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OPP Docket

Environmental Protection Agency Docket Center (EPA/DC), (28221T)

1200 Pennsylvania Avenue N.W.

Washington, DC 20460-0001

Re: Comments on EPA Proposal To Revoke Chlorpyrifos Tolerances  
EPA-HQ-OPP-2015-0653

## I. INTRODUCTION

On behalf of Earthjustice, Pesticide Action Network, Natural Resources Defense Council, Farmworker Justice, United Farm Workers, Farm Labor Organizing Committee, and California Rural Legal Assistance Foundation, we submit these comments on the Environmental Protection Agency's ("EPA's") proposal to revoke all chlorpyrifos tolerances. 80 Fed. Reg. 69,080 (Nov. 6, 2015). We applaud EPA's intention to revoke all chlorpyrifos tolerances as it is supported by the best science and public policy, and we urge EPA to act quickly to finalize the proposed rule. We are attaching comments that we and others submitted in the chlorpyrifos registration review docket, including EPA's December 2014 Revised Human Health Risk Assessment ("RHHRA")<sup>1</sup> and hereby incorporate those comments by reference in their entirety.<sup>2</sup>

Chlorpyrifos is a widely used, dangerous pesticide that causes poisonings of workers and bystanders every year and is associated with alarming neurodevelopmental impairments to children exposed during early life stages. EPA's acceptance of the extensive scientific evidence of adverse brain impacts to children is welcome, even though long overdue. EPA now recognizes the imperative to protect children against chemically induced loss of IQ, developmental delays, loss of working memory, attention disorders, and other neurodevelopmental impairments. Yet it is setting its regulatory target in a way that remains under-protective since it is not based on the brain impacts, but rather on cholinesterase inhibition. EPA has found that the adverse brain impacts correlate to far lower exposure levels than those that cause cholinesterase inhibition. EPA must ensure that it is regulating to protect children from exposures that could cause any harm, including neurodevelopmental harm.

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<sup>1</sup> US EPA, Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2014), at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0195>.

<sup>2</sup> Earthjustice, *et al.*, Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (2015), at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0848> (**Attachment 1**).

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.

EPA is appropriately proposing to revoke all tolerances and thereby end all food uses of chlorpyrifos. EPA should act expeditiously to finalize these tolerance revocations and cancel the associated uses. It should also move quickly to cancel all chlorpyrifos uses – even non-food uses – based on the risks posed to workers and bystanders and the serious extent and nature of those risks. EPA identified such risks in its December 2014 RHHRA, but has failed to date to stop uses that put workers at risk.

In the proposed revocation, EPA indicates that commenters must identify any earlier comments that they wish EPA to address and that it will treat as waived any comments that are not so identified. We disagree with this approach; EPA should consider all comments submitted on the RHHRA in this tolerance revocation proceeding, even if not resubmitted or incorporated by reference, because EPA has yet to respond to the submitted comments on the RHHRA. At a minimum, EPA should consider the following comments, which are hereby incorporated by reference:

Earthjustice, *et al.*, Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Apr. 30, 2015), at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0848> (**Attachment 1**);

Faustman, Elaine M., Ph.D. DABT. Comment on US EPA's Revised Human Health Risk Assessment for Chlorpyrifos Registration Review. (Apr. 30, 2015) at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0829> (**Attachment 2**);

Gerhart, Matthew., *et al.*, Farmworker Justice, *et al.* Comments on Preliminary Human Health Risk Assessment for Chlorpyrifos Registration Review (Oct. 6, 2011), at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0098> (**Attachment 3**);

Morrissey, Barbara, *et al.* Comment on US EPA's Revised Human Health Risk Assessment for Chlorpyrifos Registration Review. (May 8, 2015) at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0842>) (**Attachment 4**);

Reeves, Margaret, *et al.* Pesticide Action Network, *et al.*, Comments on Chlorpyrifos; Preliminary Evaluation of Potential Risk from Volatilization (May 7, 2013), at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0165> (**Attachment 5**);

Sass, Jennifer, Ph.D., *et al.*, Natural Resources Defense Council, *et al.*, Comments on the Chlorpyrifos Preliminary Human Health Risk Assessment for Registration Review (Oct. 3, 2011), at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0097> (**Attachment 6**);

Tobin, Erin M., *et al.*, United Farm Workers, *et al.*, Comments on Chlorpyrifos Registration Review; Preliminary Evaluation of the Potential Risk from Volatilization (May 7, 2013), at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0157> (**Attachment 7**);

Tupper, Karl. Pesticide Action Network North America Comments on Preliminary Registration Review Work Plan for Chlorpyrifos (May 18, 2009), at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0010> (**Attachment 8**); and

Whyatt, Robin M., *et al.* Comment submitted on US EPA's Revised Human Health Risk Assessment for Chlorpyrifos Registration Review. (Apr. 30, 2015) at <http://www.regulations.gov#!documentDetail;D=EPA-HQ-OPP-2008-0850-0510> (**Attachment 9**).<sup>3</sup>

## II. THE REGISTRANTS BEAR THE BURDEN OF PROVING SAFETY.

Under the Food Quality Protection Act ("FQPA"), EPA establishes tolerances setting the maximum residue of a pesticide allowed on food, and it 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." 21 U.S.C. § 346a(b)(2)(A)(i). To find a pesticide residue safe and

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<sup>3</sup> EPA fails to address endocrine disruption effects in its proposed revocation rule. We are attaching NRDC's comments on "Use of High Throughput Assays and Computational Tools: Endocrine Disruptor Screening Program" (Aug. 15, 2015), submitted in EPA-HQ-OPPT-2015-0305, which describe how EPA's current endocrine disruptor screening program is under-protective (**Attachment 10**).

issue establish a tolerance, EPA must determine “that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure” to the pesticide, *id.* § 346a(b)(2)(A)(ii); and it must make this safety determination specifically for infants and children. *Id.* § 346a(b)(2)(C)(ii)(I) & (II).

In the proposal to revoke tolerances, EPA repeatedly states 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.”).

EPA, however, has indicated that the registrants can try to present evidence that some uses of chlorpyrifos can continue. 80 Fed. Reg. at 69,080. If registrants or growers seek to retain tolerances, the pertinent question is “whether information exists to demonstrate that such tolerance(s) meet(s) the FFDCA section 408(b) safety standard.” *Id.* It is important to note that the registrants bear the burden of proving safety, and that safety must be demonstrated on an aggregate and cumulative basis. The proponents of chlorpyrifos bear the ultimate burden of persuasion related to the chlorpyrifos registration. 40 C.F.R. § 164.80. At least one circuit has found that the burden of proof is also on the pesticide proponent for the establishment of a tolerance. *Env'tl. Def. Fund, Inc. v. U.S. Dep't of Health, Ed. & Welfare*, 428 F.2d 1083, 1092 (D.C. Cir. 1970) (citing H.R.Rep. No. 1385, 83rd Cong., 2d Sess., 5 (1954); S.Rep. No. 1635, 83rd Cong., 2d Sess., 4 (1954); 2 U.S.Code Cong. & Ad.News, p. 2629, 83rd Cong., 2d Sess. (1954)). EPA has described this exercise as determining whether appropriate labeling restrictions would mitigate the risks sufficiently so that some tolerances would not need to be revoked and the uses could continue. 80 Fed. Reg. at 69,080.

Under the FQPA, EPA cannot leave a tolerance in effect unless it can make an affirmative determination that there is reasonable certainty of no harm from use of the pesticide in accordance with the label, and it must make this finding specifically for infants and children. Here, it must also make this finding for pregnant women because EPA has determined that chlorpyrifos causes neurodevelopmental harm to children from prenatal exposure. The current body of evidence precludes a finding that there is reasonable certainty of no harm. EPA's standard modeling reveals drinking water contamination that puts infants and children at risk. The drinking water contamination consumes the entire risk cup for chlorpyrifos, meaning no food uses can be allowed.

In the face of EPA's findings in the revocation proposal, the burden is on the registrants to demonstrate based on available information that label requirements could make some uses safe. This is a heavy burden and one that will be extremely difficult, and likely impossible, to meet. And even if the registrants can present such evidence for individual uses, they must then show that there is reasonable certainty of no harm from those uses along with all other organophosphate exposures. EPA acknowledges its obligation to protect against cumulative risks from organophosphates, but it has failed entirely to take such cumulative risks into account

in this tolerance revocation proceeding. Accordingly, EPA's review of chlorpyrifos in isolation is far from protective and falls short of the FQPA's mandates.

**III. EPA MUST RETAIN ALL SAFETY FACTORS IN LIGHT OF ADVERSE NEURODEVELOPMENTAL IMPACTS OF CHLORPYRIFOS ON CHILDREN, AND EVEN WITH THE APPROPRIATE SAFETY FACTORS, FOOD AND DRIFT EXPOSURES IN ADDITION TO DRINKING WATER EXPOSURES ARE UNSAFE.**

Our comments on EPA's RHHRA (at 7-8) describe the FQPA's origins and required safety determination for pesticides to be used on food. Our comments also review (at 28-30) the purpose and longstanding basis for safety/uncertainty factors to be used when a risk assessment is the basis for a regulation to protect public health. To recap, for decades, EPA has used a combined 100-fold safety factor when using animal test data to assess human health risks from toxic exposures. This 100-fold safety factor is made up of two components: (1) an inter-species 10-fold safety factor to account for extrapolating from animal studies; and (2) an intra-species 10-fold safety factor to account for variations in susceptibility and other exposures among the human population.

The FQPA built on this past use of safety factors to ensure an ample margin of safety from pesticide exposures. The FQPA's legislative history indicated:

that a tolerance will provide a "reasonable certainty of no harm" if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined "no observable effect" level when data are extrapolated from animal studies.

H.R. Rep. No. 104-669, Part 2, at 41 (1996).

The FQPA provided for "an additional tenfold margin of safety" for infants and children to account for pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. 21 U.S.C. § 346a(b)(2)(C). Congress intended for EPA to interpret and apply this third 10-fold safety factor in furtherance of the recommendations of the pivotal National Academy of Sciences study, "Pesticides in the Diets of Infants and Children." H.R. Rep. No. 104-669, Part 2, at 43. Furthermore, an additional 10-fold uncertainty factor should also be used when there is evidence of developmental toxicity or incomplete data, and here there is abundant evidence of chlorpyrifos' developmental toxicity.

The FQPA constrains EPA's ability to eliminate or reduce safety factors. The FQPA provision directing use of an additional fetal toxicity safety factor provides that EPA can use a

different margin of safety, *e.g.*, reduce the safety factor “only if, on the basis of reliable data, such margin will be safe for infants and children.” 21 U.S.C. § 346a(b)(2)(C). As to the traditional safety factors, the legislative history establishes clear parameters for when the default 100-fold safety factor may be changed. In particular, EPA cannot reduce public health protection. It bears the burden of demonstrating that any different approach is equally protective of public health. H.R. Rep. No. 104-669, Part 2, at 41.

As we explain in our comments on the RHHRA, EPA has appropriately found, based on an extensive body of scientific literature, that chlorpyrifos exposure is associated with neurodevelopmental harm to children. EPA evaluated data on neurodevelopmental effects from experimental toxicology studies, mechanistic studies, and epidemiologic studies and found that, together, all this evidence supports the conclusion that prenatal exposures to chlorpyrifos result in adverse neurodevelopmental effects in children.

EPA appropriately integrated data from epidemiological studies when reaching this conclusion. As noted in the Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment at 7, epidemiological studies provide extremely valuable information to inform risk assessments:

Specifically, these types of human information provide insight into the effects caused by actual chemical exposures in humans and thus can contribute to problem formulation and hazard/risk characterization. In addition, epidemiologic and human incident data can guide additional analyses or data generations (*e.g.*, dose and endpoint selection for use in *in vitro* and targeted *in vivo* experimental studies), identify potentially susceptible populations, identify new health effects or confirm the existing toxicological observations.<sup>4</sup>

For the RHHRA, EPA conducted a thorough analysis of the study design and research methods used in the epidemiological studies and concluded that the studies were strong and appropriate to support the conclusion that chlorpyrifos played a role in the observed neurodevelopmental outcomes. EPA additionally reviewed these studies in the context of its Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides.<sup>5</sup> EPA again concludes that the epidemiology studies are exceedingly strong, noting:

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<sup>4</sup> EPA OPP, Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (Jan. 7, 2010) <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0851-0004> at 7 (**Attachment 11**).

<sup>5</sup> 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>.

These studies reflect different types of exposed groups in the total population which strengthens the weight of the evidence considerations regarding this stream of information. . . . EPA has considered the strengths and limitations of these studies, and believes that random or systematic errors in the design, conduct or analysis of these studies were unlikely to fully explain observed positive associations between in utero OP exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years).<sup>6</sup>

Since EPA's review of the literature for the RHHRA, peer reviewed studies have continued to be published showing that chlorpyrifos is associated with long-lasting neurological damage to children. Eleven year olds who had been exposed to chlorpyrifos in the womb had tremors in both arms that affected their ability to draw. The study's authors expressed concern that this damage could hinder these children's writing abilities and success in school.<sup>7</sup> In addition, two recent studies from the CHAMACOS cohort show that organophosphate exposure harms children's lungs.<sup>8</sup>

EPA reconstructed the chlorpyrifos doses experienced by pregnant women that were associated with serious adverse neurodevelopmental impacts in their children, like reduced IQ, loss of working memory, delayed development, and attention disorders. EPA found that the pregnant mothers would have had less than 1% cholinesterase inhibition. In other words, EPA determined that the neurodevelopmental harm occurred when the mothers were exposed to far lower doses of chlorpyrifos than what produces 10% cholinesterase inhibition, EPA's regulatory endpoint. EPA appropriately retained the FQPA tenfold safety factor because of these effects.

EPA has, however, continued to regulate based on the 10% cholinesterase endpoint, even though neurodevelopmental harm to children occurred at lower exposures, sometimes below 1% cholinesterase inhibition. And to make matters worse, it eliminated or reduced the traditional safety factors in reliance on a model developed by DowAgrosciences to try to pinpoint the exposures that will produce 10% cholinesterase inhibition. Dow has created a model, using human testing of questionable ethical and scientific quality, to be used in place of extrapolation from animal studies. *See Earthjustice Comments on RHHRA at 36-42.* In reliance on this model, EPA has eliminated the inter-species tenfold safety factor entirely and shrunk the intra-species factor for infants and children.

EPA bears the burden of proving that dispensing with or shrinking the traditional safety

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<sup>6</sup> *Id.* at 54-55.

<sup>7</sup> Rauh, V. A. *et al.*, Prenatal Exposure to the Organophosphate Pesticide Chlorpyrifos and Childhood Tremor, *Neurotoxicology* 51, 80-86 (2015) (**Attachment 12**).

<sup>8</sup> Raanan, R. *et al.*, Early-life exposure to organophosphate pesticides and pediatric respiratory symptoms in the CHAMACOS cohort, *Environ. Health Perspect.* 123, 179-85 (2015) (**Attachment 13**); Raanan, R. *et al.*, Decreased lung function in 7-year-old children with early-life organophosphate exposure, *Thorax* (2015) Dec 3. doi:10.1136/thoraxjnl-2014-206622 (**Attachment 14**).

factors will be equally protective of public health. It cannot meet this burden of proof here. First, in reducing the traditional safety factors, EPA never addressed the neurodevelopmental impacts to children that occur at lower doses than EPA’s and the Dow model’s endpoints. EPA cannot show that the shrunken safety factors are protective of these extremely serious health impacts. Second, focusing myopically on cholinesterase inhibition and embracing Dow’s model to reduce health protection violates EPA’s policy of setting its regulatory limits based on the most sensitive endpoint. 80 Fed. Reg. at 69, 083 (“EPA then evaluates the hazards to determine the most sensitive and appropriate adverse effect of concern, based on factors such as the effect’s relevance to humans and the likely routes of exposure.”). EPA also is not using a no observable effects level as the starting point for setting its regulatory endpoint since the brain impacts occurred at lower doses than the endpoint it is using. Third, EPA tries to justify not using neurodevelopmental impairments as its regulatory endpoint because the mode of action causing such impairments is uncertain. While that uncertainty may contribute to the difficulty in establishing a quantitative dose-response relationship, it provides no excuse for allowing exposures to increase and approach a level that EPA cannot find is safe. In light of the extensive evidence of adverse brain impacts from chlorpyrifos exposure at low levels, EPA cannot support a determination that there is reasonable certainty of no harm from the exposures allowed using the Dow model and shrunken safety factors.

If EPA had retained all of the safety factors, its risk assessment would show untenable risks from food and drift, as well as from drinking water. Therefore, EPA’s assertion that food and bystander exposures do not pose risk concerns is erroneous. *See* 80 Fed. Reg. at 69,082.

To calculate risk estimates for food-only exposures, EPA divided the steady state point of departure for food ( $ssPOD_{food}$ ) by the total safety factor to determine the steady state population adjusted dose for food ( $ssPAD_{food}$ ). The PAD is then compared to the estimated food exposure. If food exposure is near or in excess of 100% of the PAD, then the food exposure is a risk of concern. Using the erroneous Dow model and shrunken safety factors, EPA found no risks of concern for any population (as shown below in EPA’s Table 3, replicated below from 80 Fed. Reg. at 69,097). However, if EPA had retained the minimal necessary safety factors (10X interspecies, 10X intraspecies, 10X FQPA) for a combined total of 1000X, it would have documented risks of concern for children from food exposures alone as shown in Table 1.

**Table 1.** Comparison of EPA’s risk calculations from food only with shrunken safety factors (left 5 columns) to calculations using the appropriate combined safety factors (right 2 columns). Red highlighting indicates risks of concern for nearly every population when the normal default safety factors are used.

EPA’s Table 3 Steady State Dietary (Food Only) Exposure and Risk Estimates for Chlorpyrifos (80 Fed. Reg. at 69,097)					Food Only Risk Estimates with 1000X Combined Safety Factors	
Population Subgroup	$ssPOD_{food}$ (ug/kg/day)	$ssPAD_{food}$ (ug/kg/day)	Food Exposure	% of $ssPAD_{food}$	Recalculated $ssPAD_{food}$	Recalculated % of

(Safety Factor Used)			(ug/kg/day)		(ug/kg/day)	ssPAD <sub>food</sub>
Infants (<1 year) (40X)	103	2.6	0.186	7.2	0.103	<b>181%</b>
Children (1-2 years) (40X)	99	2.5	0.242	9.7	0.099	<b>244%</b>
Youths (6-12 years) (40X)	90	2.2	0.128	5.8	0.09	<b>142%</b>
Adults (Females 13-49 years) (100X)	78	0.78	0.075	9.6	0.078	<b>96%</b>

A combined safety factor of at least 1000X is warranted for chlorpyrifos as described above. A 1000X safety factors is required for organophosphate pesticides due to uncertainties around neurodevelopmental effects and data gaps in the toxicity database. An even larger safety factor may well be warranted for chlorpyrifos due to these effects, data gaps, and uncertainties. Indeed, EPA has employed a 3000X safety factor for terbufos under similar circumstances.<sup>9</sup>

To reduce risks to bystanders from spray drift, EPA modeled the size of buffers that would be necessary to reduce exposures below its risk level of concern (called margin of exposure). Normally, when EPA retains the traditional safety factors and the FQPA safety factor, its margin of exposure is 1000, meaning it prohibits exposures unless they are 1000 times less than the no observable adverse effects level. For chlorpyrifos, EPA set the margin of exposure at 100 for dermal exposures and 300 for inhalation exposures. Chlorpyrifos Evaluation of the Potential Risks from Spray Drift and the Impact of Drift Reduction Measures at 17-18 (July 13, 2012). EPA then modeled the buffer sizes that would be required to reduce exposures to below EPA's risks of concern. For most crops, application rates, and droplet sizes, EPA's analysis, even using these inadequate protection factors, shows that risks of concern remain at distances of 100-125 feet or more from the application site. *Id.* at 32-40. EPA's modeling is based solely on dermal exposures to adults from groundboom and airblast applications, *i.e.*, it ignores inhalation drift from application methods other than aerial spraying. *Id.* at 31.

In July 2012, the registrants agreed to impose buffers around schools, daycares, hospitals,

<sup>9</sup> Terbufos Occupational and Residential Exposure Assessment for the Registration Review Risk Assessment at 8 (Sept. 15, 2015), at EPA-HQ-OPP-2008-0119.

homes, and other places people gather, but these buffers are quite small. For groundboom applications, they are 10 feet, for airblast, they are generally 10 feet except for the highest application rates where they are 25-50 feet, and for aerial spraying they range from 10-100 feet. RHHRA at 82. If EPA used the full 1000X safety factor, far larger buffers would be needed according to EPA's own analysis. EPA ran its drift model only for distances of 0-125 feet from the application site so its modeling results do not identify the size of buffers larger than 125 feet that would be necessary to reduce risks of concern from drift. EPA's modeling demonstrates, however, that risks of concern remain with the buffers that have been put in place when appropriate safety factors are used.

IV. EPA MUST REVOKE ALL TOLERANCES TO ENSURE THAT INFANTS ARE PROTECTED FROM DRINKING WATER CONTAMINATION.

EPA is proposing to revoke all chlorpyrifos tolerances based on drinking water contamination. The documented exceedances of EPA's drinking water levels of concern from all chlorpyrifos uses compel revoking all tolerances and ending all food uses. EPA, however, is holding open the possibility that registrants and growers can submit additional information to show that some watersheds may not be at risk from certain chlorpyrifos uses. EPA should not go down this dangerous path because doing so would preclude EPA from meeting its obligation to ensure infants will be protected.

A. EPA Found Risks Of Concern from Drinking Water Contamination that Preclude Making the Required Safety Finding for Chlorpyrifos Uses.

EPA's drinking water assessment focuses on the chlorpyrifos oxon because typical drinking water treatment (chlorination) results in transformation of chlorpyrifos into the chlorpyrifos oxon. EPA assumes that all chlorpyrifos in water is converted to the oxon during treatment. 80 Fed. Reg. at 69,082.<sup>10</sup>

Using its standard drinking water assessment methods, EPA found that many, if not most, label uses of chlorpyrifos result in drinking water contamination levels that exceed EPA's levels of concern for infants and children. 80 Fed. Reg. at 69,082, 69,083.<sup>11</sup> EPA found:

[W]hen growers use maximum application rates, or even rates much lower than maximum, chlorpyrifos oxon concentrations in

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<sup>10</sup> Because more than 75% of community water systems use chlorination, EPA found the 100% conversion assumption "not overly conservative." *Id.* at 69,102. Some treatment methods might be more effective in reducing the oxon in drinking water, but they are not typically in use (and not in smaller community water systems, which EPA believes are at greatest risk). *Id.* at 69,102, 69,104.

<sup>11</sup> EPA used the steady state concentrations, which tend to be much lower than the acute levels, *e.g.*, 3.9 ppb vs. 24 ppb for infants. *Id.* at 69,101. EPA notes that "it is possible that for some limited numbers of use scenarios, the EDWC could result in an exceedance of the acute DWLOC, but not the steady state DWLOC." 80 Fed. Reg. at 69,101. If EPA relies on any refined watershed assessments, it would need to guard against any such acute exceedances.

drinking water could pose an exposure concern for a wide range of chlorpyrifos uses.

*Id.* at 69,106. As a result, EPA “cannot make a safety finding based on drinking water exposures.” *Id.*

The surface water model takes into account local soil, site, hydrology, and weather characteristics. For the regional screen, EPA also uses satellite data to determine what it calls percent cropped areas (“PCA”), which reflects the percentage of the areas in agricultural crops that could be treated with the pesticide. *Id.* at 69,085.<sup>12</sup>

A major shortcoming in EPA’s modeling is its failure to account for application of chlorpyrifos to an impervious surface (*e.g.*, building grounds and other areas that do not consist of soil or turf). Chlorpyrifos is registered for use around buildings and for mosquito control in areas that are not cropland. This omission is serious, given that the impervious surface scenarios result in the highest number of exceedances of EPA’s drinking water levels of concern and at the highest concentrations.<sup>13</sup> Despite these model results, EPA did not include the impervious surface uses in its national and regional drinking water analyses. Instead, its Updated Drinking Water Assessment states: “Due to the uncertainty associated with some urban uses (*e.g.*, wide area/general outdoor treatment) that are represented by the impervious scenarios, modeled results from the impervious scenarios are not included in this analysis. Additional clarification from the registrants is needed in order to determine if these uses pose an exposure concern.” Updated Drinking Water Assessment at 5; *see also id.* at 17 (“It should be noted that there are still a few uses, specifically urban uses (*e.g.*, wide area treatment of miscellaneous pests) that need to be clarified in order to determine the potential exposure as a result of these uses”).

EPA modeled upper and lower bound exposure scenarios by using the highest and lowest application rates, *e.g.*, tart cherries for the high end (5 applications totaling 14.5 pounds per acre per year) and bulb onions (1 application at 1 pound per acre per year) at the low end. The tart cherry scenario resulted in exceedances, while the bulb onion scenario did not. 80 Fed. Reg. at 69,102.

EPA then modeled drinking water concentrations for a single application at various application rates for a range of representative chlorpyrifos uses, many of which produced drinking water contamination above EPA’s levels of concern. *Id.* at 69,103. EPA’s surface water modeling “showed that even with only one application, several chlorpyrifos uses may exceed the DWLOC at rates lower than maximum labeled rates (both single as well as yearly), including an application rate of one pound per acre per year.” *Id.* at 69,102. EPA estimated that

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<sup>12</sup> EPA Office of Chemical Safety and Pollution Prevention, “Chlorpyrifos: Updated Drinking Water Assessment for Registration Review,” PC Code 059101; DP Barcode 424487, December 23, 2014, at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0199>. EPA did not adjust its national screening based on the PCA: “Because chlorpyrifos is used on a number of agricultural crops, as well as turf, a drinking water intake percent cropped area (PCA) adjustment factor of 1 was used.” *Id.* at 4.

<sup>13</sup> Updated Drinking Water Assessment Attachment, at EPA-HQ-OPP-2008-0850-0199.

such exceedances would occur to different extents at various locations across the country, and exceedances were expected for almost half of the uses considered at 1 or 4 pounds per acre per year. *Id.* As we explain in our RHHRA comments at 74:

For the low application rate, exceedances are expected at the 99th percentile for 51 of the 124 scenarios (41%) evaluated. For the high application rate, exceedances are expected at the 99th percentile for all but one of the uses evaluated: 20 of the 21 scenarios (95%). Indeed, the drinking water assessment notes that “The current maximum single application rates for a wide range of chlorpyrifos use scenarios may result in a 21 day average concentration that exceed the DWLOC. In total for the low and high application rates, exceedances are expected for about half (49%) of all scenarios evaluated.”

Table 8 shows that for some of the uses the 21-day exceedances are expected to occur with considerable frequency. For the Michigan cherries scenario, chlorpyrifos drinking water levels would be unsafe for almost half (42%) of the 21-day periods considered over 30 years. Table 8, 80 Fed. Reg. at 69,103. EPA concluded that:

EPA’s analysis shows that the current maximum single application rates for a wide range of chlorpyrifos use scenarios result in a 21-day average concentration that exceeds the DWLOC. And the analysis makes clear that exceedances may occur with considerable frequency.

*Id.* at 69,104.

EPA compared the model results to available monitoring data. When parameterized to reflect reported use and percent cropped areas, the modeling produces drinking water concentrations that are within a range of 10X of the measured concentrations reported in monitoring data. *Id.* at 69,102, 69,105. Because the modeled and measured concentrations were similar, EPA deemed the modeling results “not overly conservative.” *Id.* at 69,105.

These findings of extensive and unsafe drinking water contamination from chlorpyrifos form the basis of EPA’s proposal to revoke tolerances. EPA should finalize the tolerance revocations in order to protect children and comply with the FQPA.

B. It Would be Indefensible for EPA to Allow Chlorpyrifos Uses to Continue in Some Watersheds or Under Certain Conditions.

In its proposal to revoke all tolerances, EPA invites registrants and growers to submit evidence showing that drinking water contamination would not result from some chlorpyrifos uses some locations around the country. EPA bases this invitation on its belief that drinking water contamination from chlorpyrifos may occur primarily in smaller watersheds where large

quantities of chlorpyrifos are used. Basing tolerance revocations on refined watershed assessments that try to pinpoint at-risk watersheds would not be protective or consistent with the FQPA.

EPA conducted refined drinking water assessments for the Pacific Northwest and South-Atlantic-Gulf to examine potential geospatial concentration differences. At the outset, it cautioned that “it is currently challenging to assess exposure on a local scale due to the unavailability of data and wide range of characteristics (*e.g.*, environmental characteristics such as soil, weather, etc. or other variables such as drinking water treatment processes) . . .” *Id.* at 69,104. This cautionary note is well-deserved and undermines the results produced by the refined watershed assessments.

EPA nonetheless proceeded with the refined watershed assessments in which it adjusted for the percent of cropped area and evaluated a single application of 1 and 4 pounds per acre. EPA found that most of the application scenarios at the higher application rate, which reflects fruit and nut tree and turf uses, but only a few at the lower application rate, exceeded risks of concern in the Northwest. Far more uses produced risks of concern in the South-Atlantic-Gulf watershed even at the low application rate. Updated DWA at 23-27. The Updated Drinking Water Assessment (at 25) notes that even more exceedances would be expected for higher application rates or multiple applications. In order to determine whether exceedances might be expected in watersheds with drinking water intakes, EPA conducted a preliminary analysis to determine whether corn cropland overlapped with the locations of such intakes. Even considering only this one crop, EPA found substantial overlaps of potential chlorpyrifos use sites and water supplies for community drinking water systems. *Id.* at 28.

From the refined modeling, EPA asserts that the “primary source of risk comes from chlorpyrifos and chlorpyrifos oxon in drinking water in highly vulnerable watersheds (generally small watersheds where the land is agricultural and could be treated with chlorpyrifos (*i.e.*, heavily cropped areas)).” 80 Fed. Reg. at 69,080. It then asserts that small watersheds are more vulnerable than larger ones and that completion of refined analyses for the whole country might support mitigating drinking water risks through label restrictions instead of revoking all tolerances nationwide. *Id.* at 69,085.

It would be indefensible for EPA to allow chlorpyrifos uses to continue in larger watersheds or based on assumptions about the extent of use because the refined modeling is no longer conservative and it likely underestimates risks in several respects. First, EPA’s drinking water level of concern is based on the wrong regulatory endpoint – cholinesterase inhibition instead of neurodevelopmental impacts to kids from prenatal exposures. The brain impacts occur at lower levels of exposure.

Second, even for the wrong endpoint (cholinesterase inhibition), EPA shrunk the safety factors to 50X and 100X for children and adults respectively, instead of 1000X. EPA’s drinking water levels of concern are far too high by at least an order of magnitude.

Third, EPA bases its refined drinking water assessment on a single application and often

fails to consider the highest application rates allowed by the label. It also assumes that all chlorpyrifos treatment will occur on a single day at the same application rate. By making these assumptions, EPA fails to account for the reality that multiple farms and crops are often situated in a single watershed, applying chlorpyrifos on different dates and at different application rates on crops producing runoff into the same watershed.

Fourth, the overlap of chlorpyrifos use sites with drinking water intakes was conducted for only one crop – corn. This modeling is under-inclusive. For example, the regional assessment for the South-Atlantic-Gulf found that, in addition to corn, chlorpyrifos uses on cotton, soybean, vegetable, ground fruit, fruit and nut trees were all expected to result in exceedances. The actual overlap between chlorpyrifos use sites and drinking water intakes is, therefore, likely significantly higher than assumed in EPA’s regional assessment.<sup>14</sup>

Fifth, none of the water modeling considers uses of chlorpyrifos on impervious surfaces. This omission is glaring given that impervious surface uses produced the largest number of exceedances at the highest concentrations according to the Drinking Water Assessment Attachment.

For all of these reasons, EPA’s refined watershed assessments underestimate exposure and risk. EPA acknowledges that “it is currently challenging to assess drinking water exposure on a local scale due to the unavailability of data and wide range of characteristics (*e.g.*, environmental characteristics such as soil, weather, etc. or other variables such as drinking water treatment processes) that affect the vulnerability of given community drinking water contamination to chlorpyrifos oxon contamination.” 80 Fed. Reg. at 69,085. Indeed, chlorpyrifos concentrations can vary from day to day based on the amount of rainfall that flushes the pesticide residues from soil into surface water.<sup>15</sup> Under the FQPA, EPA must base its exposure assessments and tolerance decisions on reliable data. It will fall short of this obligation if it uses watershed assessments laden with unprotective and unsubstantiated assumptions to reduce protection.

C. Dow’s Proposal to Incorporate Further Unprotective and Unsupportable Assumptions into the Drinking Water Assessments Should be Rejected.

For its part, Dow has proposed watershed-specific analysis that would reduce estimated exposures based on such factors as estimates of the percent of the crop treated with chlorpyrifos

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<sup>14</sup> EPA used surrogate PCA to estimate the relative contribution of chlorpyrifos transported to surface water for 634 drinking water intakes that lack delineated watersheds, but more than 700 drinking water intakes lack a surrogate PCA. Updated Drinking Water Assessment, at 25.

<sup>15</sup> In 2001, EPA quantified the reduction in surface water contamination based on the no-spray buffers that Dow proposed and eventually included on the labels. Notably, EPA assumed that runoff would continue to occur and would lead to surface water concentrations that exceed EPA’s levels of concern for aquatic life. Rice *et al.*, OPP Environmental Fate and Effects Division, Revised Labels and Mitigation Review for Lorsban (July 31, 2001) (**Attachment 15**). EPA has not reconciled its drinking water modeling with its 2001 findings.

and specific information about local conditions.<sup>16</sup> Going down the path of trying to identify and limit pesticide use restrictions to at-risk watersheds, while leaving others at risk from chlorpyrifos use, would be a flawed and inadequately protective approach that falls short of the FQPA's mandates for several reasons.

First, there is no national water monitoring system designed to produce the data that can show with confidence the worst case outcomes from use of a pesticide in accordance with label directions. EPA recognizes that monitoring "generally does not provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days." 80 Fed. Reg. at 69,085; *see also* Updated Drinking Water Assessment at 29. To produce valid measurements of peak concentrations, sampling frequency would need to approximate the duration of exposure of concern. Some of the best monitoring programs, like the US Geological Survey's NAWQ Assessment, conduct sampling according to a schedule that is not tailored to when chlorpyrifos applications occur or peak concentrations are likely. 80 Fed. Reg. at 69,105.

Second, there also is no mandatory, nationwide use reporting system. The systems that exist suffer from data gaps and limitations that impede their ability to provide accurate estimates of chlorpyrifos use. Available estimates for pesticide use data are based on survey information collected by the National Agricultural Statistics Service, National Pesticide Use Data, or EPA, and the US Geological Survey (USGS) has created a method for estimating annual pesticide use in U.S. counties called EPest. These pesticide use reporting programs have significant limitations. For example, they cover only agricultural crops and not other uses. Moreover, for specialty crops, "fewer surveys are usually available to estimate application rates and there are a greater number of years with unreported crop acreage, potentially resulting in greater uncertainty in use estimates."<sup>17</sup> For the EPest model, the estimates are based on available survey data, and the underlying datasets have not been consistently available for each region surveyed, resulting in further uncertainty in the use estimates. Similar limitations exist for the other pesticide use reporting programs.<sup>18</sup>

A recent study illustrates the limitations of currently available pesticide use data, drawing from air and rain sampling conducted by USGS in 1995 and 2007 in the Mississippi River

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<sup>16</sup> Meeting between Dow AgroSciences (DAS) and EPA (Sep. 10, 2015), at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0853> (DAS presented eight actionable concepts for refining predictions of surface water concentrations).

<sup>17</sup> Thelin, G.P., and W.W. Stone, "Method for Estimating Annual Atrazine Use for Counties in the Conterminous United States, 1992–2007," U.S. Geological Survey Scientific Investigations Report, 2010-5034. USGS, 2010 (**Attachment 16**).

<sup>18</sup> Thelin, G.P., and W.W. Stone, "Estimation of Annual Agricultural Pesticide Use for Counties of the Conterminous United States, 1992–2009," U.S. Geological Survey Scientific Investigations Report, 2013–5009. USGS, 2013 (**Attachment 17**).

Valley.<sup>19</sup> Chlorpyrifos was the second most frequently detected insecticide in air in 1995 (38%).<sup>20</sup> Annual chlorpyrifos use has been on the decline for the past several years, dropping in Mississippi from over 19,000 kg in 1995 to 2 kg in 2007. However, in 2007, air monitoring detection frequency of chlorpyrifos increased to 95%, with a mean air concentration only slightly less than in 1995. This discrepancy may have been due to erroneous pesticide use estimates since the estimates are only as good as the data on which they are based, and the EPest model generates use estimates even where data are unavailable.<sup>21</sup> These and other serious limitations in available pesticide use estimates makes them an unreliable basis for assuming chlorpyrifos will be used differently than what the label allows. EPA therefore cannot credibly rely on use estimates to assume reduced exposure to chlorpyrifos in drinking water.

Third, relying on current usage information to predict reduced exposures is factually flawed because usage varies depending on many factors such as changing crop patterns and pest pressures. For example, the amount of chlorpyrifos used in California remained relatively constant from 2009-2011, declined from 2011 to 2012, but then increased by almost 35% in 2013. The number of acres treated also increased by 18% in 2013 (*see* Table 2 below). Such variations likely occur throughout the country, but the extent and where is unknown as California is the only state that requires comprehensive pesticide use reporting and for which accurate pesticide use information is available.

**Table 2. Chlorpyrifos use in California.** Data from California Pesticide Information Portal shows that both the amounts of chlorpyrifos used and the acres treated with chlorpyrifos can vary significantly from year to year. (CALPIP <http://calpip.cdpr.ca.gov/main.cfm>; Query used: Year= 2009-2013; Chemical= Chlorpyrifos; Pounds Chemical Applied; Amount Treated; Unit Treated)

Year	2009	2010	2011	2012	2013
Millions of pounds chlorpyrifos used	1.25	1.29	1.30	1.10	1.48

<sup>19</sup> Majewski, Michael S., Richard H. Coupe, William T. Foreman, and Paul D. Capel, "Pesticides in Mississippi Air and Rain: A Comparison between 1995 and 2007: Pesticides in Mississippi Air and Rain," *Environmental Toxicology and Chemistry* 33, no. 6 (June 2014): 1283–93. doi:10.1002/etc.2550 (**Attachment 18**).

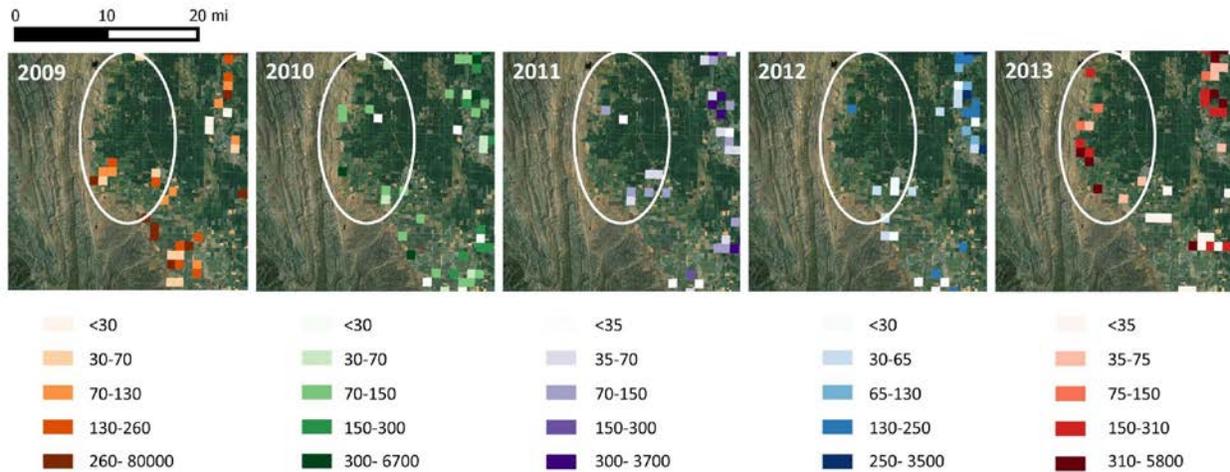
<sup>20</sup> Interestingly, malathion was detected less frequently that year (29%), even though its reported usage was greater than chlorpyrifos.

<sup>21</sup> Use estimates for some pesticides did not correlate well with other published usage rates for some crops and years. Thelin and Stone, 2013. Chlorpyrifos has been identified as a pesticide that had a "low estimate of 2 kg (the value reported by the USDA NASS) [that] was very different from the high estimate of 14,000 kg." Majewski *et al.* 2014.

<b>Millions of acres treated with chlorpyrifos</b>	0.93	1.1	1.2	1.1	1.3
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Furthermore, the locations of reported chlorpyrifos applications exhibited highly variable patterns, with some locations showing consistent usage patterns and rates from year to year, while others experienced highly variable usage, as shown in Figure 1.

**Figure 1.** Maps of California pesticide use reporting (PUR) data for chlorpyrifos show considerable variation in chlorpyrifos use geospatially from year to year. There is fairly consistent chlorpyrifos use in the upper right corner of each map, while the area within the white circle shows a high amount of variability. Each colored pixel represents a “section”, an area of approximately 1 square mile. The darker the shade of the pixel, the more chlorpyrifos was used in that section. Legends below maps show the sum of pounds of chlorpyrifos used in each section. The area shown in the maps is surrounding Williams, CA - approximately 30 miles west of Yuba City. PUR data mapped using QGIS 2.8.2.



EPA should reject Dow’s proposal to rely on current usage data to try to pinpoint risks for specific watersheds since there is little if any assurance that current usage data will capture real-world patterns of chlorpyrifos usage over time. The California data show that crops, land use patterns, and pesticide use patterns can vary significantly, and it is EPA’s mandate to ensure that all watersheds will be protected regardless of how use patterns change from year to year. If, as often happens, use patterns change at specific sites, unsafe contamination levels could ensue.

Fourth, not only would it be factually fraught to rely on the fragmented data on current usage that exist, but it also would be legally impermissible to base FQPA safety determinations on assumptions that exposures will be less than what the label allows. FQPA requires EPA to make safety findings based on the intended and authorized use of a pesticide. Cf. 21 C.F.R. §

70.3(i) (regulations implementing analogous FFDCSA safety standard, which FQPA amended, define “safe” to mean “there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use”). For pesticides, EPA’s tolerance regulations establish the residues allowed on food, and the pesticide labels it approves under FIFRA establish the allowable use conditions designed to keep residues below tolerance amounts. It is through the label that EPA authorizes pesticide use and it is the label restrictions that are binding and enforceable under FIFRA. 7 U.S.C. §§ 136(ee), 136j(a)(2)(G). EPA can meet its obligation to ensure there is reasonable certainty of no harm only through what it commands and what it can enforce. It is therefore the label that must ensure that there will be no residues above the tolerance levels and reasonable certainty of no harm in the aggregate from chlorpyrifos use. In other contexts, agencies must regulate to prevent the on-the-ground harm that is authorized by the agency, rather than assume that something less than what is authorized will occur. *See, e.g., Conservation Council for Hawaii v. Nat’l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1220-21 (D. Haw. 2015) (“[T]he MMPA makes clear that it is the authorized take that must be evaluated in determining whether there will be a negligible impact.”); 40 C.F.R. Part 51, App’x W § 8.2 (assumptions about background concentrations of pollutants for Prevention of Significant Deterioration Permits must be based on the maximum amounts that background sources are allowed to emit, unless those other sources have legally binding limits).

Moreover, FQPA likely precludes use of percent of crop treated data (“PCT”) in this tolerance revocation proceeding. FQPA authorizes EPA to consider available data on the percent of food actually treated with the pesticide *when assessing chronic dietary risk*. 21 U.S.C. §346a(b)(2)(F). In addition, before considering percent of crop treated data in setting tolerances, EPA must make a series of findings concerning reliability of the data, whether the data provide a valid basis to show what percentage of food is likely to contain pesticide residues, and whether the data underestimate exposure in local areas or for any populations groups. *Id.*

In keeping with the FQPA, EPA has historically used percent of crop treated data only in assessing chronic exposures, which are defined as exposures manifesting themselves over one year or longer. 72 Fed. Reg. 39,318, 39,325 (July 18, 2007). It has refrained from relying on such data in assessing acute exposures because doing so would “mask[] the highest levels of pesticide residues expected in food by averaging residue values from treated and untreated commodities in estimating pesticide exposure.” *Id.* It appears that EPA departed from this practice by using PCT in its assessment of acute food risks. 80 Fed. Reg. at 69,084, 69,096. Doing so, however, runs afoul of the FQPA provision authorizing use of such data only in assessing chronic, not acute, risks.

Dow’s proposal to use percent of crop treated data in watershed-specific assessments is even more troubling. The FQPA authorizes use of available data, if reliable and valid, on “the percent of *food* actually treated with the pesticide chemical.” 21 U.S.C. §346a(b)(2)(F). Dow is urging EPA to use percent of crop treated data to reduce the estimated amounts of chlorpyrifos that will migrate into drinking water supplies. The rationale for using percent of crop treated data in assessing exposure to residues of a pesticide on food may have little applicability to drinking water contamination. The amount of pesticide residues on food crops and people’s food

consumption patterns are not valid predictors of levels of drinking water contamination. Chlorpyrifos, for example, is regularly applied in orchards early in the growing season before emergence of the fruit. Such spraying would obviously leave no residues on the fruit. It could, however, produce runoff in spring storms and contaminate drinking water supplies. Similarly, pesticide labels often preclude harvesting food crops for a designated period of time after the last pesticide application, thereby reducing pesticide residues on food. Drinking water contamination, however, can occur during that interim period of time. EPA would be unable to make the reliability and validity determinations that are prerequisites to using percent of crop treated data in its drinking water assessments.

Resorting to refined or watershed-specific assessments to allow come chlorpyrifos uses to continue would be indefensible for another reason. EPA's drinking water assessments use a 21-day steady state assessment in lieu of a longer chronic assessment timeframe because of characteristics of cholinesterase inhibition from organophosphate exposures. 80 Fed. Reg. at 69,082. While this approach might be justified when assessing cholinesterase inhibition, there is no evidence and EPA has made no findings that the 21-day exposure time frame is adequate to protect against neurodevelopmental harm from chlorpyrifos exposures. For all of these reasons, EPA should refrain from basing its chlorpyrifos tolerance revocation determination on refined or watershed-specific drinking water assessments.

V. EPA MUST PROTECT CHILDREN, WORKERS, AND BYSTANDERS FROM PESTICIDE DRIFT AND VOLATILIZATION.

Under the FQPA, EPA must consider all aggregate exposures in its human health risk assessments. EPA's proposed revocation analysis erroneously assumes that there is no risk to children and other bystanders from pesticide drift, dust, take-home exposures, and volatilization and therefore it underestimates the risks.

A. The Buffers Adopted by the Registrants Are Inadequate to Protect Children and Other Bystanders from Pesticide Drift.

As our comments on the RHHRA recount, chlorpyrifos causes poisonings of children and other bystanders every year. Air monitoring studies have detected chlorpyrifos at schools and other sites at levels exceeding EPA's risk levels of concern.

While EPA conducted a drift assessment, its assessment grossly understates the risks for several reasons. First, EPA used 10% cholinesterase inhibition as its regulatory endpoint and shrunk the safety factors to 100X and 300X. EPA's assessment therefore does not assess neurodevelopmental harm or lead to mitigation to protect against this type of harm.

Second, EPA assessed drift based on dermal contact with treated surfaces for ground boom and airblast applications, but ignored inhalation exposures for all types of applications except aerial spraying. Inhalation brings chemicals directly into the blood stream since the function of lungs is to transport gases from the air into the blood, and from there all through the body including the brain and fetal circulation. This is very different from dermal exposures,

where the outer corneal layer of the skin is designed to protect the body from harmful exposures, and chemicals must traverse significant cellular layers before contacting the blood stream. EPA therefore significantly underestimated bystander exposures to spray drift – likely by hundreds or thousands of times – by ignoring inhalation, which is a highly significant route of exposure. Our comments relate other flaws in EPA’s drift assessment that similarly lead to understating the risks.

EPA’s drift assessments led to buffers put in place around schools, playgrounds, homes, hospitals, and other places people gather. However, these buffers are far too small to prevent chlorpyrifos exposures at harmful levels. Again our comments describe the many ways in which the small buffers are inadequate to protect against drift exposures and harm. EPA must take these exposures into account if it considers backing away from the proposal to revoke all chlorpyrifos tolerances.

B. EPA Has Failed to Conduct an Aggregate Exposure Assessment Based on All Exposures to Children and Bystanders.

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. This statement is completely at odds with how an aggregate risk assessment is supposed to be done. In an aggregate risk assessment, individual risks from different exposure pathways are added together in order to evaluate whether the compiled risks may exceed the level of concern, even if any one individual risk does not.

EPA cannot legitimately assert that no spray drift will occur past a 10-foot buffer zone (the smallest buffer zone for a sensitive site). Indeed, EPA already modeled how much spray drift travels past the much larger aquatic buffer zones of 25, 50 and 150 feet (*see* Table 10, Updated Drinking Watershed Assessment at 16) using AgDRIFT. It follows that spray drift will also move past the sensitive site buffer zones, and EPA can use the same model to estimate potential bystander exposures to such spray drift and dust contaminated from spray drift. These risks from spray drift must be aggregated together with other risks for bystanders. Even if risks from the spray drift alone did not exceed EPA’s levels of concern, which we dispute, the point of an aggregate assessment is to add multiple individual risks together. It is well documented that bystanders in agricultural communities experience greater pesticide exposures because of pesticide drift and volatilization, but EPA is not accounting for these exposures.<sup>22</sup>

As we noted in our comments on the RHHRA at 49-50, another source of exposure which EPA fails to account for in the aggregate exposure assessment is chlorpyrifos in contaminated

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<sup>22</sup> Coronado, G. D. *et al.* Organophosphate Pesticide Exposure and Residential Proximity to Nearby Fields: Evidence for the Drift Pathway. *J. Occup. Environ. Med.* 53, 884–891 (2011) (**Attachment 19**); Bradman, A. *et al.* Determinants of organophosphorus pesticide urinary metabolite levels in young children living in an agricultural community. *Int. J. Environ. Res. Public Health* 8, 1061–1083 (2011) (**Attachment 20**); Faustman, E. M. Comment on US EPA’s Revised Human Health Risk Assessment for Chlorpyrifos Registration Review. (2015). at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0829> (**Attachment 2**).

dust. This is a significant exposure pathway for young children in agricultural communities and must be added into the aggregate risk calculation.

C. EPA Has Erroneously Discounted Chlorpyrifos Volatilization

Based on Dow's nose-only vapor studies, EPA has concluded that inhalation of chlorpyrifos vapors causes no adverse effects. We dispute this conclusion for the reasons set out in our comments on the RHHRA, including flaws in the Dow studies.

Furthermore, even if valid, the studies do not justify completely discounting volatilization as a significant pathway by which chlorpyrifos moves from fields and thus contributes to human exposures. It is well established that when chlorpyrifos volatilizes, it partitions between the vapor phase and particulates.<sup>23</sup> The amount of chlorpyrifos sorbed to particulate matter in the air depends most strongly on the amount of total suspended particulate matter, temperature and relative humidity.<sup>24</sup> But Dow's nose-only vapor studies address exposures to chlorpyrifos only as a vapor, not as particulate matter. EPA has found that exposures to chlorpyrifos particulates do cause adverse effects. In fact, an acute inhalation study of rats exposed to particulate chlorpyrifos was used to set a lowest observed adverse effect level or LOAEL for cholinesterase inhibition. 80 Fed. Reg. at 69,087. In the real world, after chlorpyrifos is applied, it will volatilize, attach to particles, and move off fields, where it can be inhaled. Human exposures to chlorpyrifos particles resulting from volatilized material must be considered in the aggregate exposure assessment. This could contribute significantly to bystander exposures, given that EPA acknowledges that volatilization is a major pathway by which chlorpyrifos moves off fields.

Indeed, when EPA assessed volatilization from chlorpyrifos in 2013, it found that chlorpyrifos often volatilizes and travels long distances, and that buffers of 0.5 mile to almost 1 mile would be required in some cases to prevent exposing bystanders to risks of concern.<sup>25</sup> These findings are tragically borne out by reported pesticide poisoning incidents far from the fields. For example, workers in Washington State were sickened by chlorpyrifos being applied about a mile from their worksite.<sup>26</sup> Chlorpyrifos movement and redeposition at distances ¼ of mile or greater from the site of application has been documented,<sup>27</sup> and weather conditions such

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<sup>23</sup> Agency for Toxic Substances and Disease Registry, 1997, Toxicological profile for Chlorpyrifos. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service at 112 (*available at* <http://www.atsdr.cdc.gov/toxprofiles/tp84.pdf>) (Attachment 21).

<sup>24</sup> Degrendele, C. *et al.*, Pesticides in the atmosphere: a comparison of gas-particle partitioning and particle size distribution of legacy and current-use pesticides. *Atmos. Chem. Phys. Discuss.* 15, 23651–23681 (2015) (**Attachment 22**).

<sup>25</sup> Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization, at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0130>, at 6 and 34.

<sup>26</sup> Morrissey, B. & Prado, J, Comment on US EPA's Revised Human Health Risk Assessment for Chlorpyrifos Registration Review. (2015) at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0842>) (**Attachment 4**).

<sup>27</sup> "Aerial Movement and Deposition of Diazinon, Chlorpyrifos and Ethyl Parathion" <http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/eh9304.pdf> (**Attachment 23**).

as fog can increase such movement.<sup>28</sup>

EPA notes in its Updated Drinking Water Assessment (at 42):

While volatility has been observed to be a major route of dissipation of chlorpyrifos in the environment, the extent of deposition following volatilization and the area of deposit off a treated field is unknown . . . Volatility is the likely reason chlorpyrifos is detected in remote regions or in precipitation collected from locations far from potential applications sites. In addition, in some cases chlorpyrifos monitoring is conducted from irrigation canals which discharge to streams and rivers and chlorpyrifos is not observed in the irrigation water yet samples of river water reveal concentrations of chlorpyrifos. This may be the result of volatilization followed by redeposition.

Not only has EPA improperly discounted vapor exposures based on Dow's flawed nose-only vapor studies, but it has completely ignored exposure to chlorpyrifos particles that travel far from the fields through volatilization. It must account for and protect against such exposures in its risk assessments and in any determination to back away from its proposal to revoke all tolerances.

#### VI. EPA SHOULD IMMEDIATELY START CANCELLATION PROCEEDINGS TO PROTECT WORKERS

In its RHHRA, EPA identified over 125 scenarios where workers face risks of concern from various handling tasks and many situations in which re-entry periods are far too short to protect field workers from risks of concern. EPA should take immediate steps to protect workers from these risks and initiate cancellation proceedings to stop these uses altogether.

Tolerance revocation would afford workers protection because revocation of a tolerance ends the use of the pesticide on that food crop. Under FIFRA, EPA cannot register pesticide uses that cause unreasonable adverse effects and that term is defined 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." 7 U.S.C. § 136(bb)(2). Accordingly, for all revoked tolerances, the registration of chlorpyrifos on that food must be cancelled and the food use will end.

The FQPA directs EPA to coordinate FQPA actions to revoke tolerances with any related, necessary FIFRA action. 21 U.S.C. § 346a(l). This direction specifically refers to any action to revoke tolerances. It therefore compels EPA to initiate cancellation proceedings to

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<sup>28</sup> California Environmental Hazards Assessment Program. "A Field Study of Fog and Dry Deposition as Sources of Inadvertent Pesticide Residues on Row Crops." Sacramento, CA: State of California Department of Food and Agriculture, Division of Pest Management, Environmental Protection and Worker Safety, Environmental Monitoring and Pest Management Branch., November 1989 (*available at* <http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/eh8911.pdf>) (**Attachment 24**).

accompany and ensure full implementation of tolerance revocations.

In December 2014 in its RHHRA, EPA identified these worker risks 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). 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 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) (“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 process.

As our comments on the RHHRA demonstrate, EPA’s findings of unacceptable work risks understate the risks. In its occupational risk assessments, EPA has made assumptions that are at odds with real-world exposures. For example, it assumes workers are exposed for no more than 8 hours per day over a 5-day work week. In the harvest season, workers are in the field more hours per day and more days per week. And it is not fair to assume that exposures end when the work in the fields is over. For that assumption to be valid, the workers would need to have access to shower and laundry facilities (separate from what they and their families use) so that exposures would end and they would not bring home residues of chlorpyrifos. Because of these systemic under-estimates of risk, the risks of concern identified by EPA in its chlorpyrifos worker risk assessment are only the tip of the iceberg.

EPA’s failure to afford farmworkers the same level of protection as this country affords other workers is a prime example of environmental injustice. 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 Executive Order No. 12,898, 59 Fed. Reg. 7629 (Feb. 11, 1994). In particular, EPA is 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 more than one year ago. EPA should take immediate steps to stop these unacceptable risks and initiate cancellation proceedings to protect workers and others from the harms that chlorpyrifos causes wherever it is used.

## VII. EPA MUST ACT EXPEDITIOUSLY TO REVOKE TOLERANCES AND END USES OF CHLORPYRIFOS.

In the proposed revocation rule, EPA has proposed to make the revocations effective 180 days after publication of the final rule, and it has invited comments on possibly extending that time frame for tolerance revocation. 80 Fed. Reg. at 69,080, 69,106. In light of the serious

adverse health impacts of chlorpyrifos exposures, and the disproportionate burdens on farmworker communities, EPA should make the proposed revocations effective within 30 days of publication of the final rule.

\* \* \* \* \*

For all of these reasons, as well as those presented in comments on the RHHRA (ours and others), and the full record in the registration review proceeding, EPA should act expeditiously to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos uses.

Respectfully submitted,



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*On behalf of Earthjustice, Pesticide Action  
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