignored data gaps in estimating exposure risk. These concerns are detailed further below.

The IRED Does Not Account for the Toxicity of Metabolites and Stereoisomers

Though EPA has abundant data for dietary exposure to chlorpyrifos, its PDP and FDA databases only include monitoring data for residues of the chlorpyrifos parent compound. As stated in the IRED, the Agency has concluded that the primary metabolite of chlorpyrifos, 3,5,6-trichloro-2-pyridinol (TCP), does not induce cholinesterase inhibition, and exhibits effects only at doses higher than those producing ChEI with chlorpyrifos, and therefore, is less toxic than chlorpyrifos (58 Fed. Reg. 19,354(April 14, 1993)) (IRED p. 16). However, compared with chlorpyrifos, TCP is stated to be “more mobile and significantly more persistent in many soils, especially under anaerobic conditions” (IRED p.20). Further, the Agency states in the IRED that, “upper-bound estimated environmental concentrations of TCP exceeded chronic DWLOCs for children” (IRED p. 16). This is especially disconcerting, given the “evidence of increased susceptibility of rabbit fetuses relative to dams” (IRE p.16). Recently published experimental evidence of the toxicity of chlorpyrifos oxon and TCP in animals\textsuperscript{xx}, and in a human cell line\textsuperscript{xx} emphasize the need for inclusion of metabolites in the risk assessment. The impact of these metabolites on developing animals – where even short-lived compounds could conceivably have irreversible effects on the nervous system – heightens the need for prudence in carrying out cumulative assessments. EPA appears to have no requirement for chemical-specific pharmacokinetic studies in fetal animals that would aid in discerning the contribution of toxic metabolites, such as the chlorpyrifos oxon and TCP, to children’s risk. Until data are available that are specific to parent compound/metabolite mixtures for chlorpyrifos, from all exposure sources, any risk assessment involving this chemical would be incomplete, and likely less protective of public health than is required by law. Under FQPA, EPA is to set tolerances so as to "ensure that there is a reasonable
certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.” NRDC therefore asserts that the Agency is unjustified in its determination that “residues of TCP are not of concern for the chlorpyrifos dietary assessment,” and “can therefore be excluded from the tolerance expression.” (IRED p. 17).

Buried Assumptions Underestimate Risk

Many OP assessments contain buried or outdated assumptions that receive little or no recognition in the risk characterization, despite their less-than-health-protective impact on final risk estimates. These assumptions tend towards a lesser, rather than a greater, certainty of no harm to infants and children. EPA should acknowledge as much. Outside scientists have criticized many of these assumptions as not being sufficiently protective.

Some specific examples from the chlorpyrifos and other OP assessments, drawn from the draft SOPs, illustrate the problem better:

- **EPA assumes all “toddlers,” aged 1 to 6 years, weigh 33 pounds (15 kg).** EPA bases its assumption on the mean or average weight for three year-olds. Because home pesticide exposures and risks are calculated on a per pound basis, EPA’s baseline assumption about a toddler’s weight will tend toward risk estimates that understate true risks for smaller toddlers and younger infants whose brains and nervous systems are developing more rapidly and are therefore more vulnerable than those of older children.

- **EPA bases its estimate of a toddler’s exposure to a chlorpyrifos-contaminated surface due to hand-to-mouth activity on the ludicrous assumption that this activity occurs just 1.56 times per hour.** Then-Assistant Administrator L. Goldman, a pediatrician, as well as EPA’s latest scientific advisory panel all singled out this assumption as being particularly inadequate. The latter panel also indicated that assessment of a child’s mouthing behavior would be incomplete if it focused only on hand-to-mouth exposures. Children put objects other than fingers in their mouth, and these objects may carry pesticide residues and be ingested. Children also eat “feral” food — food that’s dropped on the floor and which picks up residues from contaminated linoleum, carpet or other household surfaces. In any case, the hand-to-mouth value EPA currently uses as its “conservative” assumption is roughly 16 times lower than the value obtained from a recent study of 30 children. Those children put fingers in their mouths 26 times per hour on average, with some children showing the behavior up to 70 times per hour. While EPA has proposed to change its guidelines to a value of 20 times per hour, this is still an average value. Moreover, until
the change is final, the agency continues to use the dramatically low value of 1.56 times per hour — a value which any parent will recognize as ridiculously low.

Since FQPA’s mandate for a reasonable certainty of no harm means that EPA must set tolerances so as to fully protect even exceptionally exposed children (i.e. EPA must set tolerances to protect all children, including all “major identifiable subgroups” of children at greater risk), and not merely the average child, use of these central tendency estimates are inappropriate. These concerns apply equally to the characterization of risk from residential exposure of agriculture uses such as spray drift, residential residue track-in, exposures to farm worker children, and exposures to children in and around schools.

It is clear the above central tendency assumptions are not health-protective of more highly-exposed and susceptible populations; EPA must stop making any claims of conservatism, and should instead acknowledge that current assessments using the draft standard operating procedures may be likely to understate true exposure for many children.

**Reliance on Unenforced and Unreliable Mitigation Downplays Exposure**

It is disturbing that the risks to workers for mixing, loading and applying chlorpyrifos to agriculture crops exceed safe levels, even when presuming full compliance with mitigation recommendations. Furthermore, it is widely recognized that training and monitoring workers for use of PPE is inadequate, and moreover, workers in hot fields often cannot tolerate PPE. EPA therefore should not assume that PPE will mitigate the risk from certain scenarios when real life experience suggests PPE cannot be relied upon. These particular chemical uses may not be found "safe", and by definition cause "unreasonable adverse effects on the environment" under FIFRA. Therefore EPA should issue a Notice of Intent to Cancel (NOIC) and proposal to revoke their tolerances.

The Agency has proposed to mitigate occupational risks partially through lengthening the re-entry interval (REI) for most crops. Although this seems at face value to be a health-protective step, in practice it has no mitigation value whatsoever. There is no enforcement for REIs, and therefore, lengthening such REIs, like requirements for increased PPE, are routinely ignored\textsuperscript{iv}. Poor compliance with a mitigation effort that may sound reasonable on paper will not protect exposed individuals. It is clearly stated under FIFRA §3(C)(5) that “The Administrator shall register a pesticide if the Administrator determines that…..when used in accordance with widespread and
commonly recognized practice it will not generally cause unreasonable adverse effects on the environment”. This passage illustrates that EPA cannot rely on mitigation methods, such as PPE and REIs, which are unenforced and poorly followed.

**Exporting Hazards**

Although chlorpyrifos is listed as a “restricted use” pesticide in the US, it is exported in high volume: 7 to 9 million pounds annually since 1997 (8,570,694 in 2000). In fact, a recent article by C. Smith states that, according to customs records, between the years 1997 through –2000, nearly 65 million pounds of severely restricted or forbidden pesticides in the United States were exported; more than 22 tons per day. More than 55% of these products were exported to developing countries for agriculture use. The International Labor Organization estimates that 60 to 90% of children estimated to be working in Africa (80 million), Asia (152 million), and Latin America (17 million) are working in agriculture. These children are exposed to toxic pesticides in the fields, from drinking and washing water, through contaminated clothing, and in their homes. The U.N. Commission on Human Rights stated that “[a]llowing the export of products recognized to be harmful is immoral.” The mitigation requirements in this IRED include respirators with an organic-vapor removing cartridge and a pesticide-approved prefilter, chemical-resistant outerclothes, enclosed-cab machinery, emergency equipment readily available, and storage containments for discarding single-use chemically-resistant overclothes. It is inconceivable that these are “readily available” to mixers, loaders, applicators, and fieldworkers in developing countries. Clearly, new labeling requirements will have no mitigation effects for these men, women, and children workers.

**No Estimate of Risk Associated with Greenhouse and Nursery Uses**

Of further concern, the IRED states that post application risks to nursery and greenhouse workers were unassessed, due to lack of data (IRED pp. 40, 89). This lack of data is insufficient justification to ignore the obvious risk of such registered uses. NRDC maintains that this must be considered an important gap in data required to conduct a complete risk assessment, and contributes to the underestimation (in this case, complete ignorance) of risk in this IRED.

**RISK TO FARMWORKER CHILDREN**

*Farmworker Children Are an Identifiable High-Risk Group*

In measuring the extent of exposure and in determining aggregate exposure, EPA should acknowledge farmworker children to be a major, identifiable subgroup of consumers whose
unique, increased level of exposures must be taken into account. NRDC’s report, *Trouble on the Farm*, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use (this report is hereby incorporated by reference). These exposures are particularly important for children given their greater potential susceptibility, hand-to-mouth behavior and other behaviors in the home. These nearly 1,000,000 children are deserving of protection under the “reasonable certainty of no harm” health standard under the law.

EPA’s refusal to apply a sufficient margin of safety for children (at least 30X) in its chlorpyrifos assessment is inconsistent with the need for additional protections for the fetuses of pregnant farmworker women who may be exposed while their mothers are at work, and the risks facing neonates who are brought to the fields to accompany their parents due to lack of day care. These babies, who face exposure to an extremely potent neurotoxin at vulnerable stages of development are *not* employees and may *not* be disregarded on the grounds they face an *occupational* risk (Farmworker Justice Fund, Comments to the EPA’s Pesticide Docket on the Preliminary Risk Assessment for Chlorpyrifos, December 23, 1999).

The legal analysis submitted by Farmworker Justice Fund to the Pesticides Docket for the chlorpyrifos risk assessment remains relevant:

“In setting, modifying or revoking tolerances, the FQPA directs the EPA to consider, *inter alia*, ‘available information concerning the ... effects of *in utero* exposure to pesticide chemicals.’ § 408 (b)(2)(C)(I)(II). In the case of threshold effects, FQPA also directs the EPA to add an additional 10-fold (or other) margin of safety for infants and children ‘to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.’ *Id.* at 408(b)(2)(C)(ii). In explaining its method of implementing the 10-fold safety factor to the SAP, the EPA expressly stated that it would *not* consider prenatal exposures to the unborn children of pregnant farmworker women because such exposures are ‘occupational’ and hence, not within the contemplation of the FQPA. *See Presentation for the FIFRA Scientific Advisory Panel by Office of Pesticide Programs, Health Effects Division on FQPA Safety Factor for Infants and Children* (March 1998). The statutory language which directs the EPA to consider the effects of ‘in utero’ or ‘pre-natal’ exposures to pesticides makes *no* exception for occupational exposures. Nor could such an exception make sense since it is patent that a fetus or unborn child cannot work. In an
analogous context, the California Supreme Court has held that a child, who was injured in utero when his pregnant mother was exposed to carbon monoxide at work, could not be prevented from filing suit in tort by the workers compensation bar, which prohibits an employee from suing his or her employer. *Snyder v. Michael’s Stores Inc*, 16 Cal.4th 991, 945 P.2d 781, 68 Cal.Rptr.2d 476 (1997). The Court dismissed the notion that the unborn child could be deemed an ‘employee’ as ‘wholly without merit.’ The Court also noted that every other court to consider this question - except one - had reached the same conclusion (and the only exception was a lower California court whose decision was effectively overruled by the *Snyder* case). Since an unborn child cannot be an ‘employee,’ its pesticide exposure cannot be ‘occupational.’”

Thus, any prenatal exposure to the fetuses of farmworkers must be considered in the determination to set the FQPA margin of safety for infants and children. Although the Agency applied a 10X FQPA factor, given the extremely neurotoxic action of chlorpyrifos, the demonstrated increased vulnerability of fetuses and neonates, and the lack of a NOEL, NRDC maintains that this is woefully insufficient to provide a margin of safety for these vulnerable sub-groups.

**Drift and Take-Home Exposures to Chlorpyrifos**

Even setting aside the issue of whether an unborn child in a farmworker mother’s womb is exposed as a result of “occupational” activity when the mother is in the fields, it is clear beyond peradventure that EPA must consider fetal and childhood exposure of farm children and fetuses as a result of drift, take-home exposure, drinking water exposure in farm areas, in-field “day care,” and other farm child exposure resulting from proximity to the fields. These comments are discussed in detail in the NRDC Report *Trouble on the Farm.*

The scientific literature and common sense demonstrate that children and others experience substantial potential exposures through drift from crop spraying, and through take-home exposures when, for example, pesticides are exhaled from parents’ lungs or brought home on boots, work clothes, etc. Pesticides used on lawns, gardens and nearby farms end up in soil and are tracked into the home on shoes and pets. One common lawn herbicide, 2,4-D, has been found to persist in carpet dust up to a year after lawn application. For methyl-parathion, for example, 34% of original residues remained in clothes even after 10 launderings—a level high
enough to kill insects and present a health risk to humans. Chlorpyrifos is expected to cause long-lasting take-home exposure problems (IREP p. 41).

EPA’s current policy, as stated in the spray and dust drift label policy, is clear. The Agency is obligated to protect public health from all pesticide exposures, including those resulting from spray and dust drift:

“EPA’s position on pesticide drift is that applicators must not allow pesticide spray or dust to drift from the application site and contact people, animals, and certain sensitive sites, including structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, or rangelands. The Agency believes this is prudent public policy. It sets high but appropriate standards for applicators to protect people and the environment.”

In certain “sentinel” populations, such as farmworker children who live in a pesticide-rich environment, these non-dietary sources may account for most of a child’s exposure regardless of whether there is registered indoor use. Reports in the medical literature describe numerous preventable illnesses and deaths among children with such “take-home” exposures. NRDC’s report, Trouble on the Farm, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use (this report is hereby incorporated by reference). These exposures are particularly important for children given their greater potential susceptibility, hand-to-mouth behavior and other behaviors in the home.

EPA is now considering building into its pesticide risk assessments the fact that worker risks may "spill over" to the families of workers and to fetuses that workers may carry on and off the job. For example, pregnant women working or living on or near farms may very well have pesticide exposures that clearly fall within the purview of the FFDCA section 408 aggregate safe exposure requirement—particularly (but not exclusively) when the exposures occur off the work site due to take-home/drift exposures. Current EPA practice, including the current chlorpyrifos risk assessment, is to consider an additional FQPA 10X margin of safety, when applicable, only to consumers of food crops and not to exposed workers and their families. Given the certainty of drift and take-home exposures with many pesticides, including chlorpyrifos, the Agency is obligated to expand its exposure assessment to include these risks from agriculture use. EPA’s failure to incorporate these real-life exposures into its risk assessments will result in final risk estimates that are not adequately protective of human health. If data are lacking to quantify such
exposures, it is essential to incorporate an additional margin of safety to assure that use of the chemical is consistent with a reasonable certainty of no harm to children until more precise data can be generated, as required by the FQPA.

As detailed in the above discussion, it is invalid to presume, as the IRED does, that by canceling residential uses of chlorpyrifos, there will no longer be a risk of exposure to fetuses and children. NRDC asserts that so long as agriculture uses remain, the risk of exposure to fetuses and children is certain.

**DIETARY EXPOSURE IS UNDERESTIMATED**

*EPA’s Acute Dietary Exposure Estimate Is Flawed and Unlawful*

For chlorpyrifos, as with other OPs, the Agency used estimates of the percentage of crops treated (%CT) from BEAD (Biological Economic Analysis Division) to derive the acute dietary risk estimate, rather than assuming the more conservative approach of 100% crop treated (IRED p. 18; Acute dietary risk assessment). Using %CT in estimating acute risk violates governing law. The FQPA specifically authorized EPA to consider the percent of crop treated (%CT) “when assessing chronic dietary risk . . . only if the Administrator” makes four specific findings about data reliability. FFDCA § 408 (b)(2)(F) (emphasis added). By contrast, the law nowhere allows EPA to use %CT in assessing acute dietary risk. Of course, the law’s distinction between chronic and acute risks makes perfect sense. Congress understood that the likelihood that a person will experience harm from chronic exposures over time could be affected by the overall percentage of that crop treated with that chemical. On the other hand, in examining the acute harm resulting from a single exposure, it is irrelevant whether a large or small percentage of that crop was treated with that pesticide. *Any* amount of a crop treated at a level causing acute harm could not be characterized as assuring a “reasonable certainty of no harm,” making it completely inappropriate and unlawful to use %CT in assessing acute dietary risks. Using %CT to assess acute risk is in direct violation of the FQPA.

In the case of chlorpyrifos, BEAD estimated a maximum of 53% crop treated for apples, and only 1% CT for grapes. By using %CT, rather than assuming 100% CT, the Agency has underestimated risk for affected individuals by as much as 100X for grapes (used 1%CT), and 1.8X for apples (used 53% CT). This is especially important given that the mitigation measures proposed in this IRED include reducing tolerances for both apples (currently 1.5 ppm) and grapes (currently 0.5 ppm) to 0.01 ppm. Simple math reveals that the Agency has underestimated the
risk estimate for grapes by 100X, and then reduced the tolerance by 50X, resulting in an overall increase by 50X in allowable risk. For apples, the Agency has underestimated risk by 50X, and then reduced the tolerance by 150X, resulting in a real-reduction of only 100X. Since apples and grapes are acknowledged to be the largest contributors to dietary exposure (especially for children), this is extremely worrisome\textsuperscript{xxxviii} (IRED p. 18). Further, the acute dietary risk assessment for chlorpyrifos indicates that without mitigation, exposure from residues on fresh apples exceeds the allowable risk for children 1-6 yrs by over 300X (aPAD=364\%)\textsuperscript{xxxix} (IRED p. 19), rendering the above 50X increase completely inappropriate and the above 100X reduction wholly inadequate.

The mitigation proposed, which is limited to the above described insufficient tolerance changes and new labeling requirements, which are unenforced and poorly adhered to, is unlikely to result in any substantial reductions in exposure.

\textit{Drinking Water Exposures Do Not Account for Toxic Metabolites}

For drinking water, the chlorpyrifos metabolite TCP is not included in the tolerance expression, despite being identified in a number of environmental fate studies. Compared with chlorpyrifos, TCP is stated to be “more mobile and significantly more persistent in many soils, especially under anaerobic conditions” (IRED p.20). Further, the Agency states in the IRED that, “upper-bound estimated environmental concentrations of TCP exceeded chronic DWLOCs for children” (IRED p. 16). This is especially disconcerting, given the “evidence of increased susceptibility of rabbit fetuses relative to dams” (IRED p.16). Given the demonstrated evidence of exposure to TCP in food and drinking water, and the increased vulnerability of children and pregnant women, NRDC believes the Agency is unjustified in not including TCP exposure in its tolerance assessment.

Under FQPA, drinking water exposures (through ingestion, inhalation, and dermal absorption from hand-washing and showers) at least must be estimated. "Refinement" of drinking water data in a risk assessment may be an appropriate long-term goal, but it is scientifically unjustified for EPA to intentionally circumscribe the scope of the risk assessment by ignoring these exposures in the interim. Where EPA lacks drinking water monitoring data for specific chemicals or toxic metabolites, it should make quantitative or qualitative estimates and be frank in its description of both the assumptions, the uncertainties, and the limitations of the data.
Inclusion of complete, real-world drinking water exposures to chlorpyrifos and its metabolites such as TCP at sites of maximum likely exposure in an aggregate exposure assessment is critical for two additional reasons. First, EPA decision-makers should be presented with a risk assessment that reflects the entire range of real-life exposures to the chemical in question. Second, because exposure to OP-contaminated drinking water will tend to add to the estimated risk, its inclusion in the preliminary risk assessment is necessary to demonstrate, in the most transparent way, the urgency of taking immediate steps to reduce that risk. When EPA fails to incorporate real-life drinking water OP exposures into its risk assessments, it will tend toward risk estimates that are less than health-protective. If data are lacking to quantify drinking water exposure to individual OPs, the use of an additional 10X margin of safety is essential to assure that use of the chemical is consistent with a reasonable certainty of no harm to children until more precise data can be generated.

**Water Monitoring Data Is Not Designed to Detect Peak Levels**
The IRED states that surface water estimates were based on the USGS NAWQA monitoring data, which reported the maximum dissolved chlorpyrifos concentration was 0.4 ppb (IRED p.21).

**Surface Water**
Combined USGS data for state, local, national, and multi-state studies that measured chlorpyrifos concentrations in surface water detected the pesticide at 7 of 108 (6%) sites sampled. Most of these data do not include TCP or other chlorpyrifos metabolites. Chlorpyrifos has medium runoff potential due to its relatively low water solubility, 2 mg/L, (Becker and others, 1989; Goss, 1992), though some of its metabolites are more soluble and persistent A chlorpyrifos flux as a percentage of use of 0.15 has been measured in the Minnesota River. Chlorpyrifos is also, of course, used in non-agricultural settings, and can thus drift or runoff directly into surface water bodies in areas of high population density. In two out of nine studies that measured chlorpyrifos concentrations in surface waters, its concentration exceeded EPA's water quality criteria for aquatic organisms in some samples (0.083 μg/L [83 ng/L] – acute; 0.041 μg/L [41 ng/L] – chronic).

**Ground Water**
Data from the Mid-Continent Pesticide Study shows that chlorpyrifos was present in the ground water in 4.2% of the wells sampled. Cohen and others (1990) found the chlorpyrifos transformation product 3,5,6-Thrichloro-2-pyridinol in ground water in Cape Cod, Mass.
Chlorpyrifos has been detected in 0.6% of wells sampled, according to the U.S. EPA’s Pesticides in Ground Water Database.\textsuperscript{li} Long (1989) detected chlorpyrifos in the ground water of 30% of 56 sites examined beneath pesticide mixing and loading facilities in Illinois.\textsuperscript{lii} The maximum concentration detected was 0.5 μg/L. Habecker (1989)\textsuperscript{liii} detected a maximum surface soil concentration of chlorpyrifos of 41,000 μg/kg at pesticide mixing and loading sites in Wisconsin. Krapac and others\textsuperscript{liv} detected a maximum surface soil concentration of 26,000 μg/kg at agrichemical facilities in Illinois.

\textbf{EPA Must Consider Exposures at Areas of High Water Contamination.}

With the exception of the extraordinarily high exposures that would be suggested by the data for mixing and loading areas, these monitoring data generally are not targeted to areas of anticipated maximum exposure, which are the areas that FQPA requires that EPA consider in setting “safe” tolerances considering aggregate exposure. EPA, therefore, must at least estimate such maximum exposure levels using modeling.

Using the PRZM/EXAMS screening model, estimated 90-day average and peak chlorpyrifos concentrations were 6.7 and 40 ppb respectively. However, EPA did not rely upon these model estimates. Rather, the IRED estimated acute exposures at 0.026 to 0.4 ppb, based on the 95\textsuperscript{th} percentile of the monitoring data. This is a full 100X lower than the 40 ppb estimate derived from the PRZM/EXAMS model.

NRDC contends that, contrary to the assertions of conservatism in the IRED (IRED pp. 21-22), these estimates likely underestimate actual levels substantially. Water monitoring sample sites are not necessarily correlated with chlorpyrifos use sites, and in particular, may miss sites where multiple fields are treated with chlorpyrifos resulting in pooled runoff into a common water source. In fact, the IRED states, “it is not clear that they [monitoring data] represent the most vulnerable groundwater where chlorpyrifos is used most intensively” (IRED p.22). Monitoring of surface water is likely to be subject to the same problem. Levels of chlorpyrifos in pooled runoff sites are likely to be many times higher than single field sites. Similarly, data collection is not timed to correspond with worst-case scenarios, such as closely following chlorpyrifos applications, or following large storm runoff events, and thus most often misses these highly toxic environmental exposures.

\textbf{AGGREGATE RISK ESTIMATE IS INADEQUATE}
Under the FFDCA, a pesticide tolerance can only be established if “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.” FFDCA § 408(b)(2)(A)(ii). Aggregate exposure is the total exposure to a single chemical or its residues that may occur from dietary (i.e., food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

The FQPA requires assessment of both dietary and non-dietary, non-occupational pesticide exposures in the aggregate, and FIFRA demands that EPA protect against pesticides’ unreasonable health and environmental effects. Both good science and public health protection demand routine assessment of aggregate exposure because real-world exposures aggregate – that is, pesticides are used in a wide variety of settings and formulations likely to result in multiple exposure sources. Yet EPA has failed to do an adequate aggregate assessment in its chlorpyrifos assessment.

In addition to food and water exposures, the aggregate assessment must take into account exposures due to air drift and migration of contaminated soil, especially in agricultural areas, residential exposures from registered uses (including golf courses, greenhouses, and nurseries), residential “take-home” exposures to families of those directly exposed to the OP through its agricultural uses, as well as exposures from uses that do not conform with the label, where there is an indication that these uses occur.

When lacking actual data on any these various sources of non-dietary exposure, EPA should not simply assume that the particular route of exposure is unimportant or nonexistent, as it has chosen to do with respect to chlorpyrifos. For example, in the chlorpyrifos IRED, the Agency has ignored the contribution to risk from chlorpyrifos metabolites, which are highly toxic and persistent (IRED p.17), from spray drift and take-home exposures associated with agriculture uses (IRED p. 41), and from greenhouse and nursery uses (IRED p. 40). The risk characterization should clearly note that failure to include all possible routes of exposure will tend to bias final estimates of aggregate risk so that they will understate rather than overstate true risks. In other words, EPA’s risk estimates are less rather than more protective of public health. Moreover, when there are not actual data to confirm the absence of exposure to a pesticide across any particular route, EPA must incorporate an additional safety factor to account for this lack of complete exposure data.
LEVEL OF REGULATION MUST ENSURE A REASONABLE CERTAINTY OF NO HARM FOR ALL FETUSES, INFANTS, AND CHILDREN

EPA may not sacrifice the hundreds or thousands of children who may exceed the reference dose for a particular OP. Under FQPA, the burden is upon the advocate of a tolerance to prove (and upon EPA to find) that there is a reasonable certainty that no children will be harmed in EPA’s pesticide decisions. Thus, if the best evidence suggests that hundreds or even thousands of children will exceed the reference dose for an OP, EPA is forbidden by statute to find a reasonable certainty of no harm to these particular infants and children, and the Agency should not issue a tolerance at that level.

Instead, in EPA’s proposed approach – which is styled as a “highly refined” Monte Carlo risk analysis – the agency regulates dietary residues of individual OPs at the 99.9th percentile. EPA seeks to mask in this approach the fact that even regulation at the 99.9th percentile, for a pesticide commonly used on a ubiquitous children’s food, means that 0.1% of all American children under age six (around 24,000 children in all) could exceed the chronic RfD every day, based on the best information available to the agency. Further, a child exposed to multiple organophosphate pesticides may fall within the 99.9th percentile for one, but lie above the safety threshold when cumulative OP risks are calculated. No reading of the statute will support any approach that allows hundreds or thousands of children to exceed the reference dose. Regulating dietary residues of chlorpyrifos at the 99.9th percentile directly violates the plain statutory language of the FQPA.

HUMAN TESTING

In 1999, chlorpyrifos registrants submitted to EPA a never-published, non peer-reviewed study in which volunteers had been intentionally dosed with chlorpyrifos for the purpose of discovering a no-effect level, and therefore influencing regulatory levels for this nerve system poison. In previous years, human tests of chlorpyrifos have been performed on small groups of prison “volunteers” as well, and the results submitted for consideration by EPA. The human tests submitted by chlorpyrifos registrants should be rejected by EPA. The purpose of using results from human testing is to justify the establishment of less stringent safety standards. Intentionally dosing human subjects with known poisons – with no medical benefit to the subjects –is illegal, unethical, and unscientific.
Human testing of pesticides violates the Nuremberg Code, adopted by American judges in the wake of the Nuremberg “Doctors Trials” of Nazis following World War II. The Nuremberg Code has been relied on by state and federal courts as establishing rock bottom minimum legal standards for human testing. Furthermore, EPA’s consideration of the chlorpyrifos human tests would clearly be unethical and in contravention of the Helsinki Declaration, the Common Rule, FIFRA, and the EPA Scientific Advisory Panel/Science Advisory Board report on human testing. Finally, the scientific value of the results of the chlorpyrifos human tests is negligible at best. The tests involved so few subjects that the risks to the broader population—especially the most vulnerable subgroups—cannot be meaningfully assessed. The IRB process used to justify the tests, the “voluntary” consent process used, and many other aspects of the chlorpyrifos human tests were in clear violation of ethical and legal requirements of the Nuremberg Code, Helsinki Declaration, the Common Rule, FIFRA, and the EPA Scientific Advisory Panel/Science Advisory Board report on human testing.

We note that, in December 2001, the Agency requested that the National Academy of Sciences conduct a review of the scientific and ethical issues posed by use of these studies. The Agency has stated that during the Academy’s deliberations, and until a policy is in place, the Agency will not consider or rely on any such studies, whether previously or newly submitted. NRDC urges the Agency to adhere to this position, and to refrain from any consideration of these studies. EPA must reject the use of human tests, consistent with sound scientific practice and pursuant to EPA’s ethical and legal obligations.

Thank you for the opportunity to provide these comments.

Respectfully submitted,

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iv Kate Hallward, Anne Katten, Margaret Reeves and Kristin Schafer, Facing Poison in the Fields: California Farmworkers and Pesticides (1999); Shelley Davis and Rebecca Schleifer, Indifference to Safety (1999)

Columbia Legal Services, Enforcement of Farm Worker Pesticide Protection in Washington State (November 1998)


ix Majewski et al, 1995, supra, at 159t.

x Ibid at 159t, 161.

xi Smith, op cit.

xii Makris S, Raffaele K, Sette W, Seed J. A retrospective analysis of twelve developmental
xv this list of buried assumptions and underestimates of risk is similar to that cited in the EPA Trichloroethylene Health Risk Assessment, Review Draft, August, 2001, section 1.4
xvi Huff RA, Abu-Qare AW, Abou-Donia MB. Effects of sub-chronic in vivo chlorpyrifos exposure on muscarinic receptors and adenylate cyclase of rat striatum. Arch Toxicol. 2001 Oct;75(8):480-6
xviii Huff RA, Abu-Qare AW, Abou-Donia MB. Effects of sub-chronic in vivo chlorpyrifos exposure on muscarinic receptors and adenylate cyclase of rat striatum. Arch Toxicol. 2001 Oct;75(8):480-6
xxi FFDCA Sec. 408 (a)(2)(C )(ii)(I)
xxiv Kate Hallward, Anne Katten, Margaret Reeves and Kristin Schafer, Facing Poison in the
Fields: California Farmworkers and Pesticides (1999); Shelley Davis and Rebecca Schleifer, Indifference to Safety (1999)
Columbia Legal Services, Enforcement of Farm Worker Pesticide Protection in Washington State (November 1998)

xxix Makris et al. op cit.
xxxi Mott, L, Our Children at Risk: The 5 Worst Environmental Threats to Their Health, Natural Resources Defense Council, San Francisco, CA, 1997
xxxiv Solomon, G. Trouble on the Farm: Growing Up with Pesticides in Agricultural Communities, 1998, citing Laughlin, J, Gold R, Laundering Pesticide Contaminated Clothing, University of Nebraska, Lincoln
xxvii ibid, p. 2-3, in bold.
xxix ibid, p. 3, Table 1.
xlii Larson et al, 1997, supra, at p. 192-93
xliii Ibid at p. 264-65
xlvii Richards, R.P., and Baker, D.B., 1993, Pesticide concentration patterns in agricultural drainage


Kisicki JC. 1999. A rising dose toxicology study to determine the No-Observable-Effect-Levels (NOEL) for erythrocyte acetylcholinesterase (AChE) inhibition and cholinergic signs and symptoms of chlorpyrifos at three dose levels. Dow AgroSciences LLC, study ID: DR# K-044793-284. FOIA RIN-0938-00 to NRDC.


Exhibit 3
January 30, 2002

Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Chlorpyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision;
Docket Control Number OPP-34203G

Dear Sir or Madam:

The Attorney General of the State of New York submits these comments on the Environmental Protection Agency’s chlorpyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision (hereinafter collectively “IRED”) pursuant to the November 14, 2001 Federal Register notice (66 Fed. Reg. 57,073-57,074). These comments supplement the Attorney General’s December 27, 1999 comments (amended January 3, 2000) (OPP-34203), and October 20, 2000 comments (OPP-34203C) on the preliminary and revised health and ecological risk assessments for chlorpyrifos. These comments are submitted pursuant to an extension granted by the project manager, Tom Myers.
I. Introduction

The IRED proposes to establish and/or leave in effect chlorpyrifos tolerances, or allowable residues, from 0.01 to 15 milligrams per kilogram (mg/kg) or parts per million (ppm) on a variety of foods. Many of these foods are widely consumed by children. For the reasons set forth below, the tolerances proposed in the IRED are not safe and will result in unreasonable adverse impacts on human health and the environment. The IRED therefore fails to fulfill the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) and the Federal Food Drug and Cosmetic Act, as amended by the Food Quality Protection Act (“FQPA”). Both FIFRA and the FQPA require that EPA ensure that human exposures to chlorpyrifos residues in food are safe and are protective of both human health and the environment. Continued agricultural use of chlorpyrifos on food crops presents unacceptable risks to human health and the environment even if the mitigation measures proposed in the IRED are fully implemented. Moreover, the IRED fails to address the ecological threats posed by continued use of chlorpyrifos. Chlorpyrifos products therefore should not be deemed eligible for reregistration for use on food and the IRED does not support such a determination.

II. Summary of the Attorney General’s Comments on the IRED

A. The FQPA requires that EPA find chlorpyrifos “safe” for use on food before determining eligibility.

The IRED does not set forth a finding that chlorpyrifos is “safe.” Such a finding of safety is a necessary, legal prerequisite under the FQPA for EPA to allow chlorpyrifos to remain in widespread use on food in the United States. As set forth in recent scientific studies, chlorpyrifos residues on foods, even at the lowest levels, may cause adverse health effects and therefore are not safe, particularly for children. The IRED does not set forth a finding of safety and, indeed, does not support such a finding.

B. The FQPA requires that EPA consider cumulative risks and endocrine disruption effects before determining eligibility.

EPA’s failure to complete either a cumulative risk assessment for all organophosphates or an endocrine disruption screening program results in an
understatement of the risks posed by chlorpyrifos. In the absence of this information, EPA cannot find that tolerances are safe or determine that chlorpyrifos products are eligible for reregistration.

C. **FIFRA requires that EPA find no unreasonable adverse effects on human health and the environment from chlorpyrifos.**

The IRED fails to set forth a level of exposure that will have no effect on human health and ignores documented ecological impacts from single exposures. There is strong evidence of adverse effects on the young at the lowest doses tested. Establishing a level at which no effects on the young are seen is critical to determining whether adverse effects are unreasonable under FIFRA's standard for reregistration. The IRED also ignores documented ecological impacts from wildlife exposures to chlorpyrifos. The IRED does not support a finding of eligibility under FIFRA.

D. **The IRED fails to protect against the ecological risks posed by chlorpyrifos and violates the Endangered Species Act.**

The Endangered Species Act ("ESA") mandates that EPA consider whether agricultural and other uses of chlorpyrifos jeopardizes endangered and threatened species. EPA apparently has not consulted with the U.S. Fish and Wildlife Service ("FWS") and has disregarded the biological opinions issued by FWS finding that endangered and threatened species are seriously jeopardized by the continued use of chlorpyrifos. The IRED does not propose actions specifically designed to protect endangered and threatened species and therefore is in violation of the requirements of the ESA.

E. **The IRED’s inadequate analysis of human health risks does not justify EPA’s finding that chlorpyrifos is eligible for reregistration.**

The IRED and the underlying health and environmental risk assessments on which it is based are inadequate to support a finding of reregistration eligibility because EPA has not accurately evaluated dietary exposure and consequently has failed to adequately assess human health risks.
F. The IRED does not establish a level at which no adverse effects are observed and fails to apply an additional “safety” or uncertainty factor to account for this deficiency.

The data suggest that there is no level of exposure to chlorpyrifos that is without adverse effects on developmental neurotoxicity in the young, and it is impossible to establish a true “No Observed Adverse Effect Level” (“NOAEL”) for chlorpyrifos. The IRED instead utilizes a “Lowest Observed Adverse Effect Level” (“LOAEL”) in analyzing developmental neurotoxicity adverse effects of chlorpyrifos exposure (IRED, p. 16). The use of a LOAEL is inadequate to accurately assess risk, and, at the very least, requires application of an additional tenfold “safety” or uncertainty factor.

G. The IRED underestimates human exposure.

The IRED fails to assess the widespread presence of chlorpyrifos residue in more than one third of the foods, tested by the United States Food and Drug Administration (“FDA”) as a part of its annual “Total Diet Study.” Many of the foods with chlorpyrifos residues are baby foods. The IRED also significantly undervalues human exposure by failing to consider residue data showing repeated exceedances of statutory tolerance levels and the presence of chlorpyrifos on foods widely consumed by children for which no tolerance has been set (e.g., carrots, celery, potatoes and other foods).

H. The IRED fails to address the persistent illegal presence of chlorpyrifos on foods for which no tolerances are established.

The IRED does not address the persistent and illegal use of chlorpyrifos on foods for which no tolerance is set and erroneously fails to include residues on these foods in calculating dietary exposure. The presence of chlorpyrifos residue on these foods is a “presumptive tolerance violation” and, as a matter of law, are considered “unsafe.”
I. The IRED’s reregistration eligibility finding was predetermined by the June 2000 Memorandum of Agreement between EPA and Registrants.

The June 2000 MOA between EPA and the registrants predetermined the outcome of the entire chlorpyrifos reregistration process, but specifically the results reached in the IRED and the previously-issued risk assessment. This predetermined result was reached without the benefit of public review and comment and is not in conformance with the procedural requirements of FIFRA.

J. The IRED contains inadequate risk mitigation measures with respect to dietary exposure, occupational and ecological exposure and risks.

The IRED does not address the continued unacceptable dietary, occupational and ecological exposures even assuming there will be strict compliance with all proposed, albeit unenforceable, mitigation measures. More importantly, the IRED incorrectly assumes that the mitigation measures will be adequate not only to protect workers but to protect the general population (including women, children and infants) and ecological receptors as well. There simply is no evidence in the record that the mitigation measures will significantly reduce the unacceptable risks to human health and the environment required by the FQPA and FIFRA.

K. The IRED’s attempt at Codex harmonization is flawed.

The IRED’s attempt to harmonize the EPA-set U.S. tolerances for chlorpyrifos with the often vastly different international standards will increase exposure and risk to human health in the United States from both domestic and imported foods. The IRED does not consider adopting the Codex international standards that are more stringent than the U.S. tolerances. The IRED also fails to propose measures to assure that chlorpyrifos residues on imported food do not exceed the U.S. tolerances.

III. Background

Chlorpyrifos is the most widely used organophosphate insecticide in the United States. It is used to control insects on an extensive variety of food crops for human consumption and on feed crops for animal consumption. The annual total domestic usage of chlorpyrifos in the United States for the years 1987 through
1998 was approximately 21 to 24 million pounds of the active ingredient (ai) (IRED, p. 1). The largest agricultural applications of chlorpyrifos are on corn (about 5.5 million pounds ai).

Chlorpyrifos is a developmental neurotoxin. That is, it impairs brain and central nervous system development. Chlorpyrifos shares with other organophosphates a common mechanism of toxicity that adversely impacts human health.

Chlorpyrifos was first registered in 1965. Registered uses since then have included its use on food and feed crops, golf courses and greenhouses, and its use for structural termite control, home and garden pest control, and as a mosquitoicide. Permissible residue levels or numerical "tolerances" for chlorpyrifos are set forth in EPA's regulations, 40 C.F.R. § 180.342.

Chlorpyrifos is also used and its residue found on a variety of food crops for which EPA has not established by regulation a tolerance. These food crops include cantaloupe, spinach, winter squash, potatoes, celery, carrots, green beans and lettuce.1 As more fully discussed below, the presence of chlorpyrifos residues on these crops is illegal per se and violates the FQPA.2

In 1999 EPA began the process of assessing the human health and ecological impacts of chlorpyrifos for the purpose of determining whether chlorpyrifos products should be reregistered under the FQPA and FIFRA. In October, 1999, EPA issued a preliminary risk assessment that outlined both the human health and ecological impacts of chlorpyrifos. On December 29, 1999, the Attorney General submitted comments on the preliminary risk assessment and asserted that it was deficient in several respects.3

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1 United States Department of Agriculture ("USDA") PDP Residue Data for Chlorpyrifos, 1993-1999 (Exhibit A).


In a June 2000 Memorandum of Agreement with EPA, the registrants of chlorpyrifos products agreed to voluntarily cancel registrations for certain uses, including home and garden uses, termiticide uses, and its use on tomatoes. The registrants’ voluntary cancellation of these uses was contingent upon EPA granting the pending applications for reregistering chlorpyrifos products that would continue to be used primarily on food (MOA, ¶ 2-5).

On August 16, 2000, EPA issued a final, revised human health and environmental effects risk assessment for chlorpyrifos as part of FIFRA’s reregistration process (OPP-34203C). On October 20, 2000, the Attorney General submitted comments on the revised risk assessment. These comments stated that continued use of chlorpyrifos on food posed a significant risk to human health and the environment, that all uses on food should be cancelled, and that reregistrations should be denied. The Attorney General’s comments demonstrated that the risk assessments were flawed, that chlorpyrifos is not safe for continued agricultural use, and that it therefore is not eligible for reregistration.

Among the specific points raised in the Attorney General’s comments on the risk assessments were the following deficiencies:

- Failure to apply appropriate FQPA safety factor.
- Failure to consider the cumulative impacts of chlorpyrifos exposure when viewed with exposures to other organophosphate pesticides.
- Failure to consider aggregate exposure pathways from food and other sources such as air and drinking water.
- Data gaps and the absence of sufficient data (e.g. cumulative risk assessment and endocrine disrupter screening) to support tolerance decisions and eligibility determination.
- Failure to include and consider recent toxicity studies showing adverse health effects at extremely low levels of exposure and to apply appropriate uncertainty factors.
- Failure to include and consider relevant data showing the significant adverse ecological impacts on fish and wildlife from

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4 See the Attorney General’s October 20, 2000 comments on the final revised risk assessment. The position in those comments that chlorpyrifos should not be reregistered was set forth in other public comments, including those of the Natural Resources Defense Council.
widespread agricultural use.

- Underestimation of potential human exposures from dietary and non-dietary sources.
- Failure to incorporate environmental justice considerations with respect to farm worker and minority exposure.
- Failure to assess the chlorpyrifos metabolite, TCPy.
- Failure to assess risks associated with inert ingredients.
- Improper methodology in assessing risk.
- Failure to demonstrate the effectiveness of proposed mitigation measures to reduce exposure and risk.

On September 28, 2001, EPA issued the IRED finding chlorpyrifos eligible for reregistration and continued use on food. The IRED does not address or correct the deficiencies set forth in the Attorney General’s previous comments on the risk assessments and does not respond to those and other comments submitted by interested parties. Despite the opportunity in the IRED to correct deficiencies in the human health and ecological risk assessments, EPA is continuing an apparently undeterred course to reregister chlorpyrifos products for use on food in violation of both FIFRA and the FQPA.

IV. Summary of the IRED’s Findings

The IRED proposes to establish and/or leave in effect chlorpyrifos residue levels or tolerances on food of between 0.01 and 15 ppm (IRED, Table 29, pp. 67-71). Thus, the IRED determined that agricultural use of chlorpyrifos on food and feed crops will continue. In addition to registered uses for food and feed crops, the IRED determined that chlorpyrifos will continue to be used on golf courses, in greenhouses, for non-structural wood treatments such as utility poles and fence posts, and as a mosquitocide (IRED Executive Summary p. 1). Use of products for pre-construction structural termite control also will be allowed to continue (IRED p. 1). The IRED recites that, pursuant to the June 2000 MOA with the registrants, the use of chlorpyrifos as a post-construction termiticide is being phased out (IRED, pp. 12-13).
The IRED proposes to leave in effect chlorpyrifos tolerances currently allowed by regulation for the following foods:

- almonds
- asparagus
- bananas
- beets
- broccoli
- Brussels sprouts
- cabbage
- cattle meat
- cauliflower
- Chinese cabbage
- citrus fruits
- corn
- cucumbers
- dried beans
- eggs
- figs
- kiwi fruit
- milk
- onions
- peaches
- peanuts
- pears
- plums
- peppers
- pumpkins
- radishes
- rutabagas
- soybeans
- strawberries
- sweet potatoes
- turnips
- turnip greens
- walnuts
- wheat
- peppermint and spearmint oil
- goats meat (including byproducts e.g., cheese)
- pork meat (including byproducts, e.g. bacon and sausage)
- all poultry products (including chicken and turkey)
- sheep meat (including byproducts e.g., cheese)

(IRED, Table 29, pp. 67-71).

The IRED proposes to establish by regulation new chlorpyrifos tolerances for the following foods:

- apple pomace
- clover
- cotton, gin byproducts
- dried grapes
- filberts
- grass, hay, forage and seed
- lettuce
- macadamia nuts
- pecans
- raspberries
- wheat, hay
- aspirated grain fractions
(IRED, Table 29, pp. 67-73)

The IRED proposes to lower tolerances for the following foods:

- apples
- citrus oil
- corn oil
- sweet corn
- grapes
- sunflower seeds
- sorghum (fodder, grain and forage)
- vegetables, leafy, Brassica

(IRED, Table 29, pp. 67-71).

Finally, the IRED proposes to revoke tolerances for the following foods:

- blueberries
- caneberries
- cherimoya
- dates
- feijoa (pineapple guava)
- leeks
- lima beans, forage
- mushrooms
- nectarines
- peas, forage
- sapote
- seed and pod vegetables (okra and dill)
- snap beans, forage
- sorghum milling fractions
- soybean, forage
- sugarcane
- tomatoes

(IRED, Table 29, pp. 67-71)

The IRED proposes mitigation measures to reduce the unacceptable risk posed by chlorpyrifos including elimination of termicide uses and use on certain foods, label changes providing for reduced application rates and buffer zones, and worker protection requirements. Relying on the August 2000 revised risk assessment, the IRED states that implementation of these mitigation measures should reduce occupational, ecological and dietary risks from food to acceptable levels (IRED, pp. 75-79; 91-92). The IRED notes that some occupational exposure to chlorpyrifos from termicide use continues to pose excessive risks despite these mitigating measures (IRED, pp. 2; 7). The IRED also notes that, even from a single application, chlorpyrifos poses a serious ecological threat to many
non-target aquatic and terrestrial animals (IRED, pp. 2; 52-56).

V. The IRED fails to meet the legal requirements of the FQPA, FIFRA and the ESA

A. The FOPA requires that EPA find chlorpyrifos “safe” for use on food.

As set forth in the IRED (Table 29), most of the existing tolerances for chlorpyrifos on food set forth in EPA’s current regulations, 40 C.F.R. § 180.342, will remain in effect. A limited number of tolerances will be lowered or revoked. The IRED therefore constitutes EPA’s final determination “to establish” and/or “to leave in effect” tolerances for chlorpyrifos residues on food within the meaning of FQPA Section 408(B)(2), 21 U.S.C. § 346(a)(B)(2).

The standard governing EPA’s decision to establish or leave in effect a pesticide tolerance is set forth in FQPA Section 408(b)(2)(A). That section states that 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) (emphasis added).5 Thus, the FQPA requires EPA to determine the safety of chlorpyrifos tolerances before establishing or leaving in effect any tolerance, before finding chlorpyrifos eligible for reregistration under FIFRA, and before allowing it to remain on the market in widespread use on food. Although the IRED proposes to establish and leave in effect chlorpyrifos tolerances, it does not find those tolerances “safe.” In fact, the IRED repeatedly expresses concerns with its safety (IRED, p. 65-66).

EPA’s attempt to veil the IRED’s final determination to by terming the reregistration eligibility decision “interim” is belied by the practical effect of the determination, which is to continue indefinitely the use of chlorpyrifos on food at essentially the same tolerance levels currently in place. The IRED acknowledges that the FQPA-required safety determination is not being done at this time (IRED, p. 66), yet reaches the conclusion that chlorpyrifos is nonetheless eligible for reregistration. This approach is unacceptable and contrary to the FQPA’s express

5 The term “safe” as used in Section 408(b)(2)(A) means “that the Administrator has determined that there is a reasonable degree of certainty that no harm will result from aggregate exposure to the pesticide chemical residue...” from a variety of sources. See 21 U.S.C. § 346a(b)(2)(A).
mandate to establish or leave in effect a tolerance only after finding, with a reasonable degree of certainty, that it is safe. 21 U.S.C. § 346a(b)(2)(A). The approach taken in the IRED is clearly not what Congress intended.

In 1996, the FQPA was passed by Congress with the express intention of requiring EPA “promptly to commence such [pesticide tolerance re-evaluation] proceedings as are warranted under FIFRA and the new [FQPA] Section 408 of the FFDCA, as soon as there is sufficient information with respect to the dietary risk of a particular active ingredient and no later than when a determination is made as to whether pesticides containing a particular active ingredient should or should not be reregistered.”6 (Emphasis added.) The FQPA’s statutory deadlines are the best evidence of the urgency with which Congress viewed the much-needed re-evaluation of older pesticides like chlorpyrifos.7 Indeed, the FQPA mandates that one third of all pesticides be reviewed by August 1999; the second third by August 2002; and the last third by August 2006. See 21 U.S.C. § 346a(q)(1).8 EPA’s determination in the IRED to continue the use of chlorpyrifos on food indefinitely, without a determination as to its safety, is contrary to the letter and the spirit of the FQPA as set forth in the statute’s legislative history.

The FQPA’s requirement of finding a tolerance “safe” is a threshold determination without which the process of reregistration eligibility decision-making under FIFRA should not proceed. Indeed, as detailed below, a similar standard for reregistering a pesticide is set forth in FIFRA and requires EPA to find that chlorpyrifos will not cause unreasonable adverse effects on human health and the environment. 7 U.S.C. § 136a-l(g)(2)(C) [referring to the standard in 7 U.S.C. § 136a(c)(5)(D)]. The IRED fails to make this finding under FIFRA as well.

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7 Chlorpyrifos was first registered in 1965 without the benefit of the health or ecological impact data required to register a pesticide today.

8 EPA has not met the first statutory deadline to reassess one third of all pesticides by August 1999. See FQPA section 408(q)(1)(A), 21 U.S.C. § 346a(q)(1)(A).
B. The FQPA requires that EPA consider cumulative risks and endocrine disruption effects.

The FQPA expressly requires that EPA consider 1) the cumulative risks posed by chlorpyrifos and other organophosphates with a common mechanism of toxicity, and 2) the endocrine disrupter effects of chlorpyrifos. 21 U.S.C. § 346a(b)(2)(D)(v) and (viii). The IRED concedes that neither has been considered and thereby violates the express requirements of the FQPA.

1. The IRED fails to consider cumulative risks posed by chlorpyrifos with other organophosphate pesticides.

The IRED concedes that the chlorpyrifos risk assessment is for only that individual organophosphate and does not consider the cumulative risks from other pesticides or substances sharing a common mechanism of toxicity (IREDS, p. 65-66). This approach is contrary to the FQPA. In establishing or leaving in effect chlorpyrifos tolerances, FQPA Section 408(b)(2)(D)(v) requires that the EPA Administrator “shall consider, among other relevant factors ... available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity.” 21 U.S.C. § 346a(b)(2)(D)(v) (emphasis added). In the absence of a cumulative risk assessment for all organophosphates, the IRED cannot support a finding that chlorpyrifos tolerances are “safe.”

It is undisputed that chlorpyrifos is one of several organophosphates having a common mechanism of neurotoxicity. This means that chlorpyrifos and the other organophosphates adversely affect the brain and central nervous system. That finding has been made by the Agency for Toxic Substances and Disease

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9 Indeed, the IRED itself concedes that, without the cumulative risk assessment, it “does not fully satisfy the reassessment of the existing chlorpyrifos food residue tolerances as called for by FQPA” (IREDS, p. 65).

The available scientific literature is replete with studies and data showing the cumulative toxicity of organophosphates as a chemical group. The IRED proposes to establish and leave in effect tolerances without considering the cumulative impact of exposure to all organophosphates. Under the FQPA, this is a mandatory factor that EPA must consider prior to reaching the tolerance-setting and eligibility determination set forth in the IRED. The absence of a cumulative risk assessment makes the IRED’s determination contrary to the express provisions of the FQPA. 21 U.S.C. § 346a(b)(2)(d)(v).

Even in the absence of the required cumulative risk assessment, the chlorpyrifos data by itself shows that chlorpyrifos exposure, poses excessive dietary risks, particularly to infants and children. If other organophosphate risks were also considered (as they would be in a cumulative risk assessment), the assessment would undoubtedly result in even greater risks. There are clearly enough scientific data and residue information on chlorpyrifos to conclude that it poses such a cumulative risk with other organophosphates that it cannot be considered safe under the FQPA. In fact, the chlorpyrifos data alone are sufficient to support immediate regulatory action to protect public health by revoking tolerances on food and denying reregistration.

2. The IRED lacks an evaluation of potential endocrine disruption effects.

Similarly, the IRED fails to consider whether chlorpyrifos may have effects on the human endocrine system. FQPA Section 408(b)(2)(D)(viii) requires the EPA Administrator to consider whether chlorpyrifos “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.” 21 U.S.C. § 346a(b)(2)(D)(viii). This means that EPA must consider and determine whether chlorpyrifos has endocrine disruption effects.


13 Id.
before establishing or leaving in effect the tolerances and before finding chlorpyrifos eligible for reregistration. 21 U.S.C. § 346a(b)(2)(D)(viii). The IRED merely acknowledges that the endocrine screening program is not complete or finalized and states that “chlorpyrifos may be subjected to additional screening and/or testing” in the future to determine its endocrine disruption effects (IRED, p. 74). The IRED fails to set forth either a time frame or a process under which this “additional screening and/or testing” will take place.

The IRED does not consider or evaluate whether chlorpyrifos has the potential to affect and disrupt the endocrine system (IRED, page 74). Recent literature reports show such adverse impacts.14 The FQPA requires EPA to consider this impact in assessing tolerances on food and the IRED’s failure to include this factor is contrary to that requirement, 21 U.S.C. § 346a(b)(2)(D)(viii). The evaluation of potential endocrine disrupter risks will necessarily lead to the conclusion that human health risks may be increased.

The IRED notes that chlorpyrifos may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption (IRED, page 74). Chlorpyrifos must be evaluated for potential endocrine disrupter effects before the chlorpyrifos risk assessment can be considered complete and before a reregistration eligibility decision is reached.

The IRED fails to meet the mandating requirements of FQPA. Section 408(b)(2)(D)(v) that cumulative and endocrine disruption effects be considered before establishing or leaving in effect a tolerance and before determining reregistration eligibility. As stated above, these deficiencies are not mitigated by EPA’s denomination of its determination as “interim,” since the effect of the IRED is to leave existing tolerances in place and permit unsafe exposures to continue.

C. FIFRA requires that EPA find no unreasonable adverse effects on human health and the environment from continued use of chlorpyrifos.

In addition to not meeting the FQPA standard, the IRED also does not fulfill FIFRA’s legal requirement to find that chlorpyrifos will not cause unreasonable

adverse effects on human health and the environment. FIFRA Sections 3(c) and 4(g) provide that EPA shall reregister a pesticide only after determining that “it will perform its intended function without unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C) and § 136a-1(g)(C). The IRED repeatedly recognizes strong evidence of adverse impact on both human health and the environment but, in the face of this evidence, finds chlorpyrifos eligible for reregistration (IRED, pp. 64-66). The IRED’s reregistration eligibility determination is therefore unsupported by the record and not in conformance with the legal standard set forth in FIFRA Sections 3(c) and 4(g). 7 U.S.C. § 36(a)(5)(c) and § 136a-1(g).

D. The IRED fails to protect against the ecological risks posed by chlorpyrifos and violates the Endangered Species Act.

The IRED’s analysis of the ecological risks, particularly to endangered species, is flawed. The IRED states that chlorpyrifos and its degradate, TCP, are persistent in the environment (IRED, pp. 47-48) and bioaccumulate in tissue (IRED, p. 52). The IRED also states that a single application of chlorpyrifos poses a “high risk” to numerous species and that multiple applications increase this already high risk (IRED, p. 52). The IRED notes that the U.S. Fish and Wildlife Services (“FWS”) has published five opinions in which the agency found that more than one hundred endangered and threatened species are in jeopardy or are adversely affected by the use of chlorpyrifos (IRED, p. 53). The IRED concludes that the endangered species levels of concern are significantly exceeded (IRED, p. 53). The IRED recites the significant risks chlorpyrifos poses to numerous other species (IRED, pp. 53-56) and its “widespread and persistent presence in aquatic areas throughout the nation.” (IRED, p. 55)

In light of the IRED’s recitation of the foregoing significant ecological risks, it is troubling that the IRED then concludes that these risks are outweighed by the benefits of chlorpyrifos and its continued agricultural use (IRED, p. 65). The IRED fails to identify the specific benefits of chlorpyrifos, however. The IRED also attempts to justify its risk/benefit analysis on the basis of untried and unproven “mitigation measures” (IRED, p. 64). These measures will have little impact on agricultural uses, which represent the most significant routes of ecological exposure, because the widespread use of chlorpyrifos on food will continue.
Because of the significant ecological impacts, the IRED’s finding that chlorpyrifos is eligible for reregistration is contrary to both FIFRA and the Endangered Species Act (“ESA”). FIFRA expressly requires EPA to find that chlorpyrifos will not cause unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(5). The IRED does not support that finding. Moreover, the significant adverse ecological effects of chlorpyrifos, particularly on endangered species, are not outweighed by any benefit by its continued use.

The ESA requires that every federal agency insure that its “action” (such as reregistering a pesticide) is not likely to jeopardize any endangered or threatened species. See 16 U.S.C. § 1536(a)(2). In furtherance of this objective, the ESA requires that EPA confer with the FWS on any action likely to jeopardize endangered or threatened species. See 16 U.S.C. § 1536(a)(5). After conferring, with EPA, FWS is then required to issue an opinion detailing whether an agency’s action will jeopardize or otherwise affect a species. See 16 U.S.C. § 1536(b)(3)(A). As the IRED notes (p. 53), the FWS has issued not one but five biological opinions finding that chlorpyrifos seriously jeopardizes endangered and threatened species. FWS has not changed those opinions and yet the IRED disregards them entirely in violation of the ESA. The IRED’s attempt to justify the continued use of chlorpyrifos by continually pointing to the proposed mitigation measures is without merit. The IRED simply does not explain how these measures will curtail adverse impacts on various species.

E. The IRED’s inadequate analysis of human health risks does not justify EPA’s finding that chlorpyrifos is eligible for reregistration.

The IRED and the underlying health and environmental risk assessments on which it is based are inadequate to support a finding of reregistration eligibility because EPA has not accurately evaluated dietary exposure and consequently has failed to adequately assess human health risks. EPA has not evaluated current tolerances in the context of recent scientific studies showing adverse health impacts at the lowest doses evaluated. These adverse impacts such as neurobehavioral and developmental effects are evident at doses lower than those that cause cholinesterase inhibition. The IRED therefore utilizes an incorrect endpoint (cholinesterase inhibition) rather than neurobehavioral effects in the young reflected in recent studies.
The dietary risks set forth in the IRED are based on incorrect assumptions regarding both exposure to chlorpyrifos and the toxic effects of chlorpyrifos on the young. The dietary risks would be considered unacceptable, and therefore not “safe” under the FQPA standard, if EPA accurately calculated exposure and considered newer studies showing toxicity at lower levels of exposure. The IRED fails to adequately review and assess current tolerances for chlorpyrifos in light of recent studies and data that show adverse effects particularly on neonatal cognitive and immune system functions. None of these studies was able to determine a dose level at which no adverse effects were seen, indicating that a threshold level for these effects has not been found. The safety of the LOAEL and the current and proposed tolerances, therefore, cannot be demonstrated.

Under section 408(b)(2)(A)(i) of the FQPA, 21 U.S.C. § 346a(b)(2)(A)(i), EPA may establish or leave in effect a tolerance for pesticide residue on food “only if the Administrator determines that the tolerance is safe.” To be deemed “safe,” chlorpyrifos tolerances would have to be eliminated on most foods and/or reduced so substantially, the formulations and/or application rates changed so drastically, that it would have questionable efficacy against pests. To be reregistered, a pesticide must have demonstrated efficacy to control pests at the label application rate or it cannot be registered. See FIFRA, 7 U.S.C. § 136a(c)(5). In short, chlorpyrifos cannot be found “safe” at the current tolerances that the IRED proposes to retain but may not be efficacious at reduced application rates. It therefore is not eligible for reregistration under FIFRA.

F. The IRED does not establish a level at which no adverse effects are observed and fails to apply an additional safety or uncertainty factor to account for this deficiency.

Studies cited in the IRED show adverse health effects from chlorpyrifos exposure at very low levels. The health effect seen in these studies is cholinesterase inhibition. Cholinesterase inhibition, however, is not the appropriate “end point.” There are other more subtle neurotoxic adverse effects beyond cholinesterase inhibition that the IRED does not consider. These adverse developmental effects on brain function are persistent behavioral consequences and

15 See footnotes 16, 18-25, infra, and accompanying text.
often are seen over the long term, and are as troubling as cholinesterase inhibition.\textsuperscript{16}

The IRED found adequate evidence of susceptibility for infants, children, and women of reproductive age to retain the FQPA ten-fold safety factor (IRED, pp. 16-17). In addition to this evidence, however, recently reported studies not included in the IRED, and apparently not considered by EPA, provide further compelling evidence of adverse health effects and increased susceptibility of the young from exposure to chlorpyrifos. These recent studies show neurological and immune system effects on neonatal animals at the lowest doses tested. Recent data suggest that there is no level of exposure to chlorpyrifos that is without adverse effects on developmental neurotoxicity in the young, and it is impossible to establish a true “No Observed Adverse Effect Level” (“NOAEL”) for chlorpyrifos. The IRED instead utilizes a “Lowest Observed Adverse Effect Level” (“LOAEL”) for cholinesterase inhibition only in analyzing developmental neurotoxicity adverse effects of chlorpyrifos exposure (IRED, p. 16). The use of a LOAEL is inadequate to accurately assess risk and, as detailed below, requires the application of an additional tenfold “safety” or uncertainty factor because there is no established level of exposure that is entirely without adverse effects.\textsuperscript{17} Moreover, a NOAEL for cholinesterase inhibition is not the most sensitive end point.

Of particular note is a recent research report finding that neonatal exposure to chlorpyrifos in rats at doses that produce no overt toxicity and no cholinesterase inhibition, nevertheless elicited both immediate and long-term deficits in coordination indicative of neurological effects.\textsuperscript{18} Indeed, behavioral performance was affected \textit{during} the period of exposure to levels as low as 1 mg/kg body weight


\begin{footnote}{17} The IRED and the FQPA both use the term “safety factor” to refer to a factor meant to account for the uncertainties in determining risk. That term is interchangeable with the term “uncertainty factor,” but for purposes of these comments the term “safety factor” will be used.\end{footnote}

\begin{footnote}{18} Dam, K., Seidler, F., Slotkin, T., “Chlorpyrifos exposure during a critical neonatal period elicits gender-selective deficits in the development of coordination skills and locomotor activity.” Developmental Brain Research 121: 179-187 (2000) (Exhibit B).\end{footnote}
on post-natal days 1 to 4. The behavior also was affected in the postweanling period *several weeks after the termination of exposure*. The IRED fails to recognize that, based on the results of this recent study, adverse human health effects caused by chlorpyrifos exposure may not be immediately detected, may appear well after exposure, and are observed before cholinesterase inhibition is seen. Accordingly, cholinesterase inhibition is not the only effect by which to judge the risks of chlorpyrifos.

A second recent report also indicated behavioral alterations in the absence of classic signs of cholinesterase inhibition or cholinergic toxicity. A third study reports that exposure of neonatal rats to 1 mg/kg chlorpyrifos produced lasting changes in neural function and long-term deficits in immune competence. Yet another report shows alterations in behavioral performance at a dose of 1 mg/kg that persist or emerge long after termination of exposure and well after the restoration of cholinesterase activity. Finally, a recent study found behavioral effects at a dose of 0.3 mg/kg in weanling rats even though there was no evidence

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19 Id.

20 Id. This study confirms that adverse neonatal effects occur after termination of exposure and without continued exposure. Further, these behavioral/neurological effects were evident after dosing the young animals for only 4 days following birth, which indicates that the time period of exposure may be of critical importance.


of cholinesterase inhibition. The IRED fails to recognize that, based on the findings of these recent studies, exposure to chlorpyrifos causes behavioral impacts at very low doses and well before cholinesterase inhibition becomes evident.

These studies taken together indicate that a NOAEL has not been identified, that effects can occur at lower levels than those assumed in the IRED, that adverse effects are seen in the absence of cholinesterase inhibition, and that chlorpyrifos can cause behavioral, immunological and neurological effects well after termination of low level exposure. Indeed, this recent research shows that these potentially serious developmental effects have no demonstrated threshold of exposure.

At a minimum, the studies set forth above demonstrate the need for an additional safety or uncertainty factor of ten when deriving a reference dose from a LOAEL instead of a NOAEL. An additional safety factor of ten is a default assumption that is applied in chemical risk assessments to account for the uncertainty associated with the use of a LOAEL in place of a NOAEL, and for other data inadequacies, such as short exposure duration testing for neurological and developmental effects. Using this additional safety factor is consistent with recent guidelines on the use of uncertainty factors. It is also consistent with recent developments in the selection of safety or uncertainty factors to account for interhuman variability in pharmacokinetics and pharmacodynamics.


This additional safety factor to address the absence of a NOAEL was not applied in the IRED. The IRED only applies three ten-fold safety factors, or a safety factor of 1,000, when a fourth safety factor is called for. The first ten-fold safety factor accounts for the variation in sensitivity among the human population (the intraspecies variation) (IRED, p. 15); the second ten-fold safety factor accounts for the uncertainty involved in extrapolating animal data to humans (the interspecies variation) (IRED, p. 15); and the third ten-fold FQPA safety factor accounts for the increased sensitivity of infants and children (IRED, p. 16). The addition of fourth ten-fold safety factor is necessary to account for the uncertainties associated with the failure to establish a NOAEL that derives from the IRED’s use of cholinesterase inhibition as the sole end point. Indeed, in the context of pesticide exposure, EPA recognizes the application of this additional ten-fold safety factor in the absence of a LOAEL but fails to apply it (IRED, p. 6). At a minimum, an additional ten-fold safety factor must be applied, bringing the total safety factor to 10,000 (10 x 1000), rather than the 1,000 safety factor proposed in the IRED. This is a prudent and rational approach to assessing the risks associated with chlorpyrifos and is consistent with both the FQPA and well settled approaches to conducting risk assessments.

If an additional safety factor of ten is applied, many of the assessments provided in the IRED change, thereby undermining EPA’s conclusion that chlorpyrifos exposure falls within the “risk cup” and therefore is eligible for

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29 The IRED (p. 6), refers to the EPA Notice to Registrants, “Worker Risk Mitigation For Organophosphate Pesticides,” Pesticide Registration Notice 2000-9, (September 29, 2000). This EPA Notice recommends the use of an additional safety or uncertainty factor to account for the use of a LOAEL rather than a NOAEL (Notice 2000-9, p. 4).
reregistration and continued use on food. For example, the acute dietary (food only) risk estimates for chlorpyrifos show that for children ages 1 to 6, roughly estimate post-mitigation exposure to chlorpyrifos will account for 82% of the acute population adjusted dose ("aPAD") and 51% of the chronic population adjusted dose ("cPAD"). The IRED concludes that these aPAD and cPAD percentages are not of concern because they are below 100% (see IRED, p. 17-19). With the application of the additional safety factor of ten to account for the absence of a NOAEL, the aPAD and cPAD percentages will be significantly increased, resulting in unacceptably high percentages of 820% and 510%, respectively. These are well in excess of the percentages of concern identified in the IRED and the "risk cup" runneth over.

G. The IRED Underestimates Human Exposure.

The IRED fails to assess the presence of chlorpyrifos residue in more than one third of the foods tested by the United States Food and Drug Administration ("FDA") as a part of its annual "Total Diet Study." Many of the foods containing chlorpyrifos residues are baby foods. The FDA’s data are the best evidence of direct, repeated and significant childhood dietary exposure. These data are generally ignored in the IRED, however, which favors analyzing theoretical or

30 The terms aPAD and cPAD are used to characterize the acute, or immediate, and the chronic, or long term, dietary risk posed by chlorpyrifos.

31 See FDA "Total Diet Study; Summary of Residues Found, Market Baskets (91-3 -- 99-1") (September 2000) (Exhibit C). The FDA tested 319 foods, including baby foods and other foods widely consumed by children. Chlorpyrifos residue was found at varying levels in 110 of 319 foods, or in one-third of the foods tested. Examples of the foods tested on which chlorpyrifos residues were found are: french fries, hamburgers, hot dogs, pizza, potato chips, carrots, peaches, peanuts, peanut butter, various breads, bagels, doughnuts and Danish pastries, graham crackers, saltine crackers, egg noodles and macaroni, pancake mix, chocolate chip cookies, milk chocolate candy bars, fruit flavored cereals, raisin bran cereals, granola, popcorn, apples, oranges, peaches and pears (Exhibit C). It is reasonable to conclude that most of these foods may be extensively consumed by children. The IRED’s failure to accurately assess this documented exposure is indicative of the IRED’s overall inadequacy to support any finding of “safety” for the proposed tolerances under the FQPA.

32 Id. The following baby or “junior” foods were found to have chlorpyrifos residue: applesauce, strained peaches, pears, rice cereal, teething biscuits, apple cereal, mixed vegetables, custard pudding and fruit dessert (Exhibit C).
“anticipated” exposures rather than actual exposures.

The IRED also fails to adequately assess occupational exposures. Even assuming full compliance with mitigation measures for workers (use of maximum personal protective equipment and engineering controls, lengthening re-entry intervals, etc.), the IRED states that the exposures and risks to workers are still in excess of levels considered acceptable (IRED, pp. 3; 28-40; and 74-75). The IRED fails to explain why chlorpyrifos is eligible for reregistration in the face of continued occupational risks and the recognition that the proposed mitigation measures will be inadequate to protect workers.

Workers may also inadvertently expose family members by bringing chlorpyrifos residues home on clothing and personal items. Further, there is no assessment of exposure to greenhouse and nursery workers due to a lack of data in this area (IRED, p. 40). These additional exposure scenarios have not been properly evaluated in the IRED. Indeed, EPA cannot adequately assess occupational exposure and risk in the absence of additional data.

The IRED also fails to assess exposure to sensitive subpopulations such as children who work in or live near fields where chlorpyrifos is applied, including the children of farm workers. Residential areas are very developed near farms at a rapid pace. These children may be exposed to chlorpyrifos on a body weight basis at levels substantially in excess of these encountered by adults. Since adult farm worker populations are already found to be well above acceptable exposure levels in the IRED (pp. 29 and 40), children living in the same environment can be presumed to be exposed to even greater unacceptable risks.

As raised in the previous comments of the Attorney General, there is strong evidence of widespread population exposure to chlorpyrifos as measured by the presence of the chlorpyrifos metabolite 3,5,6-trichloro-2-pyridinol (“TCPy”) in urine. As part of the National Human Exposure Assessment Survey TCPy was detected in urine samples from children age 3 to 13 in the general population.33 TCPy was found in 93% of the 261 urine samples from children, with a maximum concentration of 45 micrograms per liter. Notably, TCPy levels were not

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significantly higher for subjects from households reporting greater than average pesticide use compared with households reporting less frequent pesticide use.

This information strongly suggests that dietary sources are a major exposure pathway to chlorpyrifos. Elimination of home and garden and termiticide uses will have only marginal benefit to reduce population exposure. Most importantly, TCPy urinary concentrations were up to two times higher in children than the levels observed in comparable studies in adults. Again, this study reflects the greater exposures and consequently greater risks to children from chlorpyrifos in food.

H. The IRED fails to address the persistent illegal presence of chlorpyrifos on foods for which no tolerances are established.

The IRED does not address the persistent and illegal use of chlorpyrifos on foods for which no tolerance is set and erroneously fails to include residues on these foods in calculating dietary exposure. From 1993 to 1999, chlorpyrifos residue repeatedly appeared on foods for which no regulatory tolerance is set. These foods include apricots, cantaloupe, carrots, celery, olives, olive oil, potatoes, spinach, and winter squash. The consistent presence of chlorpyrifos in these foods from 1993-1999 does not represent an aberration or infrequent misuse.

The presence of chlorpyrifos residue on these foods is a "presumptive tolerance violation" within the meaning of the USDA Pesticide Data Program Annual Residue Summary, (Exhibit A). These foods, as a matter of law, are considered "unsafe" under FQPA Section 408, 21 U.S.C. § 346a(a)(1). Use on


35 See USDA Pesticide Data Program 1993 to 1999 (Exhibit A) and FDA Market Basket Survey, 1991-1999 (Exhibit C).

36 The USDA refers presumptive tolerance violations in its data to EPA for enforcement. Despite the presence of chlorpyrifos residues on numerous foods for which no tolerance is set, neither the registrants nor EPA has taken action to curtail the presence of chlorpyrifos on these foods for which no tolerance is set or the improper use of chlorpyrifos on these foods by growers.
these foods is also illegal under FIFRA. See 7 U.S.C. §136j(a)(1)(S) and the FQPA, 21 U.S.C. § 346a(a)(1).

The IRED fails to assess these additional, non-registered uses nor include them in estimating dietary exposure. Dietary exposures, therefore, are understated significantly and the IRED's "risk cup" calculations are flawed. Most importantly, the IRED does not propose mitigation measures to curtail future dietary exposures caused by the illegal presence of chlorpyrifos residues on these foods.

I. EPA's reregistration eligibility finding was predetermined by the June 2000 Memorandum of Agreement between EPA and the registrants.

The June 2000 MOA between EPA and the registrants predetermined the outcome of the entire chlorpyrifos reregistration process, but specifically the results reached in the IRED and the previously-issued risk assessments. This predetermined result was reached well before the human health and ecological risk assessments were completed and the eligibility decision made without the benefit of public review and comment. This predetermined result is not in conformance with the procedural and substantive requirements of the FQPA and FIFRA.

The public was never notified nor given the opportunity to comment on the fact that in June 2000 EPA had decided to grant the reregistrations and allow the continued use of chlorpyrifos products on most foods at the existing tolerances. The MOA was also not made available electronically from EPA's website docket. A party desiring to review the MOA was forced to obtain it directly from EPA.

In the MOA, EPA essentially agreed to approve reregistration applications for chlorpyrifos products and allow its continued use on food at most of the existing tolerances in exchange for the registrants' voluntary cancellation of home and garden and termiticide uses. (MOA, p. 4, ¶¶ 4 - 5.) The MOA provided that the registrants' compliance with the terms of the MOA, including label changes and other mitigation measures, guaranteed EPA's approval of the reregistration applications for agricultural products that are used on food. (MOA, ¶¶ 4 - 5; 12). In fact, the MOA opens with this commitment by EPA: "EPA has no current intention to initiate cancellation or suspension proceedings under section 6 of FIFRA with respect to the issues addressed in this Agreement." (MOA, p. 1.) The term "issues addressed in this Agreement" refers to and includes all products currently before EPA for reregistration for use on food. These products are listed
in attachments to the MOA (See MOA Appendices B and C).

Thus, well before the full reregistration process was completed, EPA had reached an agreement with the registrants to continue uses on food without regard to the well-documented health effects and the pervasive presence of chlorpyrifos on foods for which it is not approved. This predetermined result is contrary to the mandated public participation provisions of FIFRA. Moreover, it improperly impairs EPA’s statutorily-mandated responsibility to make health-based decisions related to the safety of chlorpyrifos for use on food. The IRED and the underlying MOA represent a predetermined result to a supposedly objective and fair process that appears to place the business interests of the registrants above human health concerns.

J. The IRED contains inadequate risk mitigation measures, particularly with respect to dietary, occupational and ecological risks.

The IRED recommends risk mitigation measures (IRED, pp 74-75) but other than discontinued use on tomatoes and lowering the tolerance on apples, does not propose mitigation measures that will be effective in actually reducing dietary exposure. The IRED also recommends mitigation measures to reduce occupational and ecological risks but lacks any basis for concluding that those measures will be effective. Moreover, the IRED does not propose a regulatory requirement ensuring that the recommended mitigation measures are implemented and EPA lacks any enforcement mechanism to assure compliance.

In any event, the recommended mitigation measures are wholly inadequate to address the risks posed by chlorpyrifos residues on food because the actual allowable residues will essentially stay the same as current uses. (Compare IRED, Table 29 with 40 C.F.R. § 180.342.)

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37 See (Exhibit ), USDA Pesticide Data Program 1993 to 1999; FDA “Total Diet Study; Summary of Residues Found, Market Baskets 91-3 -- 99-1” (September 2000).

38 These occupational and ecological mitigation measures include reduction in application rate and number of applications per season, establishing no-spray buffer zones, and increased use of personal protection equipment for workers.
K. The IRED’s Attempt At Codex Harmonization Is Flawed

The IRED discusses “harmonizing” the EPA-set, U.S. tolerances with the Codex Alimentarius Commission’s maximum residue levels (MRLs) (IRED, p. 72). The Codex MRLs are international food safety standards set under the auspices of the World Health Organization. These international standards set tolerances for pesticide residue on food.

The term “harmonization” is undefined and the IRED lacks any discussion of the standards governing the Codex MRLs. The Codex MRLs are inconsistent with EPA’s tolerances in for chlorpyrifos (Compare 40 C.F.R. §180.342 with IRED, Table 30, p. 73). Many of the Codex MRLs for chlorpyrifos are higher (less stringent) than the current or proposed U.S. tolerances (IRED, p. 73, Table 30). The IRED’s “harmonization” of the Codex MRLs with EPA’s standards may significantly affect the level of chlorpyrifos residues on foods imported into the United States and may increase human exposure if tolerances are harmonized upward. The IRED does not analyze this additional exposure.

In the interest of harmonization, the IRED proposes raising the tolerance for dried grapes (or raisins) from the EPA tolerance of 0.5 ppm to the Codex MRL of 1.0 ppm. (IRED, p. 73, table 30). There is no existing tolerance for dried grapes in 40 C.F.R. § 180.342. The IRED erroneously notes that the U.S. tolerance is 1 ppm, presumably relying on the tolerance for grapes. Raisins are widely consumed by children. The IRED fails to explain or justify this additional two-fold increase in exposure to children and does not assess this additional risk in the context of total dietary exposure. Moreover, there is no requirement that EPA harmonize U.S. tolerances with the Codex MRLs. Rather, the FQPA requires that EPA only provide its reasons for departing from the Codex MRLs for imported foods. See 21 U.S.C. § 346a(b)(4). The departure would be fully justified solely for reasons of public health. If harmonization is undertaken, however, EPA must clearly state its reasons for departing from the U.S. tolerances and provide a rational basis for doing so. The IRED fails to state any reason whatsoever for increasing the tolerance for dried grapes.

EPA must require food imports to meet the EPA-set U.S. tolerances. This must be clarified in the IRED because imported foods reach U.S. markets in significant amounts (IRED, p. 73). If EPA intends to “harmonize” U.S. tolerances with the Codex MRLs, and thereby allow higher chlorpyrifos residues on imported
food, the IRED must state that clearly so the public and Congress are aware that the FQPA and FIFRA will not be complied with and EPA will not enforce its tolerance regulations.

Notably, although higher for most foods, the Codex MRLs for chlorpyrifos are lower (and therefore more protective) for some foods, including cabbages, cauliflower, citrus fruits, cottonseed, lettuce, onions and peppers (IRED, p. 73, Table 30). Codex MRLs are set based on scientific toxicity data. The IRED fails to explain why these lower tolerances should not be adopted by EPA or "harmonized" by changing the U.S. tolerances. The Codex set lower tolerances clearly would be more protective of public health. This downward "harmonization" to the lower tolerance also would achieve the objective of eliminating barriers to trade in U.S. exports that is a cornerstone of the General Agreement on Tariffs and Trade (GATT) and the North America Free Trade Agreement (NAFTA). The adoption of these lower tolerances is particularly compelling in light of the deficiencies in the IRED noted above.
VI. Conclusion

In summary, EPA has not fulfilled the legal mandates in the FQPA, FIFRA and the ESA to protect public health and the environment. The IRED has underestimated the risks posed by chlorpyrifos. Accordingly, it cannot be considered eligible for reregistration.

Should you have any questions about the submitted information, please feel free to contact us at the numbers listed below.

Very truly yours,

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References


Food and Drug Administration, Total Diet Study Summary of Residues Found, Market Baskets (91-3--99-1), September 2000.


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