Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Pose Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos

Petitioners:

United Farm Workers
California Rural Legal Assistance Foundation
Farmworker Association of Florida
GreenLatinos
Labor Council for Latin American Advancement
League of United Latin American Citizens
Learning Disabilities Association of America
Migrant Clinicians Network
National Hispanic Medical Association
Pineros y Campesinos Unidos del Noroeste

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PETITION FOR EMERGENCY AND ORDINARY SUSPENSIONS OF CHLORPYRIFOS USES THAT POSE UNACCEPTABLE RISKS TO WORKERS AND PETITION TO CANCEL ALL USES OF CHLORPYRIFOS

INTRODUCTION

On behalf of United Farm Workers, League of United Latin American Citizens, Labor Council for Latin American Advancement, National Hispanic Medical Association, Farmworker Association of Florida, Pineros y Campesinos Unidos del Noroeste, Migrant Clinicians Network, Learning Disabilities Association of America, California Rural Legal Assistance Foundation, and GreenLatinos, we hereby file this combined petition asking the Environmental Protection Agency ("EPA") to suspend and cancel chlorpyrifos uses.

In the suspension petition, we ask EPA to suspend all uses of chlorpyrifos that: (1) pose unacceptable risks of acute pesticide poisonings to workers, as found by EPA in its Revised Human Health Risk Assessment ("RHHRA") in December 2014, at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0195; and (2) pose unacceptable risks of brain impairments to children from prenatal exposures of their farmworker mothers, which occur at lower levels of exposure than acute poisoning thresholds and therefore encompass additional chlorpyrifos uses. In addition to seeking an ordinary suspension, we seek an emergency suspension to ensure workers will not be exposed to these risks of concern during the time it will take to put an ordinary suspension in place.

The cancellation petition asks EPA to cancel all uses of chlorpyrifos to protect workers, their families, and the public from the harm caused by chlorpyrifos through our food, drinking water, work, and play.

This petition relies on and expressly incorporates:

- The Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos filed by Natural Resources Defense Council and Pesticide Action Network, North America in September 2007 ("2007 Petition") (Exh. 1);
- EPA's risk assessments and supporting materials compiled in its registration review of chlorpyrifos, and the full docket in registration review in Regulations.gov - Docket EPA-HQ-OPP-2008-0850;
- EPA's proposed revocation of all chlorpyrifos tolerances and the full record in the revocation docket in Regulation.gov – Docket EPA-HQ-OPP-2015-0653; and
- The comments submitted in the above dockets by Earthjustice, Farmworker Justice, the petitioners, NRDC, and PANNA and the other materials submitted with such comments.[1]

[1] Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Apr. 30, 2015), in EPA-HQ-OPP-2008-0850 (Exh. 2); Earthjustice *et al*., Comment on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 5, 2016), in EPA-HQ-OPP-2015-0653 (Exh. 3).

PETITION FOR EMERGENCY AND ORDINARY SUSPENSIONS OF CHLORPYRIFOS USES THAT POSE UNACCEPTABLE RISKS TO WORKERS

SUMMARY

Chlorpyrifos is one of the pesticides most often identified as the culprit when workers and bystanders suffer acute pesticide poisonings. Year after year, chlorpyrifos has been associated with an alarming number of pesticide poisonings, and in many states, it is regularly identified among the five pesticides linked to the highest number of pesticide poisoning incidents. This trend is particularly significant given the widespread under-reporting of pesticide poisonings due to such factors as inadequate reporting systems, fear of retaliation, and reluctance to seek medical treatment.

In 2000, after ending all home uses due to harm to children, EPA re-registered chlorpyrifos, allowing its use to continue in agriculture, despite finding numerous risks of concern to farmworkers that went unmitigated. In its most recent assessment completed in 2014, EPA identified more than 200 uses of chlorpyrifos that pose risks of concern to workers. For pesticide handlers, EPA found that unacceptable risks would remain for 126 exposure scenarios, 32 seed treatment scenarios, and numerous greenhouse worker activities, even with maximum protective clothing and gear and engineering controls. For field workers performing tasks like hand harvesting and thinning, EPA found that many re-entry intervals may need to be doubled to prevent unsafe exposures. EPA's findings demonstrate that chlorpyrifos cannot be used in a way that is safe for workers, and support our call for a full ban on the pesticide in the accompanying petition to cancel all chlorpyrifos uses.

But the harm is happening now. Two full growing seasons have passed since EPA finalized its risk findings, confirming that thousands of workers are regularly being exposed to untenable risks. While EPA proposed in October 2015 to revoke chlorpyrifos food tolerances, it has indicated that it might back away from a complete ban, its proposal does not address nonfood uses, and the ban on food uses would not become effective for months or even years. In the meantime, workers are in harm's way.

By failing to take steps to protect workers from unacceptable risks, EPA has violated its own policies of imposing mitigation to reduce or eliminate such risks, and doing so as the risks are documented, rather than waiting for the conclusion of the registration review process. EPA initiated discussions with the registrants to reduce the harm to workers to no avail. After those discussions broke down, EPA represented to a court in June 2015 that it needed to take regulatory action.

This petition seeks such regulatory action. Not only should EPA initiate cancellation proceedings to end all chlorpyrifos uses, but EPA should also take immediate steps to eliminate the admitted acute poisoning risks of concern to workers that will occur during the cancellation process. First, EPA must suspend the chlorpyrifos uses that it found in its RHHRA pose risks of concern to workers.

Second, EPA must also take immediate steps to stop exposures to pregnant workers that can cause brain damage to their children from prenatal exposure. In its 2014 RHHRA, EPA

acknowledged the extensive body of peer reviewed science correlating *in utero* chlorpyrifos exposure and damage to children's brains in the form of reduced IQ, loss of working memory, motor delays, attention disorders, and structural brain abnormalities, and EPA found that these brain impacts occur at a fraction of the levels EPA uses as its regulatory endpoint to prevent acute poisonings.

Nonetheless, EPA has continued to base its risk assessments on acute poisoning risks, even though it acknowledges this approach is under-protective. Doing so exposes pregnant women to levels of chlorpyrifos that could cause serious brain damage to their children. To make matters worse, EPA used a model developed by Dow AgroSciences based on human studies to try to pinpoint the exposures that correspond to EPA's acute poisoning endpoint. Because the model measures effects directly in people, EPA eliminated a tenfold safety factor that is ordinarily in place to account for uncertainties in extrapolating from animal studies to people. Not only is EPA being under-protective by regulating to prevent acute poisonings when brain damage can occur at a fraction of the exposure limits EPA has set to prevent acute poisonings, but it has reduced safety tenfold. As a result, the risks to children from prenatal exposures are outrageously high. This petition asks EPA to suspend all uses that EPA would have identified as posing risks of concern if it had not eliminated the tenfold safety factor. We do not believe this step will eliminate all harmful prenatal exposures to workers, but it will be a step in the right direction in the near-term while EPA pursues cancellation of all chlorpyrifos uses.

Due to their exposure on the job as well as from food and water, workers are the most at-risk population. EPA should immediately suspend the chlorpyrifos uses that: (1) it has already found pose acute poisoning risks of concern to workers; and (2) EPA would have identified as posing risks of concern if it had not eliminated safety factors because these exposures create untenable risks of damaging children's brains from prenatal exposures. EPA should do so on an emergency basis, followed by an ordinary suspension.

BACKGROUND

I. CHLORPYRIFOS POSES RISKS OF CONCERN TO WORKERS AND THEIR FAMILIES.

Chlorpyrifos is a widely used organophosphate pesticide first registered by EPA in 1965. Organophosphate compounds were developed as chemical warfare agents in World War II and adapted for use as insecticides after the war. It should come as no surprise that chemicals developed as a nerve gas weapons would have deleterious effects on people who come into contact with them when they are used as insecticides.

Chlorpyrifos 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.[2] Eight million pounds are used annually in agriculture, including one million pounds each

[2] EPA, Chlorpyrifos Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures at 7 & Appendix C (July 13, 2012), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0105.

on corn and soybeans.[3] It is also used on golf courses, in greenhouses, and for seed treatments. Its widespread use has exposed people through the air, in water, and through the foods they eat. In California air monitoring, chlorpyrifos was the pesticide having the highest number of detections in its 2011, 2012, and 2013 air monitoring, and surface water monitoring in California agricultural regions in 2006-2010 documented exceedances of California's limits in nearly 10% of the samples.[4] The unacceptable harms to children exposed to chlorpyrifos on lawns and in their homes led EPA to negotiate a phase out-of-home uses in 2000.

Workers are exposed when they handle pesticides and when they re-enter treated fields. Workers, their children, and other bystanders are exposed to chlorpyrifos through drift and volatilization, as well as on their food and in the water they drink. Children can also be harmed by *in utero* exposures.

Chlorpyrifos has repeatedly been among the top pesticides causing acute pesticide poisonings of workers, their families, and others who live near places where it is applied. Year after year, chlorpyrifos has been identified as one of the top five pesticides associated poisonings in many states.[5] California's pesticide exposure incident database contains 289 definite, probable, or possible chlorpyrifos exposure incidents from 2001 through 2013.[6]

The actual incidence of chlorpyrifos poisonings is much higher due to under-reporting of pesticide incidents. In its proposed Worker Protection Standard revisions, EPA rightly acknowledges that "[u]nderreporting of pesticide incidents is a challenge," and assumes that only 25% of acute pesticide incidents are reported.[7] Farmworkers are deterred from reporting

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[3] *Id.*

[4] Vidrio, E., *et al*., Cal. Dept. of Pesticide Regulation, Air Monitoring Network Results (2013), at http://www.cdpr.ca.gov/docs/emon/airinit/amn_vol1_final.pdf; X. Zhang *et al*., Cal. Dept. of Pesticide Regulation, Analysis of Chlorpyrifos Agricultural Use in Regions of Frequent Surface Water Detections in California (2012), at http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/zhang_chlorpyrifos_report.pdf (Exh. 28).

[5] Geoffrey M. Calvert *et al.,* Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005, 51 Am. J. Indus. 51:883, 892, Table V (2008) (Exh. 4) (chlorpyrifos among top five pesticides in agricultural pesticide poisoning cases in California 1998-2005); Washington Department of Health, *Pesticide Data Report Washington State: 2010-2011 Agency Data*, at 26 (June 2013) (Exh. 5)(chlorpyrifos among top five pesticides in definite, probable, and possible agricultural cases in 2010-2011 in Washington).

[6] Exhibit 6, from http://www.cdpr.ca.gov/docs/whs/pisp.htm (query for chlorpyrifos 2001-2013).

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

pesticide illnesses due to fear of retaliation, health care workers often lack the training to diagnose illnesses from pesticide exposures, and there is no national pesticide incident reporting system that could be utilized by clinicians and others who work with farmworkers.[8]

Chlorpyrifos is acutely toxic and causes the sudden onset of what resembles a severe case of flu. 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, and sometimes convulsions, respiratory paralysis and even death in extreme cases. Declaration of Philip J. Landrigan, M.D., M.Sc. (Sept. 2016) (Attachment 1).

Some reported poisoning incidents provide cursory descriptions of the illnesses:

> In 2007, 26 vineyard workers in Tulare County, California, who were poisoned by drift from a nearby almond orchard, experienced nausea, vomiting, dizziness, difficulty breathing, blurred vision, rashes, throat irritation, and numbness in their fingers and tongues.[9]
>
> In 2012, a worker spraying chlorpyrifos developed neurological, gastrointestinal, and respiratory symptoms, even though he was wearing complete personal protective equipment.
>
> In 2014, a worker air blasting chlorpyrifos had chest pains and exacerbated asthma when a branch ensnared his respirator and it fell off.
>
> In 2014, a field worker tying apple tree branches across a field from airblast spraying to bare apple trees went to the emergency room for neurological and gastrointestinal symptoms.
>
> In 2014, a worker pruning in a vineyard went to the hospital for gastrointestinal and

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Learning from Listening: Results of Yakima Farmworker Focus Groups About Pesticides and Health Care (2004) (Exh. 7).

[8] U.S. Gen. Accounting Office, Pesticides on Farms: Limited Capability Exists to Monitor Occupational Illnesses and Injuries 9 (1993), *available at* http://archive.gao.gov/t2pbat4/150612.pdf; *see also* Geoffrey M. Calvert *et al.,* Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005, 51 AM.J. INDUS. MED. 883, 894-95 (2008) (Exh. 4) (discussing reasons why agricultural workers are deterred from seeking health care and why health care professionals misdiagnose acute pesticide poisonings).

[9] Case 2007-689, in Exh. 6.

respiratory symptoms due to drift from airblast spraying in adjacent fields.[10]

In addition to acute poisonings, a growing body of published scientific research links exposure to chlorpyrifos with neuro-developmental harm to children's brains. The attached Declaration of Dr. Philip J. Landrigan, an acclaimed pediatrician, epidemiologist, and occupational medicine expert describes how children's brains are particularly vulnerable to brain damage from low-dose exposures and attests to the overwhelming scientific evidence that chlorpyrifos causes brain damage from prenatal exposures. A robust and extensive body of published animal studies reveals cognitive, motor control, and social behavior impacts from chlorpyrifos exposures. Three rigorous epidemiology studies that track children whose mothers were exposed to organophosphates, including chlorpyrifos, during their pregnancies have found significant neurodevelopmental impairments. Prenatal exposures correlate with harm to children's brains in the form of reduced IQ, loss of working memory, attention 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 are disproportionately exposed to chlorpyrifos and other organophosphates.[11]

In its RHHRA, released in December 2014, EPA acknowledged the strong convergence in the findings from the animal studies and the three mother-child cohort studies and found that prenatal chlorpyrifos exposure is correlated with long-lasting brain damage to children. EPA reiterated this finding and extended it to all organophosphates in its September 2015 Literature Review on Neurodevelopment Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides.[12]

II. THE OVERLAPPING STATUTES REGULATING PESTICIDE USE

EPA regulates pesticides under two, overlapping statutes, the Federal Food, Drug and Cosmetic Act ("FFDCA") and Federal Insecticide, Rodenticide and Fungicide Act ("FIFRA").

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[10] Comment Letter on RHHRA from Washington Department of Health attaching summaries of incidents investigated by the Department of Health and found to be definitely, probably, or possibly due to chlorpyrifos exposure (May 8, 2015) (Exh. 8).

[11] Asa Bradman *et al*., Pesticides and their Metabolites in the Homes and Urine of Farmworker Children Living in the Salinas Valley, CA, 17 J. Exposure Sci. and Envtl. Epidemiology 331 (2007) (Exh. 9); Lesliam Quirós-Alcalá *et al*., Pesticides In House Dust From Urban And Farmworker Households In California: An Observational Measurement Study, Environmental Health 10:19 (2011), http://www.ehjournal.net/content/10/1/19 (Exh. 10); Gloria D. Coronado *et al*., Organophosphate Pesticide Exposure and Residential Proximity to Nearby Fields: Evidence for the Drift Pathway, J Occup Environ Med. (Aug. 2011); 53(8): 884–891. doi:10.1097/JOM.0b013e318222f03a (Exh. 11); Robert Gunier *et al*., Determinants of Agricultural Pesticide Concentrations in Carpet Dust, 199 Envtl. Health Perspectives 970 (July 2011) (Exh. 12); Asa Bradman *et al*., Determinants of Organophosphorus Pesticide Urinary Metabolite Levels in Young Children Living in an Agricultural Community, 8 Intl. J. Envtl. Research & Public Health 1061 (2011) (Exh. 13).

[12] https://www.regulations.gov/%23!documentDetail;D=EPA-HQ-OPP-2008-0440-0039.

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).

EPA issues tolerances to establish 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. *Id*. § 346a(b)(2)(C)(ii)(I), (II). "Aggregate exposure" includes "all anticipated dietary exposures and all other exposures for which there is reliable information," including drinking water exposures. *Id*. § 346a(b)(2)(A)(ii); *see also id*. § 346a(b)(2)(D)(vi). EPA must also assess the impacts on infants and children of cumulative exposures to pesticides that have a common mechanism of toxicity. *Id*. § 346a(b)(2)(C)(i)(III). EPA has the authority to revoke a tolerance if it finds a pesticide residue would not be safe. *Id*. § 346a(b)(2)(A)(i).

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 only be registered for a food use if 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).

FIFRA authorizes EPA to issue a notice of intent to cancel a pesticide registration if it appears that the pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136(b). Issuance of a notice of intent to cancel has been characterized as a determination that the administrative process should commence because "there is a substantial question about the safety of a registered pesticide," *Envtl. Defense Fund v. Ruckelshaus*, 439 F.2d 636, 643 (D.C. Cir. 1989), and this standard has been described as "even less rigorous than the typical 'reason to believe' with which many agencies begin enforcement proceedings." *National Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 643 (D.C. Cir. 1989). It has long been recognized that the burden of persuasion is on the registrant in a cancellation proceeding. *Envtl. Defense Fund v. Ruckelshaus*, 439 F.2d 584, 592-93 (D.C. Cir. 1971).

The notice merely starts the cancellation process; in practice, it can take many years before the pesticide use actually ends. First, before issuing a notice of intent to cancel, EPA generally conducts a lengthy review with numerous risk assessments and opportunities for public comment, and it must generally provide the Department of Agriculture and EPA's Scientific

Advisory Panel at least 60 days to comment on the notice. 7 U.S.C. §§ 136(b), 136w(d). Second, the administrative hearing process can take time. For example, after EPA issued a notice of intent to cancel most chlordane uses in 1974, cancellation proceedings spanned more than three years. The parties reached a settlement in 1978 that phased out the registrations over four more years and allowed existing stocks to be used even after the phase out ended. *National Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 639 (D.C. Cir. 1989). Third, the administrative law judge determination can be appealed to the Environmental Appeals Board, and the Board's determinations can be appealed to a Circuit Court of Appeals. Moreover, even when a registration is cancelled, EPA often allows existing stocks to be used for years, as illustrated by the chlordane settlement. *See, e.g., id*.; 56 Fed. Reg. 29,362 (June 26, 1991) (EPA's existing stocks policy).

Because ending the use of harmful pesticides can take so long, FIFRA authorizes EPA to suspend a pesticide use pending cancellation if it "determines that action is necessary to prevent an imminent hazard during the time required for cancellation." 7 U.S.C. § 136d(c). FIFRA defines "imminent hazard" as "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment," which includes harm to people. *Id*. § 136(l).

There are two types of suspensions: (1) ordinary; and (2) emergency. To issue an ordinary suspension, EPA must; (1) provide advance notice to the registrant that includes imminent hazard findings; (2) issue a notice of intent to cancel prior to or concurrently with the suspension notice; and (3) afford the registrant an opportunity for an expedited hearing on whether an imminent hazard exists. *Id*. § 136d(c)(1). A final order following a hearing is subject to judicial review solely on the imminent hazard issue, but the only available judicial remedy is a stay of the suspension order pending the outcome of the cancellation proceeding. *Id*. § 136d(c)(4).

EPA may issue an emergency suspension order when EPA determines that an emergency exists that does not permit a hearing to be held in advance of notification to the registrant of the suspension. The emergency suspension order remains in effect during any hearing and pending completion of a final order on suspension. *Id*. § 136d(c)(3).

This petition seeks both an ordinary and an emergency suspension to protect workers and their families from pesticide poisonings and other harm from chlorpyrifos.

III. EPA HAS FAILED TO TAKE ACTIONS TO PROTECT WORKERS FROM THE SERIOUS RISKS EPA HAS FOUND FROM CHLORPYRIFOS.

EPA has documented serious risks to workers as part of its regulatory reviews of chlorpyrifos. Based on EPA policy and specific conclusions it has reached regarding chlorpyrifos, EPA must obtain mitigation to reduce or eliminate such risks, and if such mitigation is not voluntarily forthcoming from the registrant, EPA must pursue regulatory action. For chlorpyrifos, EPA tried in 2015 to convince the registrants to reduce harmful worker exposures without success. Over a year ago, it told a court that it needed to initiate regulatory action, but it has not done so. Now is the time for EPA to act.

A. EPA Has Found That Hundreds of Chlorpyrifos Uses Pose Risks of Concern to Workers.

When EPA reviews a pesticide to determine whether it meets the statutory safety standards, it conducts a series of risk assessments addressing, for example, food, drinking water, drift and volatilization exposure to children and bystanders, and workers. As its standard approach in assessing worker risks, EPA identifies risk levels of concern to workers and determines whether workers will be exposed to levels of chlorpyrifos that exceed those risk levels. For pesticide handlers, if it finds risks of concern, EPA first tries to reduce the risks through the use of protective clothing and gear. If the risks of concern are not eliminated, EPA then considers requiring engineering controls, like closed mixing systems. If none of these strategies eliminates the risks of concern, EPA will consider reducing application rates or eliminating the application method. For risks of concern to field workers, EPA uses restricted re-entry intervals to keep field workers out of the fields until exposures will be reduced. Only if re-entry intervals cannot eliminate the risks of concern will EPA consider stopping the activity or the use of the pesticide. This is the methodology EPA has used in assessing worker risks from chlorpyrifos and the other organophosphates.[13]

1. In its 2002 Interim Re-Registration of Chlorpyrifos, EPA Found, But Did Not Fully Mitigate, Acute Poisoning Risks of Concern to Workers.

The 1996 FQPA gave EPA a 2006 deadline to ensure that pesticides already in use, like chlorpyrifos, comply with safety standards adopted after the pesticides came on the market in the United States. EPA completed its first risk assessment of chlorpyrifos as part of its interim re-registration in 2002 and of the organophosphates cumulatively as a class in 2006.

In its occupational risk assessments, EPA focused on acute poisonings. To determine risks of concern, EPA first identified a regulatory endpoint, often called a point of departure, which is typically a level of exposure from an animal or epidemiology study that is not observed to cause an adverse effect (called a no observed adverse effect exposure level or NOAEL), or that is observed to pose a low risk (called a low observed adverse effect exposure level or LOAEL). For organophosphates, EPA identified exposures that result in less than 10% red-blood cell cholinesterase inhibition as the point of departure for acute pesticide poisonings. EPA then decides what safety or uncertainty factors to include in its risk calculations. In its 2002 chlorpyrifos re-registration determination, EPA used a total safety factor of 100, consisting of one tenfold safety factor that accounts for uncertainties in extrapolating from animal studies to humans (the inter-species safety factor), and another tenfold safety factor to account for variations among humans because people have different susceptibilities based on their age, developmental life stage, genetics, health conditions, diet, and exposures to other chemicals or hazards (the intra-species safety factor). For each activity reviewed in its occupational risk assessment, EPA established a margin of exposure ("MOE") by dividing the point of departure by the level of exposure associated with that activity. A MOE of less than 100 (the product of

[13] Pesticide Registration Notice 2000-9, at 5 (Sept. 29, 2000), *available at* https://www.epa.gov/sites/production/files/2014-04/documents/pr2000-9.pdf.

the two safety factors) is identified as an acute poisoning risk of concern for the workers conducting that activity.

When EPA assessed risks to workers who handle chlorpyrifos, it identified risks of concern from a variety of activities, including mixing and loading various pesticide formulations and applications using certain types of equipment like airblast sprayers and backpack sprayers. To reduce risks, EPA decided that the labels would need to be amended to require personal protective clothing, enclosed cockpits for aerial applications, water-soluble packaging for some formulations, and reductions in some application rates. Some risks of concern remained even with the added mitigation. EPA found risks of concern to field workers, but believed they could be eliminated with reduced application rates or longer re-entry intervals. EPA lacked sufficient information to assess fully risks from seed treatment and to workers who enter greenhouses after pesticide spraying.[14]

UFW and others challenged EPA's re-registration of chlorpyrifos in part because of the unmitigated worker risks. A near-final settlement of that case fell apart when intervening precedent deprived the court of jurisdiction. *UFW v. EPA*, No. 07-3950-JF (N.D. Cal. Filed Aug. 1, 2007). UFW and others then pressed EPA to address risks to workers and their families in the registration review process and by seeking EPA action on the 2007 petition to ban chlorpyrifos.

2. EPA's Ongoing Registration Review Has Documented Acute Poisoning Risks of Concern to Workers.

FIFRA directs EPA to conduct reviews of registrations every 15 years to ensure the pesticide uses meet evolving EPA standards in light of emerging scientific and empirical evidence. 7 U.S.C. § 136a(g)(1)(A). EPA moved the organophosphate pesticides, and chlorpyrifos in particular, to the head of the line due to their risks and the 2007 petition to ban chlorpyrifos.

As the foundation for that review, EPA is conducting human health risk assessments, and it is again basing those risk assessments on acute poisoning risks using 10% red-blood cell cholinesterase inhibition as its regulatory endpoint and an MOE of 100.[15] EPA addressed two

[14] Interim Reregistration Eligibility Decision for Chlorpyrifos (Feb. 2002), at https://nepis.epa.gov/Exe/ZyNET.exe/200008BM.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2000+Thru+2005&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C00thru05%5CTxt%5C00000003%5C200008BM.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL

[15] The 100X safety factor applies to women of child-bearing years. For children, EPA reduced the safety factor to 40X for chlorpyrifos and 50X for the chlorpyrifos oxon, but it used women of

sets of risks to workers in its occupational risk assessment: (1) risks to handlers who mix, load, and apply pesticides; and (2) risks to field workers who enter the fields after spraying to perform various tasks, such as weeding, thinning, and harvesting.

a. Risks of Concern to Pesticide Handlers

For the handlers, EPA assessed the registered chlorpyrifos uses based on the maximum application rate and the type of application equipment that may be used, such as helicopters, tractor-drawn equipment, open and closed mixing and loading systems, and application via hand-held equipment. For example, the maximum application rate of chlorpyrifos on citrus is six pounds per acre in Arizona and California using aerial, airblast, or groundboom spraying, but only one pound per acre using tractor drawn spreaders, and four pounds per acre using backpack sprayers. Preliminary Human Health Risk Assessment at 78 (June 30, 2011), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0025; Chlorpyrifos: Occupational and Residential Exposure Assessment (2011), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0028. Two pounds per acre can be applied using airblast equipment on grapes, while one pound per acre can be applied using a backpack sprayer. *Id*. And on Christmas trees, one pound per acre can be applied using airblast equipment, slightly less by helicopter, and less than 1/10 of that amount for backpack sprayers, handguns, and handwands. *Id*. at 80.

The other variable in EPA's risk calculation is the amount and type of protective clothing and equipment required. The Revised Human Health Risk Assessment explains: "In order to determine what level of personal protection is required to alleviate risk concerns and to ascertain if label modifications are needed, steady state exposure and risk estimates were calculated for occupational handlers of chlorpyrifos for a variety of scenarios at differing levels of personal protection including engineering controls." RHRRA at 102. Estimates of dermal and inhalation exposure were calculated for various levels of personal protective equipment ("PPE"). RHHRA at 100.

The current labels require that handlers use baseline PPE, consisting of long-sleeved shirt, long pants, shoes and socks, as well as coveralls, chemical resistant gloves, and dust/mist respirators. If risks of concern exist using the currently required PPE, EPA first evaluates increasing levels of PPE. If risks of concern remain, EPA then considers requiring engineering controls, like enclosed cabs or cockpits, water-soluble packaging, and closed mixing/loading systems. RHHRA at 100; Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review at 33 (Dec. 29, 2014), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0196. Most, if not all, current chlorpyrifos labels already require double layers of clothing, gloves, and respirators. EPA found that any additional PPE would burden workers with decreased dexterity and increase heat and respiratory stress. RHHRA at 100.

More than half of the handler scenarios pose risks of concern at the levels of PPE and

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child-bearing years as the prototype in its worker risk assessment. Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review at 32 (Dec. 29, 2014), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0196.

engineering controls currently required by the label. Updated Occupational Assessment at 10. EPA reviewed 285 handler scenarios, and found that only 132 did not pose risks of concern. EPA stated that 27 exposure scenarios could be mitigated if additional protective gear or engineering controls were required, but its data analysis suggest that the additional mitigation would be engineering controls, not additional PPE. Appendix F: Summary of Occupational Handler Risk Estimates, in EPA-HQ-OPP-2008-0850-0196 (where EPA identified risks of concern, engineering controls sometimes reduced that risk below levels of concern, but additional PPE beyond what is currently required by the label rarely did). EPA did not specify any particular engineering controls that would be appropriate and would eliminate the risk of concern.

The remaining 126 scenarios "remain a concern regardless of the levels of personal protection and engineering controls considered." Updated Occupational Assessment at 10. Risks of concern cannot be mitigated to acceptable levels for handlers who mix and load various formulations for aerial spraying, chemigation (irrigation), air blast, groundboom, and tractor-drawn spreaders, nor for workers applying some chlorpyrifos formulations by handwand, backpack sprayers, handguns, hand dispersal, and belly grinders, or for flaggers. Appendix F.

EPA often found risks an order of magnitude more severe than its level of concern. For example, EPA identified margins of exposure that were less than 10 for certain types of applications to almonds, walnuts, pecans, corn, alfalfa, cherries, strawberries, citrus, tree fruits, asparagus, and ornamental and Christmas trees. Appendix F. The risks from airblast applications are alarming, with some MOEs of less than 5 and some even less than 1. Appendix F at Table F.2. Recalling that the margin of exposure is designed to prevent exposures close to the regulatory endpoint, an MOE of 10 poses a tenfold greater risk than an MOE of 100, and an MOE of 1 exposes the worker to the actual dose that EPA's regulatory approach is designed to avoid. EPA found that, to reduce these risks, it would likely be necessary to reduce the application rate or prohibit certain types of application equipment and mtehods. Updated Occupational Assessment at 10. EPA also found that 32 seed treatment scenarios pose risks of concern to occupational handlers performing seed treatment activities in commercial settings. Updated Occupational Assessment at 10; RHHRA at 103.

b. Risks of Concern to Field Workers

EPA found risks of concern to field workers who enter the fields to perform various tasks. To protect field workers, EPA establishes prohibitions on entering the fields during a re-entry interval ("REI") after the pesticide application. Most chlorpyrifos labels have a 24-hour re-entry period, but some, *e.g.*, tree fruit activities, have an REI of up to 5 days. EPA assessed dermal exposures only without considering inhalation exposures. Updated Occupational Assessment at 37. More than 20% of the activities expose workers to unacceptably high risks of pesticide poisoning. Of 55 scenarios, EPA found that 12 activities, including irrigation, hand harvesting, scouting, and thinning, pose risks of concern for up to 10 days after application. Updated Occupational Assessment at 11, 39; RHHRA at 105.

For ornamental production in greenhouses, EPA found that an REI increase of up to 5 days may be needed to alleviate risks to workers from some formulations. Updated Occupational Assessment 39; RHHRA at 105. EPA also assessed exposures to the chlorpyrifos oxon in

greenhouses because formation of the oxon appears to be greater, it deactivates more slowly in greenhouses, and EPA has found that it is more toxic than the parent chlorpyrifos. Updated Occupational Assessment at 11; 80 Fed. Reg. 69,080, 69,082 (2015). An REI increase of up to 6 days may be needed to alleviate risks for some formulations and possibly an increase to more than 35 days for one. Updated Occupational Assessment at 11, 40-41; RHHRA at 106-07.

3. EPA Found that Children are at Risk of Brain Damage from Low-Level Prenatal Exposures and Therefore Even More Worker Activities Pose Risks of Concern.

EPA's revised human health risk assessment reviewed the "considerable and growing" body of peer-reviewed scientific literature linking neurodevelopmental effects in children to chlorpyrifos exposures. RHHRA at 25. EPA found a pattern of adverse neurodevelopmental outcomes from these studies and called the consistency of the findings of neurological effects "striking" in light of the considerable differences in study design. *Id*. at 26. Based on the peer-reviewed scientific literature of both experimental toxicology animal studies epidemiology studies, and mechanistic studies, EPA found that prenatal exposures to chlorpyrifos result in adverse neurodevelopmental effects, including delays in mental development, attention deficit disorder, pervasive developmental disorders in early childhood, and intelligence decrements in school-age children. RHHRA at 42-48.

EPA determined that the effects occurred at exposures that were too low to suppress the mothers' cholinesterase by anywhere near 10% cholinesterase inhibition, EPA's regulatory endpoint. EPA stated that the measured exposures "are likely low enough that is unlikely to result in AChE [cholinesterase] inhibition" and noted that the SAP in 2012 concurred. *Id*. at 45. In accordance with the recommendations of the 2012 SAP, EPA conducted a dose reconstruction analysis of the Columbia study and found that the highest exposure would lead to predicted cholinesterase inhibition far less than 10%. *Id*. at 46. The harmful effects to the children therefore occurred at doses lower than those that would cause 10% cholinesterase inhibition in the mothers. This means that 10% cholinesterase inhibition is not the most sensitive endpoint and is under-protective.

Based on its findings, EPA has retained a tenfold FQPA safety factor for children. In addition to the routinely used inter-species and intra-species safety factors, the FQPA directed EPA to add an additional safety factor to protect children from harm in the face of data deficiencies or evidence of prenatal toxicity. EPA appropriately retained a 10X FQPA safety factor due to fetal toxicity and the gaps in data and understanding of the mechanism and precise doses at which the neurodevelopmental impacts to children occur.

Despite finding that children experience neurodevelopmental damage from prenatal exposures less than those that cause 10% cholinesterase inhibition, EPA still used 10% cholinesterase inhibition as its regulatory endpoint in the RHHRA. In doing so, EPA is violating its policy of choosing the most sensitive endpoint in assessing risk and making registration and tolerance decisions.[16] Given EPA's findings that the peer-reviewed scientific evidence shows that children

[16] EPA OPP, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment at 8 (2002), at https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf. *See*,

may suffer serious neurodevelopmental damage at lower prenatal exposures, EPA is being under-protective. EPA has explicitly found as much and presented to the SAP a point of departure drawn from cord blood in the Columbia study to protect against brain damage to children from low-dose prenatal exposures.[17] While the SAP did not believe the point of departure could be based on a single study, it agreed with EPA that the point of departure based on 10% cholinesterase inhibition is under-protective in light of the prenatal harm at lower exposures.[18] The SAP agreed "that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell acetylcholinesterase (AChE) inhibition (i.e., toxicity at lower doses)."[19] The SAP expressed concern that "the PoDs [points of departure] based on AChE inhibition . . . may not be adequately protective of human health."[20] EPA's occupational risk assessment grossly under-estimates the risks to workers by using 10% cholinesterase inhibition as the targeted effects level when it has found that neurodevelopmental impairments to children occur *in utero* at far lower doses.

To make matters worse, EPA used a physiologically based pharmacokinetic ("PBPK") model developed by Dow AgroSciences, based primarily on studies that intentionally dose people, to try to pinpoint the levels of exposure that will produce 10% cholinesterase inhibition in people. The model is designed to predict chlorpyrifos exposures that produce 10% cholinesterase inhibition based on body weight, metabolism, and other factors. For years, Dow has been urging EPA to use its model and to eliminate standard safety factors routinely used in risk assessment to account for uncertainty. In 2011, EPA's SAP reviewed Dow's PBPK model and identified numerous scientific concerns that are described in the comments submitted by Earthjustice *et al.*

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e.g., http://www.epa.gov/pesticides/reregistration/atrazine/atrazine_update.htm, "Reproductive effects are the most sensitive effects observed in atrazine toxicity tests and, as such, our efforts to regulate the pesticide to protect against these effects through drinking water exposure will protect against all other effects that occur at higher levels."

[17] EPA, Transcript of EPA FIFRA SAP Meeting on Chlorpyrifos: Analysis of Biomonitoring Data. Meeting held April 19-21, 2016 (EPA-HQ-OPP-2016-0062), at https://www.epa.gov/sites/production/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf.

EPA OPP, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies (Mar. 11, 2016), at https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0062-0005.

EPA, Chlorpyrifos: Analysis of Biomonitoring Data - Presentation to the FIFRA SAP, April 19, 2016, at https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0062-0117.

[18] Transmittal of Meeting Minutes of the April 19-21, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with "Chlorpyrifos: Analysis of Biomonitoring Data" (July 25, 2016), at https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0062-0140.

[19] *Id*. at 18, 25, 52-53; *see also id*. at 64.

[20] *Id*. at 22.

on the RHHRA (at 33-35). Nonetheless, EPA used the flawed model without seeking further SAP review after Dow made some changes to the model. Dow's model also uses data from human dosing studies, despite criticisms of the informed consent protocol by an EPA ethics reviewer and unresolved scientific flaws. *Id*. at 36-42.

Despite these scientific and ethical concerns, EPA used the Dow model in its RHHRA and relied on the model to reduce safety factors. EPA eliminated the inter-species safety factor altogether, and it shrunk the intra-species safety factor from 10X to 4X-5X for children's exposures, although it retained a 10X for women's exposures since the Dow model lacks data reflecting how a pregnant woman's body processes chlorpyrifos. Professors and academic researchers submitted comments objecting to EPA's failure to require more stringent limits to guard against neurological harm to children.[21]

What EPA gave with one hand by retaining the 10X FQPA safety factor, it took away with the other. Given the data linking chlorpyrifos exposure to neurodevelopmental effects in children, and the levels of chlorpyrifos to which pregnant farmworkers are exposed, had EPA applied the proper safety factors, it would concluded that all uses of chlorpyrifos poses unacceptable risks to children and most to workers. It is indefensible for EPA to use Dow's model to eliminate or reduce the safety factors in light of the neurodevelopmental effects that occur at lower doses than those incorporated into the model. This approach violates EPA's policy of setting regulatory limits based on the most sensitive endpoint at which adverse effects occur and disregards EPA's mandates to protect children from prenatal toxicity.

4. EPA's Findings Under-estimate Worker Exposure.

EPA's risk findings are the tip of the iceberg. EPA's worker risk assessment under-estimates the risks chlorpyrifos poses to workers because of several omissions and flawed assumptions. First, it ignores inhalation exposures to post-application workers. Updated Occupational Assessment at 37.

Second, it ignores exposures from direct drift. Every year, workers are poisoned by pesticides when they move offsite onto neighboring fields and workers inhale droplets, particles or vapors that have drifted offsite.[22] The California Pesticide Illness Surveillance Database identifies 147 pesticide incidents in 2013 from drift, and 1297 from 2001-2013.[23] In Washington, 150 workers were impacted in drift incidents in 2007-2011,[24] the number of reported drift incidents increased substantially from 2012 to 2014, and drift complaints comprise over 1/3 of total complaints

[21] Comments on RHHRA from Drs. Whyatt, Slotkin & Hattis (Apr. 30, 2015) (Exh. 14); Comments on RHHRA from Dr. Faustman (Apr. 30, 2015) (Exh. 15).

[22] Soo-Jeong Lee *et al*., Acute Pesticide Illnesses Associated with Off-Target Pesticide Drift from Agricultural Applications: 11 States, 1998-2006, 119 Envtl. Health Perspectives 1162 (2011) (Exh. 16).

[23] http://apps.cdpr.ca.gov/calpiq (query run for drift incidents in 2013 and 2001-2013 involving agricultural spraying of pesticides).

[24] Pesticide Data Report Washington State at 28 (Exh. 5).

investigated.[25]

EPA ignores field workers' exposure to drift because the pesticide labels already prohibit spraying pesticides directly on people. Pesticides: Agricultural Worker Protection Standard Revisions, 80 Fed. Reg. 67,496, 67,521 (Nov. 2, 2015). EPA acknowledges that the "do not contact" direction and other label requirements are not "by themselves sufficient to protect workers and bystanders from being directly contacted by pesticides that are applied," *id*., yet it does not account for these exposures and drift incidents in its risk assessments. Instead, EPA looks only at drift that deposits in a field and exposures to the pesticide residues from touching the treated crop at a later time. This approach captures only a small fraction of the harm from pesticide drift and ignores the reality that the general label statement prohibiting drift onto people is inadequate to prevent drift-induced poisonings and neurodevelopmental effects.[26]

Third, EPA under-estimates risks to workers because it makes assumptions that are at odds with the real-life circumstances of the workers. For example, EPA assumes a body weight of 152 pounds, yet many younger female workers weigh less than that. It also assumes an 8-hour work day and 5-day work week. In 2008, the USDA reported that from 68-81% of hired farmworkers and 78-82% of wage and salary workers worked more than 40 hours per week. In both groups, more than 80% of the non-citizen workers worked more than 40 hours per week.[27] One of the reported incidents in California involved a mixer/loader/applicator who became sick after handling chlorpyrifos for 9 days, and another involved an applicator who became sick after several weeks of 14-hour days.[28] EPA assumed that workers shower daily and their exposures stop when the workday ends. Updated Occupational Risk Assessment at 14. Not only do farmworkers work longer days and weeks than EPA assumed, but their exposures do not stop at the end of work day because most workers lack access to showering and laundering facilities that

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[25] Washington State Dept. of Agriculture, 2013 Annual Report to the Legislature as Required by RCW 15.58.420 and RCW 17.21.350, *available at* http://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?fileName=399-PesticideManagementLegislativeReport2013Rev_3b6644dd-c2e0-451e-bc33-105383a60931.pdf.

[26] EPA found that the "do not contact" and other label requirements are not "by themselves sufficient to protect workers and bystanders from being directly contacted by pesticides that are applied." *Id*. EPA found it necessary to afford additional protection in the form of application exclusion zones that prevent workers from being in treated areas during applications. *Id*. at 67,521-22 ("additional measures are needed" because the label do not contact language has proven "insufficient" to prevent exposure of workers to drift). The requirement to suspend applications in application exclusion zones when workers or other people not handling the application are present, however, is not effective until January 1, 2018. 40 C.F.R. § 505(b).

[27] W. Kandel, USDA, A Profile of Hired Farmworkers: A 2008 Update, at 16 (July 2008), *available at* http://www.ers.usda.gov/publications/err-economic-research-report/err60.aspx.

[28] California Case 2007-571 in Exh. 6, and 1996-1293 in California Pesticide Incident Surveillance Reporting.

would end the exposure and prevent the workers from contaminated taking home dust.[29]

Fourth, EPA over-estimates the efficacy of protective clothing and engineering controls in the face of evidence that significant exposures remain. Use of PPE for protection during pesticide loading and mixing of pesticides is inadequate. "Black light and fluorescent tracers dramatically demonstrate the extent to which pesticide exposure may occur, even with the use of PPE."[30] In addition, it is well recognized that a full set of protective clothing is "cumbersome and can be very uncomfortable in hot weather, causing workers to shed their protective gear."[31] Indeed, an analysis performed by EPA scientists concluded that wearing a full body Tyvek coverall over a shirt and pants would likely produce an internal body temperature of 38.3 degrees centigrade (or 100.94 degrees Fahrenheit), at the cusp of the body temperature that is considered a sign of heat stress.[32] Thus, if a pesticide handler wore full PPE while mixing and loading pesticides, there would be a real risk that heat stress symptoms would reduce his/her alertness, creating a potential hazard, and EPA recognizes as much.[33]

Moreover, many employers do not provide adequate PPE to their employees. Among the Washington State pesticide handlers who suffered an acute pesticide related illness in 2008, 56% were missing at least one piece of required PPE; and the most common reason was that the employer did not provide it.[34] Some farmworkers may be reluctant to request the missing PPE for fear of retaliation; other farmworkers may not make this request because they do not know they are entitled to PPE, or that it is needed. In other instances, the PPE provided by the employer was in poor repair or did not fit well – problems that were especially prevalent with respirators and goggles.[35]

EPA's findings that hundreds of chlorpyrifos uses pose risks of concern under-estimate the real

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[29] Quirina M. Vallejos *et al.*, Migrant Farmworkers' Housing Conditions Across an Agricultural Season in North Carolina, 54 Am. J. Indus. Med. 533 (2011) (most labor camps in North Carolina lacked adequate bathing and laundry facilities); 80 Fed. Reg. at 67,533 (Worker Protection Standard revisions do not require that employers provide showers for handlers).

[30] Frederick M. Fishel, Exposing Pesticide Exposure Using Fluorescent Tracer Dyes (2014), *available at* http://edis.ifas.ufl.edu/pdffiles/PI/PI19900.pdf (Exh. 17).

[31] Jacobs, WW. 1982. Closed Mixing and Loading Systems and Pesticide Containers, in PESTICIDE TANK MIX APPLICATIONS: FIRST CONFERENCE 58, 61 (John F. Wright *et al*. eds., 1982) (Exh. 18).

[32] Lunchick, C, *et al.* 1988. Engineering Controls and Protective Clothing in the Reduction of Pesticide Exposure to Tractor Drivers, in PERFORMANCE OF PROTECTIVE CLOTHING: SECOND SYMPOSIUM 605, 608 (Seymour Zack Mansdorf *et al.* eds., 1988) (Exh. 19).

[33] *Id*.

[34] Washington State Department of Health, Pesticide Incident Reporting & Tracking Panel, 2009, Annual Report 61-64 (2009) (Excerpts in Exh. 20).

[35] *Id*. at 62.

risks workers face in the fields. Moreover, EPA has an obligation to consider cumulative effects from pesticides that have a common mechanism of toxicity. 21 U.S.C. § 346a(b)(2)(C)(i)(III); EPA Office of Pesticide Programs, Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses (December 2009).[36] Organophosphates have such a common mechanism in that they all suppress cholinesterase and cause acute pesticide poisonings. For that reason, EPA conducted a cumulative organophosphate risk assessment in 2006 as part of its re-registration process. And in September 2015, EPA determined that the scientific evidence documents neurodevelopmental effects on children from organophosphate pesticides *as a class* and that the FQPA safety factor must be retained.[37] In its registration review process, EPA is conducting risk assessments for each organophosphate pesticide individually, and it is consistently finding acute poisoning risks of concern to workers who are exposed to organophosphates through their work. As with chlorpyrifos, EPA is not eliminating the uses that pose such risks during the registration review process. As a result, workers are being cumulatively exposed to the same types of risks from all of the organophosphate pesticides they handle or encounter in their work.

B. EPA Recognizes Its Obligation to Take Regulatory Action to Prevent or Reduce Worker Risks, But Has Failed To Do So.

In December 2014 in its RHHRA, EPA finalized its findings of risks of concern to workers from more than 200 activities and, in its partial response to the 2007 petition to ban chlorpyrifos, EPA noted that these risks need to be reduced or eliminated. RHHRA at 10-11; EPA Provisional Response to 2007 Chlorpyrifos Petition (March 26, 2015), in *In re Pesticide Action Network North America v. EPA*, No. 14-72794 (9th Cir.). To date, however, it has taken no actions to protect workers from these risks.

EPA has a policy of mitigating risks that emerge during registration review even before that review has been completed. This policy led EPA to press the chlorpyrifos registrants to amend their labels to require buffers around schools, homes, and other populated areas to protect bystanders from pesticide drift. RHHRA at 8-9; Spray Drift Mitigation Decision for Chlorpyrifos (July 2012), at EPP-HQ-OPP-2008-0850-0103 ("Where risks are identified early in the registration review process and opportunities for early mitigation exist, the Agency will pursue those opportunities as they arise, rather than waiting for completion of a chemical's registration review in order to mitigate the risks."). That policy should similarly propel EPA to obtain immediate protections for workers, even while revocation (and cancellation proceedings) are in progress.

In keeping with this policy, EPA represented in March 2015 that it "has already begun discussions with the chlorpyrifos registrants regarding mitigation of worker risks."[38] By June

[36] *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0889-0002.

[37] EPA OPP, Literature Review on Neurodevelopmental Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides (Sept. 15, 2015), at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0119-0023.

[38] Letter from J. Housenger, Director OPP, to A. Colangelo at 4 (March 26, 2015), submitted with status report in *In re PANNA*, No. 14-72794 (9th Cir. Mar. 2015) (Exh. 21).

2015, the negotiations with industry to stop these uses or reduce exposures had broken down. EPA then told the 9th Circuit that regulatory action would be necessary, but more than a year has passed and EPA has failed to initiate regulatory action. EPA Status Report in *In re Pesticide Action Network North America v. EPA*, No. 14-72794 (9th Cir. June 30, 2015).

EPA made these representations to the 9th Circuit in a case brought by other parties – Pesticide Action Network and Natural Resources Defense Council – seeking a writ of mandamus ordering EPA to take final action on a 2007 petition to cancel all chlorpyrifos uses. In August 2015, the 9th Circuit Court of Appeals issued a writ of mandamus characterizing EPA's response to the petition as "a litany of partial status reports, missed deadlines, and vague promises of future action," and finding EPA's delay "egregious." *In re Pesticide Action Network North America v. EPA*, 798 F.3d 809, 811 (9th Cir. 2015). Noting that "EPA's latest status report says that it has 'concerns about the risks to farmworkers' who are exposed to chlorpyrifos and that 'complex regulatory proceedings' may be necessary," *id*. at 814, the court stated that there are "considerable human health interests prejudiced by the delay." *Id*. It concluded that "[i]ssuing a writ of mandamus is necessary to end this cycle of incomplete responses, missed deadlines, and unreasonable delay." *Id*. at 813. The court ordered EPA to issue a response to the petition by October 31, 2015.

By that deadline, EPA proposed to revoke all food tolerances based on drinking water contamination that poses harm to all consumers and especially grave risks to infants. 80 Fed. Reg. 69,080 (Nov. 6, 2015) (EPA "is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of section 408(b)(2) of the Federal Food, Drug, and Cosmetic Act."). While UFW, Earthjustice, and Farmworker Justice support this proposal, it does not extend to nonfood uses in the fields, greenhouses and tree farms. Moreover, EPA has indicated that it might back away from that proposal in many parts of the country.

The 9th Circuit has given EPA until March 31, 2017 to make a final revocation determination and to take final action on the 2007 petition. While we may soon see forward progress, EPA has construed the 2007 petition to encompass only a subset of chlorpyrifos uses, excluding nonfood uses and harm to workers, and there is no guarantee EPA will ban all the food uses. Even as to the food uses, EPA's proposal would allow them to continue for 180 days after it finalizes any bans, and Dow AgroSciences and agricultural trade groups will seek further delay through administrative reviews in EPA and from the courts, which could drag on for years.

EPA appears to be waiting for the revocation to be final before initiating cancellation proceedings. While such streamlining may make sense as a way to minimize administrative burdens, it leaves workers and their families unprotected for an unacceptable amount of time. And such streamlining may do little to advance regulatory action to end the nonfood uses that harm workers. Such proceedings could take another 3-5 years.

IV. EPA MUST IMMEDIATELY SUSPEND CHLORPYRIFOS USES THAT POSE RISKS OF CONCERN TO WORKERS.

Under the case law, imminent hazard is not limited "to a concept of crisis. It is enough if there is substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative process." *Envtl. Defense Fund, Inc. v. EPA*, 465

F.2d 528, 540 (D.C. Cir. 1972). EPA "is not required to establish that the product is unsafe in order to suspend registration," because it is the registrant that bears the burden of establishing safety at all times. *Envtl. Defense Fund, Inc. v. EPA*, 548 F.2d 998, 1004 (D.C. Cir. 1976). Moreover, "once the Administrator has found that a risk inheres in the use of a pesticide, he has an obligation to explain how the benefits of continued use outweigh that risk." *Id*. at 1012. If the registrant has not demonstrated benefits from particular uses, including the lack of available, feasible alternatives, then EPA's findings of serious harm over the next few years warrant a suspension.

Here, even based on a risk assessment that significantly understates risk, EPA has found that workers face acute poisoning risks of concern from hundreds of application and field activities. By EPA's own calculations, thousands of workers face these risks every year, putting them at risk of being among the farmworkers poisoned every year by chlorpyrifos. Moreover, EPA significantly understated the risks from chlorpyrifos use by reducing safety factors in reliance on Dow's model that is designed to pinpoint acute poisoning risks and not brain damage to children from prenatal exposures. Two growing seasons have passed since EPA finalized its worker risk assessment and its risk of concern findings, yet it has failed to take steps to protect workers and prevent senseless poisonings and neurological harm to workers' children.

EPA must take steps immediately to suspend the uses of chlorpyrifos that: (1) it has already found pose acute poisoning risks of concern to workers; and (2) EPA would have identified as posing risks of concern if had not eliminated safety factors, as a way to reduce the risks of damaging children's brains from prenatal exposures. Exposing workers to risks from these uses during the time it will require to work through the administrative processes of first suspending and then cancelling the uses will expose workers to an imminent hazard. *See* 7 U.S.C. §§ 136d(c)(1), 136(l).

A. <u>There is a Substantial Likelihood of Serious Harm to Workers During the Several Years it Will Take To Cancel Chlorpyrifos Uses</u>.

This petition asks EPA to take long overdue action to protect workers based on its findings that chlorpyrifos poses risks of concern from more than 200 activities that pesticide handlers and field workers regularly engage in and from additional activities that present unsafe exposures, particularly in light of the risks of brain damage chlorpyrifos poses through prenatal exposures. EPA has found that workers face acute poisoning risks of concern from hundreds of activities that put them in contact with chlorpyrifos, and it has done so despite grossly under-estimating the poisoning risks by assuming that exposures stop at the end of an 8-hour work day and occur only over a 40-hour work week, that protective equipment and engineering controls are far more effective and faithfully used than is the case, and that workers are not exposed through drift.

These findings are not new. Many echo findings made by EPA in its 2002 re-registration eligibility determination for chlorpyrifos and its EPA's preliminary human health risk assessment released in 2011. While some of the precise risk numbers have changed, the over-arching conclusions persist. For 15 years, EPA has consistently found that mixers and handlers of various chlorpyrifos formulations and air blast applicators face unacceptable risks of acute pesticide poisonings. The risks are so high that some activities are virtually certain to suppress cholinesterase. Moreover, since 2002, as EPA has undertaken fuller analyses of the risks to

handlers performing seed treatments and workers who enter the fields and greenhouses after chlorpyrifos spraying, it has found that they face poisoning risks of concern.

While EPA concluded that risks of concern from 27 of the handler exposure scenarios could be eliminated if additional engineering controls were required, EPA has not mandated such controls, nor have the registrants voluntarily put them in place. Either such controls must be mandated or the application methods must cease.

For 126 handler scenarios, EPA found that the risks of concern cannot be eliminated with engineering controls. These application methods must end.

For the field workers, EPA calculated longer re-entry periods needed to prevent exposing field or greenhouse workers to unacceptable risks of acute pesticide poisoning, but it has not lengthened the mandatory re-entry intervals. Nor have the registrants done so voluntarily.

When EPA finalized its human health risk assessment, it recognized its legal and moral obligation to eliminate these risks of concern. It announced that it would negotiate voluntary measures from the registrants to do so. However, as of June 2015, the negotiations had broken down, and EPA told the 9th Circuit it would need to take regulatory action to protect workers. While EPA has proposed revoking chlorpyrifos food tolerances, that proposal does not reach nonfood uses, and EPA has indicated that it may back away from a full ban on all food uses. Moreover, the proposal does nothing to protect any workers during the revocation process, not even the workers who work on food crops.

While the acute poisoning risks documented by EPA alone warrant suspension of the offending uses, EPA's finding that prenatal chlorpyrifos exposures damage children's brains at lower exposures cries out for immediate action to prevent such exposures. The scientific evidence is extensive, comes in the many forms – animal studies, epidemiology, and mechanistic studies – and produces consistent results.

Dow AgroSciences has hired a crew of consultants to try to disparage the epidemiology studies and EPA's findings that exposures to chlorpyrifos and organophosphates correlate with severe brain impacts in children. It is well-settled that EPA may suspend a pesticide use based on respectable scientific authority, even if EPA's findings may be controverted by other respectable scientific authority. *Envtl. Defense Fund v. EPA*, 510 F.2d at 1298. Here the evidence that chlorpyrifos damages children's brains at low doses can no longer be controverted. Reputable bodies like the SAP have confirmed EPA's findings of harm to children's brains from low-level exposures to chlorpyrifos and that EPA's current risk assessment is under-protective. These are the only defensible conclusions.

EPA recognizes that its current regulatory endpoint – 10% red blood cell cholinesterase inhibition – fails to protect children from brain damage from prenatal exposures to chlorpyrifos. The SAP has concurred in this finding.

California's Office of Environmental Health Hazard Assessment ("OEHHA") has made similar findings. Under California law, OEHHA conducts scientific peer review of human health risk

assessments prepared by California's Department of Pesticide Regulation ("DPR"). In December 2015, DPR released a draft risk assessment for chlorpyrifos that mirrored EPA's RHHRA in significant respects. In particular, DPR used 10% red blood cell cholinesterase inhibition for the point of departure, used the Dow PBPK model, and eliminated the 10X inter-species safety factor because of its use of the Dow model.[39]

OEHHA found that the point of departure and uncertainty factors were not "sufficiently protective."[40] If 10% red blood cell cholinesterase inhibition is used as the endpoint, OEHHA recommended a total uncertainty factor of 1000X to 3000X. *Id*. at 2. Dr. Landrigan likewise believes a 1000X safety factor in total is the minimum that should be required because damage to children's brains has occurred at less than levels that produced no or less than 1% cholinesterase inhibition. Moreover, 10% red blood cell cholinesterase inhibition is not a "no observable adverse effect level" in light of the harm to children's brains at lower exposures.[41]

To guard against brain damage from prenatal exposures, this petition asks EPA to suspend chlorpyrifos uses that pose risks of concern using a total 1000X safety factor. EPA has already run the numbers. Its summary tables provide the MOEs for the various worker exposure scenarios, so using a more protective aggregate safety factor simply changes the cut-off.

The recent crisis in Flint, Michigan, where children's brains have been damaged from lead in their drinking water, has justifiably garnered national attention and sparked outrage. Exposing children unnecessarily to chemicals that cause permanent, irreversible brain damage is senseless and tragic. Doing so with chlorpyrifos in the face of EPA's findings and the overwhelming evidence creates an imminent hazard that warrants immediate suspensions to prevent such harm.

B. By Failing to Prevent Unacceptable Chlorpyrifos Risks to Workers, EPA is Denying Farmworkers The Same Level of Protection Afforded Other Workers.

For most types of workers in the United States, the Occupational Safety and Health Administration ("OSHA") establishes and enforces workplace standards under the Occupational Safety and Health Act of 1970 ("OSH Act"). Mandatory OSHA standards dealing with toxic materials are required to:

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or

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

[40] OEHHA, Pesticide Exposure and Risk Assessment Peer Review: DPR's Draft Risk Characterization Document for Chlorpyrifos at 1 (June 1, 2016) (Exh. 22).

[41] EPA routinely adds an additional 3X safety factor when a point of departure is a low observable adverse effect level, rather than a NOAEL. OEHHA believes such a 3X safety factor should be used for chlorpyrifos because serious adverse effects are correlated with less than 10% cholinesterase inhibition.

> functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

29 U.S.C. § 655(b)(5). OSHA has promulgated many standards to protect workers from toxic chemicals on the job that would, if applicable, reduce farmworkers exposures and harm from pesticides.[42]

The OSHA standards, however, do not cover farmworkers. It is EPA, rather than OSHA that addresses farmworkers' exposures to pesticides, and it does so under FIFRA, rather than the OSH Act. Because EPA has addressed farmworkers' exposure to pesticides, the D.C. Circuit ruled in 1975 that EPA's entry into the field preempted OSHA regulation. *Organized Migrants in Community Action, Inc. v. Brennan,* 520 F.2d at 1161 (D.C. Cir. 1975). Preemption of OSHA is premised on the assumption that the substitute agency has specialized expertise in the particularized field that it will bring to bear in affording workers "comparable" occupational health and safety protection. *Baltimore & O.R.R. v. Occupational Safety and Health Review Comm'n*, 548 F.2d 1052, 1054 (D.C.Cir.1976); *accord Ensign-Bickford Co. v. Occupational Safety and Health Review Comm'n*, 717 F.2d 1419, 1421 (D.C. Cir. 1983); *see also Reich v. Muth*, 34 F.3d 240, 243 (4th Cir. 1994) (the purpose of OSH Act's negative preemption provision is to avoid duplicative regulation by ceding responsibility for occupational standards in particularized fields to the regulatory bodies specifically tasked with their oversight and control, while leaving to OSHA the remaining general field of regulation outside specialized areas demanding specialized expertise").

The different approaches to occupational health are illustrated by medical monitoring to detect dangerous cholinesterase inhibition and remove workers from continued exposure until their cholinesterase levels recover. In employment sectors other than agriculture, medical monitoring of workers who handle toxic chemicals, including organophosphate pesticides, is often required. *See* 29 CFR §§ 1910.1001-1910.1017. The Animal and Plant Health Inspection Service has developed a mandatory cholinesterase monitoring program for its employees who handle pesticides, including organophosphates, to control invasive pests on imported plants and food.[43] As a result, APHIS employees are required to undergo cholinesterase monitoring when they apply an organophosphate pesticide, but agricultural workers outside of California and Washington are not, even when they apply the very same pesticide. *See* Coumaphos Preliminary

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[42] *See, e.g.,* 29 C.F.R. § 1910.1000 (limiting hours employees can work with specific toxic air contaminants, including pesticides); 29 C.F.R. § 1910.1003 (calling for detailed safeguards against exposures, including closed systems, in workplaces where a range of carcinogens are used); 29 C.F.R. § 1910.134 (requiring respiratory protection when engineering controls and substitution of less toxic chemicals are not feasible).

[43] APHIS, HASP Template: Medical surveillance requirements (for workers exposed to organophosphates and carbamates), https://www.aphis.usda.gov/emergency_response/tools/how-to/htdocs/images/hasp_section6.pdf; APHIS, Chapter 7: Section 5 Cholinesterase training program (for hazardous dusts (cotton dust, asbestos, etc.), occupational bacterial and viral diseases, chemical exposures, and chemical weapon (nerve agent) exposure), https://www.aphis.usda.gov/emergency_response/tools/cleaning/htdocs/images/appendix_6b_cholinesterase_testing_program.pdf;

Human Health Risk Assessment at 45-54 (2016), at regulations.gov: EPA-HQ-OPP-2008-0023. The Army Public Health Center has also established a cholinesterase monitoring program due to exposures to nerve gas agents during deployments.[44]

EPA has not required medical monitoring of farmworkers who handle cholinesterase-inhibiting pesticides, but two states – California and Washington – have established cholinesterase monitoring programs under their state laws that incorporate occupational health standards drawn from the OSH Act. *Rios v. Washington Department of Labor and Industries*, 145 Wn.2d 483 (2002) (directing the Department to initiate rulemaking to require mandatory cholinesterase monitoring of agricultural pesticide handlers based on expert findings that such monitoring is necessary to prevent material impairment of health and feasible to protect workers from classes of pesticides that include chlorpyrifos).

EPA has long recognized that using cholinesterase monitoring to reduce employee exposures to organophosphate pesticides "is a prudent occupational health practice."[45] When it revised the worker protection standard, EPA acknowledged the efficacy of medical monitoring, yet it refused to institute such monitoring for workers who handle organophosphates and other acutely toxic pesticides. 80 Fed. Reg. at 67,538. Rather than require medical monitoring of workers handling organophosphates, EPA deferred to the registration review process to put product-specific risk mitigation measures in place. *Id*. at 67,539.

EPA similarly refused to require closed systems for all acutely toxic pesticides, again punting to the worker risk assessments and risk mitigation that would be adopted for individual pesticides during registration review. *Id*. at 67,542. While the WPS allows workers to forgo some protective equipment if a closed system is used, EPA acknowledges that this may not supply enough of an incentive for employers to use closed systems. *Id.* In other words, many, if not most, workers still lack the closed system engineering controls that EPA has identified as necessary to eliminate risks of concern.

In its worker risk assessments on individual pesticides, EPA prioritizes protective clothing and equipment to mitigate risks of concern. Only if that mitigation fails to eliminate the risks of concern will EPA consider engineering controls, and only if those controls fall short, will it consider stopping the pesticide use.

This priority scheme runs counter to the best and most prudent occupational health practices. These industrial hygiene practices, called the "hierarchy of controls," are designed to prevent harmful exposures as the first line of defense. The American National Standards

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[44] Army Public Health Center, Cholinesterase monitoring program, https://phc.amedd.army.mil/organization/phcrsouth/cmp/Pages/default.aspx; Army Public Health Center, Reference Document 230: Methodology for determining chemical exposure guidelines for deployed military personnel, at 11, 19, 96, 169 (June 2010), available at https://phc.amedd.army.mil/PHC%20Resource%20Library/RD230%20June%202010%20Revision.pdf; *see also* Department of Defense, Occupational medical examinations and surveillance manual (May 2, 2007), available at http://www.dtic.mil/whs/directives/corres/pdf/605505mp.pdf.

[45] Worker Protection Standard, 57 Fed. Reg. 38,102-01, 38,131 (Aug. 21, 1992).

Institute/American Industrial Hygiene Association Z10 2005 standard[46] provides that employers shall implement and maintain a process for feasible risk reduction based on the following preferred order of controls:

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

The hierarchy of controls prioritizes hazard elimination and substitution over less protective controls, like engineering controls, while EPA does just the opposite. In fact, EPA prioritizes the least effective measures – personal protective clothing and equipment. An assessment of the efficacy of industrial hygiene controls to limit worker exposure to pesticide drift found: "personal protective equipment (PPE) is always considered a last resort and should only be used as a method of exposure control when all other controls have been implemented and have not sufficiently reduced the hazard."[47]

Even adhering to its flawed approach, EPA has found that unacceptable poisoning risks to workers from chlorpyrifos will persist even with maximum protective clothing and gear and engineering controls. Elimination of the application method or requiring the longer restricted re-entry periods then are, in EPA's view, the only options.

For some of the risks of concern, EPA believes the risks can be reduced sufficiently through mitigation measures. EPA's worker risk assessment is opaque in that it fails to describe the needed mitigation. From the summary of the worker handler estimates, it appears that EPA has deemed engineering controls necessary, rather than more protective clothing or equipment since many, if not most, chlorpyrifos labels already require maximum PPE, and it is the addition of engineering controls that eliminates the risks of concern, where EPA believes that is possible. *See* EPA's Updated Occupational Risk Assessment Summary Tables in Appendix F. Moreover, EPA has noted that workers could suffer from heat and respiratory stress with any additional protective gear, RHHRA at 100, which would particularly be the case in places like the Central Valley, California, or Wenatchee, Washington, where heat stress is already a problem for workers in the summer.

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[46] Fred A. Manuele, ANSI/AIHA Z10-2005: The New Benchmark for Safety Management Systems, PUB. SAFETY, at 25 (Feb. 2006), at http://www.asse.org/publications/standards/z10/docs/25-33Feb2006.pdf (Exh. 23). EPA recently proposed changes to Toxic Substances Control Act regulation to require approval of a chemical as a significant new use if a hierarchy of controls similar to OSHA's is not implemented to protect workers. 81 Fed. Reg 49,598 (July 28, 2016).

[47] Justine L. Weinberg *et al.*, Application of Industrial Hygiene Hierarchy of Controls to Prioritize and Promote Safer Methods of Pest Controls: A Case Study, 124 Public Health Rep. 53-62 (2009) (Exh. 24).

The ANSI hierarchy of controls prioritizes engineering controls over PPE, as does OSHA. OSHA regulations adopt a hierarchy of controls to prevent employee inhalation, ingestion, skin absorption or contact with harmful amounts of toxic substances:

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

29 C.F.R. § 1926.55(b); *see also id*. § 1910.134(a)(1) (prioritizing engineering controls over respirators to reduce toxic air exposures); 43 Fed. Reg. 52,952 (1978) (preamble to lead standard finding repeatedly that respirators are ineffective because they create additional hazards by interfering with vision and mobility and they don't eliminate the exposure, provide inadequate protection). Requiring closed systems for mixing and loading pesticides and prohibiting air blast spraying in open cabs would both be engineering controls, while restricting re-entry into a recently sprayed field would be an administrative control.

In the 1970s, after California required closed mixing and loading systems to be used for Category 1 liquid pesticides (although not for chlorpyrifos), mixers and loaders reported incidents at 1/5 of the previous levels.[48] Since California has the largest share of U.S. receipts for agricultural crops, the mandatory use of closed systems demonstrates there the economically and technological feasibility of closed systems. Other studies have likewise documented dramatically reduced harm to workers when closed systems replaced hand pouring, although the closed mixing systems also sometimes fail to protect the workers.[49]

In its risk estimates, EPA identified over five dozen mixing and loading activities of various chlorpyrifos formulations that pose risks of concern. Its summary tables indicate that engineering controls might reduce the risks to what EPA deems acceptable risk levels for 11 of those activities. Although it is not specified in the risk assessment, it may be that closed mixing and loading systems are the engineering control EPA had in mind for some of the activities. If so, then EPA should immediately require the use of closed systems for these mixing and loading activities. For the mixing and loading activities that still produce risks of concern with engineering controls, EPA should immediately prohibit those mixing and loading activities. EPA documented risks of concern from 10 different scenarios involving mixing and loading various chlorpyrifos formulations for seed treatment, and it did not indicate that the risks could be reduced through the use of engineering controls. EPA should immediately end these mixing and loading activities as well.

In its assessment of the risks to applicators using air blast sprayers, EPA found that all of the scenarios pose risks of concern. For some crops, the risks are unconscionably severe. For 10 of the crop groups, the MOE is 10 or less, and for citrus and pecans, the MOE is less than 1. Of 14

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[48] Rutz, *Closed System Acceptance and Use in California*, *in* Pesticide Formulations and Application Systems, at 28-34 (G.B. Beestman & R.D. Vander Hooven eds. 1987) (Exh. 25).

[49] James B. Knaak *et al*., *Safety and Effectiveness in Preventing Exposure to Pesticides*, 24 Archives Envtl. Contamination & Toxicology, at 231, 244-245 (1980) (Exh. 26).

crop groups, EPA believed only 4 could be mitigated through engineering controls. The engineering control appears to be enclosed cabs with working air conditioning and ventilation systems, which can reduce exposures significantly.[50] EPA should immediately require engineering controls for air blast spraying if they are reliable. If EPA cannot ensure that the ventilation and air conditioning systems would be in working order, then enclosed cabs would be ineffective as the workers would likely be inclined to open the windows in extreme summer heat.

It should come as no surprise that EPA's risk assessments found such prevalent and serious risks from air blast spraying. EPA found unacceptable risks from air blast spraying in 2002 and did not impose sufficient mitigation to eliminate the risks. In the interim fifteen years, air blast spraying has been the culprit in numerous pesticide poisonings. In Washington State, air blast spraying is the largest source of drift exposure, comprising more than half the drift illness enforcement actions in recent years.[51]

EPA's failure to afford farmworkers the same level of protection as this country affords other workers is a prime example of environmental injustice. As EPA has recognized, pesticides disproportionately cause harm to farmworkers and their families, who are predominantly poor and majority Latino. 79 Fed. Reg. at 15,452. Farmworkers are exposed to far greater risks of poisonings on the job than industrial workers, and they and their families bear the brunt of poisonings from pesticide drift and volatilization. In addition, farmworker and poor communities may be more likely to obtain their drinking water from systems that have been contaminated by chlorpyrifos. Executive Order 12,898 on environmental justice requires EPA to identify and take steps to prevent such disproportionate pollution burdens, but EPA has failed to comply with these obligations. Executive Order No. 12,898, 59 Fed. Reg. 7629 (Feb. 11, 1994). Our comments on the RHHRA (at 76-81) explain how EPA has failed to assess and take steps to address environmental justice impacts of the harms chlorpyrifos causes, as required by the Executive Order by failing to afford farmworkers a comparable level of protection from workplace poisonings as is generally afforded to other workers. *Id.* at 80-81. To make matters worse, EPA is not even taking steps to protect workers from the unacceptable risks that it identified almost two years ago. EPA should take immediate steps to suspend these unacceptable risks and initiate cancellation proceedings to protect workers and others from the harms that chlorpyrifos causes wherever it is used.

C. Unreasonable Adverse Effects Are Presented by the Chlorpyrifos Uses Targeted by This Petition, Taking Into Account All Risks and Benefits.

Under FIFRA, an imminent hazard exists when use of a pesticide during the time it would take to complete cancellation proceedings would be likely to result in unreasonable adverse effects. 7 U.S.C. § 136(l). FIFRA defines "unreasonable adverse effects" as "any unreasonable risk to man

[50] Lunchick *et al*., at 609 (totally enclosed cab with air conditioning can reduce groundboom applicator dermal exposure 5-6-fold and airblast applicator dermal exposure 70-fold)

[51] Washington Department of Agriculture Pesticide Enforcement Actions 2014-2015, at http://agr.wa.gov/pestfert/enforcementactions.aspx (Exh. 27).

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or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* §136(bb). An unreasonable adverse effect also exists when residues of the pesticide on food are inconsistent with the FQPA's safety standard. *Id.*

In applying the former standard, EPA must consider all of the risks and benefits from the pesticide. When UFW, Farmworker Justice, Earthjustice, and others challenged EPA's reregistration of another organophosphate – azinphos-methyl – Dr. Frank Ackerman, an acclaimed economist, submitted expert declarations critiquing EPA's benefits assessment and finding that it under-estimated the risks and the harm they cause and overstated the benefits of the pesticide for crop production. Dr. Ackerman included his analysis in his book *Poisoned for Pennies: The Economics of Toxics and Precaution* at 113-28 (2008). As Dr. Ackerman explains, EPA must consider all of the costs and benefits, including the full impacts to workers and their families, the impacts to wildlife and the environment, and the availability of alternatives to growers. During the course of the legal challenge, EPA conducted a more rigorous risk-benefit analysis that led it to phase-out all uses of azinphos-methyl in the United States by September 2013. *UFW v. Administrator, EPA*, No. CV04-0099-RSM (W.D. Wash. filed 2004). In light of all the harms from chlorpyrifos, continued chlorpyrifos use cannot be justified by its benefits.

1. Risks and Harm to Workers and Their Children from Occupational Exposures to Chlorpyrifos

EPA's findings of risks of concern to workers substantiate an imminent hazard, given the magnitude of the risks, the nature of the harm, and the likelihood of numerous pesticide poisonings during the time it will take to cancel and end chlorpyrifos uses. This petition relies on EPA's findings made after years of analysis using methods EPA has developed over even longer periods of time. EPA has found unacceptable risks to workers from hundreds of worker activities, and many of the risks greatly exceed EPA's risk thresholds, some by an order of magnitude or more.

Every year, the California and Washington incident reporting systems are filled with worker poisonings from chlorpyrifos. Incident reports barely scratch the surface given the lack of a nationwide reporting system and the fear of retaliation, reluctance to seek medical care, misdiagnoses, and other disincentives to report.

These poisonings take their toll. Workers describe the onset of severe headaches and body-wrenching flu symptoms that sometimes lead to seizures, blackouts, and worse. Many workers report heightened sensitivities to pesticide illnesses that persist, and some have long-lasting neurological impacts. When workers become sick, they often become unproductive, miss work, or need to seek medical care, which may be covered by workers' comp, other public health systems, or at the workers' expense.

The risks of brain damage to children from prenatal exposures warrant suspension of additional chlorpyrifos uses that over-expose workers. Neurodevelopmental harm to children is associated with *in utero* exposures at levels that are a fraction of EPA's regulatory endpoint. The types of impacts correlated with exposure to chlorpyrifos and other organophosphates are every parent's nightmare. Every parent watches with wonder as their children start to crawl and walk, yet chlorpyrifos has delayed motor development. Parents marvel as their children start to learn, yet

chlorpyrifos reduces working memory and IQ.

Chlorpyrifos exposure is also associated with learning disabilities like attention deficit disorders that seem to be reaching epidemic proportions. These types of learning disabilities frustrate and impair the child's growth and well-being and necessitate societal investments in education, accommodations, and behavior management. Behavioral difficulties can have other societal costs when they cause children and the adults they become to act out and cause harm. These types of individual and societal harms have been well-studied and even quantified in connection with chemicals like lead, and federal agencies, including EPA, have found regulation to prevent exposures to such chemicals to be cost-effective.

In the course of registration review, EPA has documented other harms from chlorpyrifos. It has found contamination of drinking water, leading to the proposal to revoke all food tolerances. Infants are exposed to unsafe levels of chlorpyrifos from all chlorpyrifos uses. If EPA retained all of the ordinary safety factors to protect children from brain damage, its risk assessments would identify unacceptable risks from all food uses as well.

2. Other Risks and Harm from Chlorpyrifos

EPA also found that chlorpyrifos has the propensity to drift in toxic amounts. However, it ignored drift exposures to field workers and direct drift onto people when pesticides are applied. Moreover, EPA sought to prevent drift that would cause acute poisonings, even though it found that children may experience brain damage from a fraction of the exposures EPA used to reduce poisoning risks. The buffers that the registrants put in place in 2012 to reduce drift are, therefore, grossly inadequate to prevent toxic drift, and particularly brain damage to children.

The Washington Department of Health incident investigations attest to this fact. In one case in March 2015, pesticide drifted from airblast spraying onto school grounds 90 feet away and sickened three people, including a pregnant elementary school teacher. In April 2014, drift from airblast spraying 260 feet away made two people sick at their home residence, and the previous month, a farmworker became sick when chlorpyrifos drifted from airblast spraying ¼ mile away.[52]

When it comes to chlorpyrifos exposures, farmworkers and their families face a triple whammy. Workers face unacceptable risks on the job. They also take home residues of chlorpyrifos on

[52] Washington Department of Health Incident Investigation Summaries, *supra* note 52. EPA has recognized that additional prescriptions are needed in addition to the current label prohibition on applying a pesticide in a way that will contact workers or other people directly or through drift. The label prohibition, alone, has not prevented toxic drift and poisoning incidents. 80 Fed. Reg. 67,521-22 ("additional measures are needed" because the label "do not contact" language has proven "insufficient" to prevent exposure of workers to drift). EPA found it necessary to afford additional protection in the form of application exclusion zones that prevent workers from being in treated areas during applications. *Id*. at 67,521-22. The requirement to suspend applications in application exclusion zones when workers or other people not handling the application are present, however, is not effective until January 1, 2018. 40 C.F.R. § 505(b).

their clothes and bodies that expose their families – an exposure that EPA's risk assessments never addressed. Farmworkers and their families are exposed when chlorpyrifos moves through the air and exposes them to toxic drift. Such drift is ubiquitous. It can travel to a neighboring field; in fact, drift from neighboring field has constituted the number-one cause of worker poisonings in Washington State in recent years. It can reach schools, homes, and playfields, exposing children wherever they study and play. Farmworkers and their families are exposed to chlorpyrifos through volatilization – another exposure route that EPA discounted. And they, like other consumers, are exposed to chlorpyrifos on their food and in their drinking water. When all of these exposures must be taken into account, the risks are off the charts.

In addition to harm to people, chlorpyrifos causes widespread environmental harm. Surface waters in many states are in violation of water quality standards due to chlorpyrifos contamination.[53] The State of California, growers, and the public have invested extensive resources in developing plans to clean up the contamination.[54]

Chlorpyrifos is extremely harmful to fish and wildlife. Earlier this year, EPA released its biological evaluation of chlorpyrifos, which found that chlorpyrifos may affect the vast majority of the species on the Endangered Species Act list.[55] This evaluation has initiated consultation with the expert fish and wildlife agencies to determine the full extent of the harm and needed mitigation.

For Pacific salmon on the endangered species list, the National Marine Fisheries Service ("NMFS") has found that chlorpyrifos is likely to jeopardize survival and recovery of 27 of the 28 listed Pacific salmonid populations and adversely modify critical habitat designated for 25 of

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[53] *See, e.g.*, California 303(d) List of Water Quality Limited Segments in the Greater Monterey County Integrated Regional Water Management Region, at http://www.greatermontereyirwmp.org/wp-content/uploads/2012/08/AppendixG_303dList.pdf; Washington Water Quality Assessment 305(b) Report and 303(d) List (approved by EPA on July 22, 2016), at https://fortress.wa.gov/ecy/approvedwqa/ApprovedSearch.aspx; X. Zhang *et al.*, Cal. Dept. of Pesticide Regulation, Analysis of Chlorpyrifos Agricultural Use in Regions of Frequent Surface Water Detections in California (2012), at http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/zhang_chlorpyrifos_report.pdf (Exh. 28).

[54] *See, e.g.*, California Regional Water Quality Control Board, Central Coast Region, Resolution No. R3-2011-0005, Adopting Total Maximum Daily Loads and Implementation Plan for Chlorpyrifos and Diazinon in the Lower Salinas River Watershed Monterey County (May 5, 2011) , at http://www.waterboards.ca.gov/centralcoast/water_issues/programs/tmdl/docs/salinas/pesticide/sal_op_tmdl_signed_resln.pdf.

[55] Biological Evaluation Chapters and Effects Determinations for Chlorpyrifos Endangered Species Act Assessment (April 2016) (likely to adversely effect findings for 1725 of 1782 listed species), at https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment.

26 listed Pacific salmonids with designated critical habitat.[56] As of January 2004, a court order established streamside buffers to prevent chlorpyrifos from migrating into salmon streams, which are 20 yards for ground spraying and 100 yards for aerial spraying, *Washington Toxics Coalition v. EPA*, 413 F.3d 1042 (9th Cir. 2005) (upholding injunction imposing buffers during consultation). The 2008 biological opinion called for much larger buffers of 500 feet for ground applications and 1,000 feet for aerial applications.[57] While that biological opinion is being redone, it substantiates the harm chlorpyrifos causes to salmon and the need for mitigation measures beyond what is in place today to keep chlorpyrifos out of salmon streams. Salmon are infused into the fabric and economy of California and the Pacific Northwest. They provide their own suite of economic benefits to fishing communities, and form the core of Northwest Tribes' culture, economies, and way of life. Declines have had huge adverse impacts on fishing communities and on Tribes' subsistence, health, culture, and way of life.

Finally, chlorpyrifos is highly toxic to bees through direct application, drift, and residues on blooming crops or weeds.[58] The Washington State Department of Agriculture found chlorpyrifos to be among the insecticides involved in the majority of bee kill incidents between 1992 and 2005.[59] *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015) (EPA lacked sufficient scientific information to find pesticide safe when coming into contact with bees).

Once EPA finds risks of concern, it must cancel the pesticide use unless it finds that the benefits of continued use outweigh the risks. *Envtl. Defense Fund, Inc. v. EPA*, 548 F.2d at 1012. And it is the registrant that bears the burden of proving safety at all times, including in cancellation and suspension proceedings. *Id.* at 1004. The registrants must demonstrate that the benefits from any particular use outweigh these risks, including by showing the lack of available, feasible alternatives. The harm from chlorpyrifos comes in many forms, virtually every way that people, water, fish, bees, and wildlife come into contact with this neurological toxin. The risks from use of chlorpyrifos are so numerous that the burden to demonstrate countervailing benefits is enormous and cannot be met.

CONCLUSION

EPA must act expeditiously to suspend the following uses of chlorpyrifos that pose unacceptable risks of acute poisonings and brain damage to their children from worker activities: (1) those uses that EPA has found pose acute poisoning risks to workers; and (2) those additional uses that EPA would have found pose risks of concern if it had retained the tenfold safety factor it jettisoned based on Dow's model. EPA's findings of serious harm over the next few years

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[56] National Marine Fisheries Service, Endangered Species Act Section 7 Consultation Biological Opinion on Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion on 28 Listed Pacific Salmonids (2008), at http://www.nmfs.noaa.gov/pr/pdfs/pesticide_biop.pdf.

[57] Biological Opinion at 392-93.

[58] *See* Dow AgroSciences, Lorsban 15G Label (Exh. 29).

[59] http://agr.wa.gov/PestFert/Pesticides/docs/PollinatorSLNSect18.pdf.

constitute an imminent hazard and warrant a suspension of these uses. These risks are extreme and should not be allowed to continue during the time it will take to cancel all uses of chlorpyrifos. Ultimately, cancellation of all uses is the only way to protect farmworkers and their families from the full array of exposures that occurs through work in the fields, from drift to their homes and schools, in their food, and in their drinking water.

PETITION TO CANCEL ALL USES OF CHLORPYRIFOS

In addition to seeking an immediate suspension of chlorpyrifos uses that pose imminent hazards to workers, we also are petitioning EPA to cancel all uses of chlorpyrifos. We are filing this cancellation petition for two reasons: (1) to serve as a predicate for the Petition for Emergency and Ordinary Suspensions of Chlorpyrifos Uses That Pose Unacceptable Risks to Workers, which we are filing concurrently; and (2) because EPA has construed the Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos filed by Natural Resources Defense Council and Pesticide Action Network, North America in September 2007 ("2007 Petition"), as extending only to food uses of chlorpyrifos and only certain risks and harm from the pesticide.

SUMMARY OF THE REASONS FOR CANCELLING CHLORPYRIFOS REGISTRATIONS

This petition does not plow new ground. Rather, it seeks EPA action based on the 2007 Petition, EPA's registration review of chlorpyrifos, and EPA's tolerance revocation proceedings.

EPA must cancel a pesticide registration if the pesticide use "causes unreasonable adverse effects on the environment," which includes human health. 7 U.S.C. § 136d(b). FIFRA defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id*. §136(bb)(1). FIFRA also defines "unreasonable adverse effects" to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard." *Id*. § 136(bb)(2). As a result, a pesticide registration for a food crop must be cancelled if the standards of the FQPA are not met.

Chlorpyrifos uses pose unreasonable adverse effects under both of these definitions. Accordingly, EPA must initiate cancellation proceedings to cancel the registrations and end chlorpyrifos use in the United States.

I. CHLORPYRIFOS POSES UNREASONABLE ADVERSE EFFECTS TO FARMWORKERS AND THEIR CHILDREN.

The suspension petition documents the unreasonable adverse effects to farmworkers and their children from chlorpyrifos. Ongoing chlorpyrifos exposures will cause unreasonable adverse effects during the time it will take to cancel chlorpyrifos registrations, as well as over the long term. Accordingly, EPA must not only suspend chlorpyrifos uses to protect workers, but it must also cancel the registrations.

II. EPA MUST CANCEL USES OF CHLORPYRIFOS ON FOOD BECAUSE IT CANNOT MAKE THE FQPA SAFETY FINDINGS.

Chlorpyrifos poses serious risks of brain damage to children from consuming food with residues of the pesticide. As explained above in the suspension petition, EPA has finally acknowledged the overwhelming evidence from experimental toxicology, mechanistic and epidemiological studies that reveal brain and other neurodevelopmental impacts to kids from *in utero* exposures at doses far below those that cause 10% cholinesterase inhibition. Based on its findings, EPA

has appropriately retained a tenfold FQPA safety factor due to the severe prenatal neurodevelopment effects and the gaps in data and understanding of the mechanism and precise doses at which the neurodevelopmental impacts to children occur.

Despite finding that children incur neurodevelopmental damage from *in utero* exposures smaller than those that cause 10% cholinesterase inhibition, EPA persists in using 10% cholinesterase inhibition as its regulatory endpoint in the RHHRA. EPA used a model developed by Dow AgroSciences that tries to pinpoint the exposures that will produce 10% cholinesterase inhibition in people.

The comments submitted by Earthjustice and Farmworker Justice on behalf of UFW and others describe the serious scientific and ethical flaws in the model and why EPA should not have used it without additional peer review and those comments are incorporated here. Two points are summarized here. First, in February 2011, EPA's Scientific Advisory Panel found numerous flaws in the model, using terms like "very problematic," "cursory," "overstated," "inadequate," "inaccurate," "imprecise," and "incomplete."[60] Dow made some changes in the model, but EPA did not obtain another review by its Scientific Advisory Panel. Second, 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. RHHRA Comments at 28-42.

Based on the Dow model, EPA eliminated the inter-species safety factor altogether, and it shrunk the intra-species safety factor from 10X to 4X-5X for children, although it retained a 10X for women since the Dow model lacks data reflecting how a pregnant woman's body processes chlorpyrifos. The result – EPA will allow chlorpyrifos exposures to be an order of magnitude higher for pregnant women and even higher still for children. It is unconscionable for EPA to 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. Moreover, this approach violates EPA's policy of setting regulatory limits based on the most sensitive endpoint at which adverse effects occur and disregards EPA's mandates to protect children from prenatal toxicity.

As explained above in the suspension petition, EPA should, at a minimum, apply a 1000X safety factor, which is necessary (although likely not sufficient) to protect against brain damage from prenatal exposures. If EPA had used a 10000X safety factor, it would have found risks of concern to children from food. The RHHRA Comments provide calculations that show all

[60] 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.

children would be at risk, with children 1-2 years old facing the highest risks, and more than two times EPA's level of concern. RHHRA Comments at 8-9.

Therefore, EPA cannot make the Food Quality Protection Act's safety finding for chlorpyrifos. It must revoke all tolerances and cancel registrations for chlorpyrifos on food crops.

III. USE OF CHLORPYRIFOS CONTAMINATES DRINKING WATER AND POSES RISKS TO CHILDREN THAT PREVENT EPA FROM MAKING THE FQPA SAFETY FINDINGS.

Chlorpyrifos contaminated drinking water. For drinking water, even using the reduced safety factors, EPA found that drinking water concentrations of chlorpyrifos would exceed levels of concern. Given the amount of water infants and toddlers consume in infant formula and fruit juices, they are particularly at risk.

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)." 80 Fed. Reg. at 69,080; *id*. at 69,081 ("EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe."); *id*. ("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.").

As explained in the comments on the proposed revocation submitted by Earthjustice on behalf of many of the petitioners,

> Even using the wrong regulatory endpoint (cholinesterase inhibition), eliminating some of the appropriate safety factors, and omitting some significant routes of exposure, EPA still has found unacceptable risks from drinking water contamination, particularly to infants, from all chlorpyrifos uses. Based on comparisons to water monitoring data, EPA has concluded that the results of their modeling are not overly conservative. While it is proposing to revoke all tolerances based on these findings, EPA has held out the possibility that it could impose label restrictions that could prevent some of the drinking water contamination. EPA should refrain from trying to allow some chlorpyrifos uses to continue because: (1) it is through label restrictions that EPA prevents unreasonable adverse effects, like drinking water contamination, and therefore EPA must ensure that uses in accordance with the label will prevent drinking water contamination; it cannot assume that chlorpyrifos will be used in less harmful ways when those assumptions about chlorpyrifos use are not guaranteed through the label; (2) EPA has improperly reduced or eliminated safety factors; if it had used appropriate safety factors, the drinking water levels of concern would be an order of magnitude or more above safe levels (and all food uses would also produce risks of concern); (3) as EPA recognizes, data on pesticide use and surface water concentrations is spotty at best and inadequate to support valid watershed assessments; and (4) EPA has understated risks from pesticide drift, volatilization, and other aggregate exposures, and has not accounted for all cumulative organophosphate exposures. For all of these reasons, it would be under-protective for

EPA to cut corners on safety by making unsupported assumptions that drinking water contamination will be less than the modeling shows.[61]

Based on drinking water contamination alone, but certainly when drinking water risks are considered along with food and aggregate exposures, chlorpyrifos uses fail to meet the FQPA standard. Accordingly, EPA must revoke the chlorpyrifos food tolerances and cancel the chlorpyrifos registrations.

IV. EPA MUST CANCEL USES OF CHLORPYRIFOS BECAUSE AGGREGATE EXPOSURES TO CHILDREN ARE UNSAFE WHEN DRIFT, VOLATILIZATION, AND TAKE-HOME EXPOSURES ARE CONSIDEREDALONG WITH FOOD AND DRINKING WATER.

Under the FQPA, EPA must protect children and other bystanders from all aggregate exposures, including drift. It did not do so when it re-registered chlorpyrifos and all of the other old pesticides by the FQPA's 2006 deadline. It is now acknowledging its legal obligation to consider drift and volatilization exposures.

In its preliminary human health risk assessment, EPA made findings that drift exposes children to harmful chlorpyrifos exposures, and the chemical companies agreed to no-spray buffers around school grounds, play fields, residential yards, homes, daycares, nursing homes, hospitals, and pedestrian sidewalks. Creating no-spray buffers around these sensitive sites is an important step forward.

For chlorpyrifos, however, the no-spray buffers are far too small. For ground and airblast spraying, the buffers are only ten feet wide, except for very high application rates using airblast spraying where the buffers are 25-50 feet wide. For aerial spraying, the buffers range from 10-100 feet depending on the application rate and droplet size. By way of comparison, the chlorpyrifos buffers established for water bodies in 2002 are 25 feet for ground boom, 50 feet for airblast, and 150 feet for aerial spraying.

The recently imposed drift buffers fail to protect children and other bystanders for several reasons. First, the buffers do not guard against neurodevelopmental harm. EPA is using 10% cholinesterase inhibition in assessing whether children and other bystanders will be harmed, not the lower doses that cause neurodevelopmental impairments.

Second, EPA has under-estimated drift exposures, which are well documented.[62] Children and other bystanders are exposed to pesticides when droplets, particles or vapors move offsite. EPA focused primarily on children's dermal exposures to residues that have deposited on the ground. While EPA considered inhalation exposures from aerial applications, it did not aggregate

[61] Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances at 2 (Jan. 5, 2016) (Exh. 3).

[62] Cal. Air Resources Bd., Final Report for the 1996 Chlorpyrifos Monitoring in Tulare County (1998) (Exh. 30); Air Monitoring for Chlorpyrifos in Lindsay, California June-July 2004 and July-August 2005 (Exh. 31).

deposited residues and inhalation exposures, and it failed entirely to account for inhalation exposures from air blast or ground boom applications. It assumed that children and other bystanders would only be exposed for 2 hours even though many people, such as the home bound and children who are exposed at school and at home, will be exposed for far longer. EPA also made assumptions that unduly minimize the amount of pesticide residues children will encounter.

Third, EPA ignored children's exposure to chlorpyrifos through dust. Farmworker children and other children who live close to the fields are exposed to chlorpyrifos through take-home residues and dust. Yet EPA has ignored this route of exposure.

Fourth, EPA is allowing volatilization exposures based on flawed industry studies. Chlorpyrifos has a propensity to volatilize after applications and move large distances as vapors. When EPA started to look at exposures to chlorpyrifos through volatilization, it determined that buffers as large as 4000 feet may be necessary to prevent harm exposures to chlorpyrifos vapors. Dow AgroSciences then submitted two rat studies that purport to show that it is impossible to inhale enough chlorpyrifos to produce an adverse effect. The studies have significant flaws because they fail to reflect temperature and soil moisture impacts on volatilization, individual variation, and biomonitoring and incident data showing harmful exposures at distances as large as ½ mile from application sites. And continuing the pattern, EPA used 10% cholinesterase inhibition as an endpoint, rather than the lower doses that cause brain impairments in children.

EPA has failed to protect children from all of these types of exposure to chlorpyrifos. Moreover, it has failed to aggregate all of the ways children are exposed, as required by the FQPA. EPA erroneously concludes "that with the additional no spray buffer restrictions, risk concerns to bystanders from spray drift have been eliminated and therefore bystander exposures are not included as part of EPA's aggregate risk assessment." 80 Fed. Reg. at 69,097. However, an aggregate risk assessment is supposed to add all of the routes of exposure to determine whether together they exceed the level of concern, even if any one individual risk does not.

If EPA properly considered all aggregate exposures from food, drinking water, drift, volatilization, and dust, using appropriate safety factors, it would have found risks of concern from all chlorpyrifos uses. In light of these risks, EPA must issue a notice of intent to cancel the chlorpyrifos registrations.

The Administrator is required to initiate a cancellation process when "it appears to the Administrator that a pesticide generally causes unreasonable adverse effects on the environment." *National Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 643 (D.C. Cir. 1989) (quoting 7 U.S.C. § 136d(b), emphasis in original). The courts have interpreted this standard to require EPA to "initiate the administrative process whenever there is a substantial question about the safety of a registered pesticide." *Id*., quoting *Envtl. Defense Fund v. Ruckelshaus*, 439 F.2d 584, 594 (D.C. Cir. 1971). Here, unquestionably, substantial questions about the safety of chlorpyrifos are pervasive, and it is time for EPA to initiate cancellation proceedings.

V. EPA HAS FAILED TO PROTECT WORKERS AND THEIR FAMILIES AGAINST DISPROPORTIONATE HARM FROM PESTICIDE USE.

EPA's regulation of hazardous pesticides, like chlorpyrifos, presents environmental justice issues. Farmworkers are disproportionately poor and Latino. [63] They are the most exposed to pesticides and often face barriers in accessing health care. EPA's registration decisions and inaction have perpetuated and exacerbated the disproportionate burdens.

Farmworker families tend to be poor—on average, a farmworker family earns an annual income ranging from $17,500- $19,999.[64] In the top five agricultural counties in Texas (the state with the most acres of agriculture), between 10 to 30 percent of children live below the poverty line.[65] Likewise, in California (the top agricultural state by revenue), between 24 to 32 percent of children under the age of 17 live in poverty in the top three agricultural counties (compared with the state average poverty rate of 12.4 per cent).[66]

The vast majority of U.S. farmworkers are of Latin American origin—approximately 76 percent of U.S. farmworkers are of Latin American ancestry. As EPA explained in its proposed revision of the Worker Protection Standard,

> According to information published by the Department of Labor's (DOL) NAWS in 2001-2002, 75% of agricultural workers in the United States were born in Mexico and 2% in Central America (Ref. 3 p. 3). A majority (81%) of this group speaks Spanish as a native language, but a growing percentage speaks languages such as Creole, Mixteco, and indigenous languages (Ref. 3 p. 17). Approximately 44% could not speak English at all, and 53% could not read any English (Ref. 3 p. 21). [67]

EPA also described obstacles farmworkers face in obtaining health care:

> In general, agricultural workers surveyed by NAWS do not use health care facilities. Estimates of agricultural workers lacking health insurance range from 77% to 85% and estimates from the late 1990s indicate only 20% of those

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

[64] U.S. Department of Labor, *National Agricultural Workers Survey* (2011-2012) ("NAWS"), *available at* http://www.doleta.gov/agworker/naws.cfm.

[65] U.S. Department of Agriculture, 2007 County-Level Poverty Rates for TX (Dec. 2008).

[66] Alice Larson, Migrant and Seasonal Farmworker Enumeration Profiles Study: California (Sept. 2000).

[67] 79 Fed. Reg. 15,444, 15,452 (2014).

> surveyed had visited a health care facility in the preceding 2 years (Ref. 5 pp. 12-13). U.S. Department of Agriculture (USDA) research, based on NAWS data, also reports that workers have difficulty entering the health care system to receive treatment. Cost was a significant barrier for two-thirds of farmworkers, while about a third listed language barriers as an impediment to receiving care. The problem is more severe among undocumented workers because they fear seeking treatment will lead to deportation or other adverse legal action (Ref. 6).[68]

Farmworkers and their families are the populations most exposed to hazardous pesticides. Not surprisingly, farmworkers have a higher incidence of pesticide poisoning than other workers.[69] Their children are also at risk. In California, the counties with the highest use of chlorpyrifos are the counties with the highest poverty levels and largest Latino populations.[70] In addition to the farmworkers, their children are disproportionately exposed to chlorpyrifos and other hazardous pesticides. In April 2014, the California Department of Public Health issued a report showing that thousands of children, disproportionately people of color, attend school in close proximity to pesticide use.[71] The report found that chlorpyrifos is the eighth most commonly used hazardous pesticide within ¼ mile of public schools in 15 California counties. Latino children made up 54.1% of the population of all public schools in the counties studied, but 67.7% of the children in schools with the top 25% pesticide use, and 91% more likely than white children to go to those schools.[72]

By allowing widespread chlorpyrifos use with inadequate safeguards, EPA has perpetuated the environmental injustices that farmworkers and their families face. It has done so in at least three ways.

First, in 2000, EPA required home uses to be cancelled because of risks to children. Children crawling on treated carpets and hugging pets after flea treatments were exposed to levels EPA deemed too dangerous. EPA, however, neglected children in farmworker communities, who are primarily Latino and poor, creating a double standard. EPA never even assessed the extent to which children in agricultural communities are exposed to chlorpyrifos through drift and residues parents take home on their clothes. After years of petitions and lawsuits, EPA now acknowledges its legal obligations to assess and protect children from toxic pesticide drift, although as discussed above its assessment is too narrow and its chlorpyrifos buffers are too small. EPA has yet to assess take-home and dust exposures.

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[68] *Id*.

[69] Geoffrey M. Calvert *et al*., Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005, 51 Am. J. Indus. Med. 883, 890 (2008) (Exh. 4).

[70] Letter from Environmental Justice Organizations to Cal. EPA Assistant Secretary for Environmental Justice and Tribal Affairs Arsenio Mataka at 2-3 (Aug. 26, 2014) (Exh. 32).

[71] Cal. Dep't of Public Health, California Environmental Health Tracking Program: Agriculture Pesticide Use Near Public Schools in California (April 2014), at http://cehtp.org/file/pesticides_schools_report_april2014_pdf.

[72] *See* Environmental Justice Organizations Letter at 5-6.

Second, EPA fails to afford the same degree of protection to farmworkers that OSHA affords industrial workers. OSHA abides by a hierarchy of controls that prioritizes prevention. This leads to elimination of the use of toxic chemicals and engineering controls that prevent the exposure. OSHA never uses PPE as the first order of protection. Instead, PPE may be used in addition to engineering controls when such controls do not eliminate the exposures. In contrast, EPA uses PPE as its first mitigation measure when it finds risks of concern. It has done this with chlorpyrifos for decades, exposing workers to unsafe exposures, many of which would have been reduced or possibly eliminated with engineering controls. Farmworkers are given second-class treatment.

Third, in assessing drinking water impacts, EPA believes the exceedances of its drinking water levels of concern will be in small watersheds where a large percentage of the crops are treated. It is highly likely that these impacted areas will be where farmworkers and their families live. Drinking water contamination, which EPA has deemed unsafe, is disproportionately harming communities of color and low-income communities.

Not only are farmworkers and their families disproportionately burdened by chlorpyrifos, but they are similarly disproportionately exposed to other organophosphate pesticides. EPA has a legal obligation under the FQPA to protect against unsafe cumulative exposures to classes of pesticides that have a common mechanism of toxicity. Organophosphates are such a class, as EPA recognized when it conducted a cumulative risk assessment in 2006 and in its Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides. However, EPA is assessing each of the organophosphates individually, without setting cumulative limits on exposures. By doing so, EPA is delaying protection for farmworkers and their families from organophosphates as a class.

CONCLUSION

EPA should act expeditiously to cancel all chlorpyrifos uses because of the harms they cause to people however they contact chlorpyrifos. EPA should move quickly to promote environmental justice for farmworker populations that have been overburdened for far too long.