October 6, 2011

Pesticide Re-evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Preliminary Human Health Risk Assessment for Chlorpyrifos Registration Review, Docket ID EPA-HQ-OPP-2008-0850

On behalf of Farmworker Justice, Pesticide Action Network, Pineros y Campesinos Unidos del Noroeste, Sea Mar Community Health Center, and United Farm Workers, we submit the following comments on EPA's preliminary human health risk assessment for chlorpyrifos. We incorporate by reference the comments of the Natural Resources Defense Council, the Farm Worker Pesticide Project, and Physicians for Social Responsibility.

Chlorpyrifos is one of the organophosphate pesticides, which EPA has long recognized "pose the greatest risk to public health." 65 Fed. Reg. 42,021 (Aug. 4, 1997). The preliminary human health risk assessment reviews convincing evidence that chlorpyrifos is even more dangerous than the agency previously believed. The revised drinking water assessment shows that many subpopulations are exposed to unsafe levels of chlorpyrifos oxon in drinking water; new air monitoring studies reveal that chlorpyrifos is present in the air at dangerous levels at many rural locations; for many uses, no amount of protective clothing or engineering controls can adequately protect workers from unsafe exposures; and recent epidemiological studies confirm that *in utero* exposure to chlorpyrifos and organophosphates have harmed the development of children. Taken together, these new lines of evidence directly contradict EPA's prior assertions that aggregate exposures to chlorpyrifos, and cumulative exposures to organophosphates, are safe.

For far too long, chlorpyrifos has poisoned workers, sickened residents, and harmed the development of our children. EPA should, without delay, initiate proceedings to revoke the tolerances and cancel the registrations for chlorpyrifos.

I. EPA Should Not Delay Issuance of a Final, Lawful Reassessment of Tolerances and Re-Registration Review Decision for Chlorpyrifos.

In 1996, Congress passed the Food Quality Protection Act ("FQPA"), which amended the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Pub. L. No. 104-170, 110 Stat. 1489 (1996). Under the FQPA, EPA can establish a tolerance only if the agency has determined that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(ii). To ensure that then-existing pesticides would comply with the new safety standard, Congress instructed EPA to reassess the tolerances and review the registrations for all pesticides. *Id*. § 346a(q)(1); 7 U.S.C. § 136a(g)(1)(A). Congress required EPA to complete all of the tolerance reassessments by 2006. 21 U.S.C. § 346a(q)(1).

EPA reviewed the registrations and reassessed the tolerances for chlorpyrifos in 2006. EPA, Reregistration Eligibility Decision for Chlorpyrifos (2006). EPA's reregistration decision violated the FQPA's requirement to consider aggregate exposure of infants and children to pesticide residues by failing to consider exposure to pesticide drift and volatilization. *See generally* Petition from United Farm Workers et al. to EPA, *Pesticides in the Air -- Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift* (2009). Thus, despite the 2006 deadline, EPA has still not ensured that there is a reasonable certainty that no harm will result from aggregate exposure of infants and children to chlorpyrifos.

Figure 1 shows the percent of the Population Adjusted Dose ("PAD") accounted for by inhalation exposure for rural residents compared to dietary exposure (food and drinking water) using the 2006 PAD of 0.0005 mg/kg-day. These data, most of it collected and publicly available prior to 2006, indicate that exposure through drift and volatilization constitutes a substantially greater fraction of total exposure than dietary exposure.

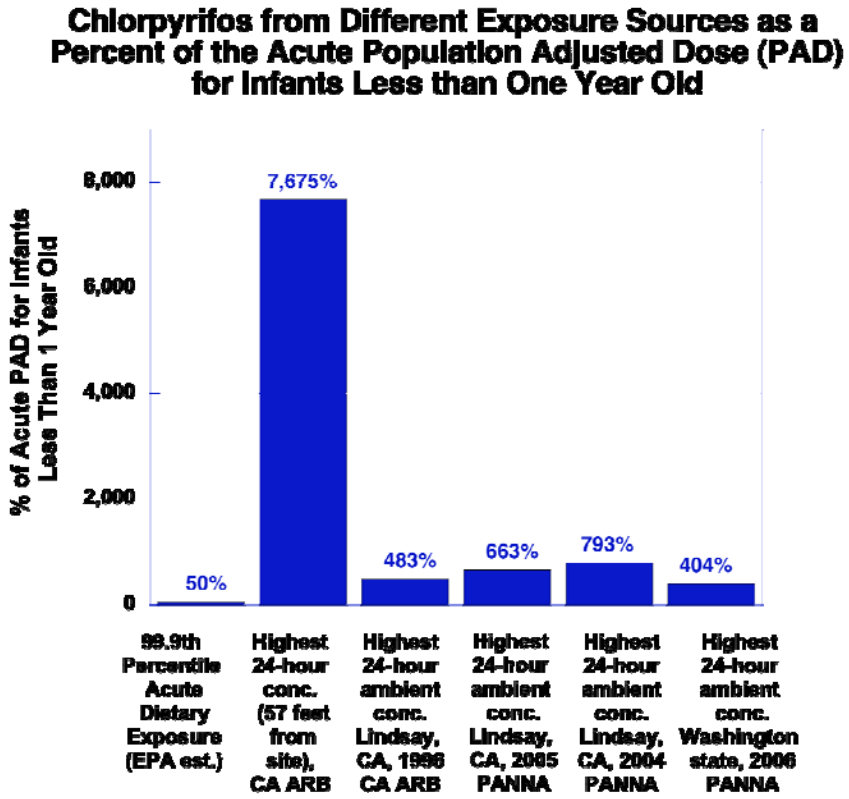

Figure 1: Exposure to chlorpyrifos from the inhalation route is very high for people living in areas of high chlorpyrifos use.

Five years have passed since the FQPA deadline for properly reassessing the tolerances for chlorpyrifos. EPA must avoid any further delay in complying with the law, especially in light of the overwhelming evidence that the current tolerances for chlorpyrifos are not safe.

II. The FQPA Requires EPA to Reassess Tolerances Based on Actual Monitoring Data Showing Unsafe Atmospheric Concentrations of Chlorpyrifos

In recent years, there have been a number of air monitoring studies for chlorpyrifos. E.g., Mills, Katherine et al., *Air Monitoring for Chlorpyrifos in Lindsay, California, June-July 2004 and July-August 2005* (2006); Fenske, Richard et al., *Organophosphorus Pesticide Air Monitoring Project* (2009). The Preliminary Human Health Risk Assessment reviews 15 air monitoring studies for chlorpyrifos in California and Washington. EPA, *Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review* at 71 (2011) [hereinafter, *Preliminary Risk Assessment*]. After comparing the data to EPA's Levels of Concern, the preliminary risk assessment concludes that the concentration of chlorpyrifos in many of the air samples[1] exceeds EPA's levels of concern. *Id*.

[1] Four out of twenty-four of the acute ambient air concentrations exceeded the level of concern, three out of five of the acute application site air concentrations exceeded the level of concern, and four out of five of the short and intermediate term application site air concentrations exceeded the level of concern. *Preliminary Risk Assessment* at 71.

The risk assessment points to purported limitations in the air monitoring studies, suggesting that the results might be discounted as a result. For example, the risk assessment notes that individuals do not stay in the same place for 24 hours, and therefore an individual may not be exposed to the concentration of chlorpyrifos measured in a 24-hour sample. *Id*. at 74. It would be unconscionable to discount the air monitoring results on this basis; indeed, they reflect the real world for rural children. Infants and young children, people who work out of the home, and older people with restricted mobility may very well spend 24-hour periods in one location, such as their homes. Most of the studies evaluated by EPA measured pesticide concentrations at residential locations, where these vulnerable people and others like them may indeed be exposed to the 24-hour concentrations measured in the studies.

Moreover, while infants and children may move from their homes to their schools, the air monitoring studies have detected high levels of chlorpyrifos at both schools and private residences. PANNA data from Lindsay, CA air monitoring studies, *Preliminary Risk Assessment* at 73. Based on the air monitoring results, EPA should assume that rural children are in harm's way where they live, go to school, and play. Moreover, it would not be credible to assume that indoor locations are safe given the likelihood that windows will be open during seasons when chlorpyrifos is applied.

In addition, it is worth noting that the HEC process does not necessarily produce reliable 24-hour reference concentrations ("RfCs") because the test animal exposures do not match anticipated human exposures. Most inhalation exposures for laboratory animals are set at a constant concentration for six hours per day, five days per week, providing time for the animals' repair systems to respond to the chemical insult during the "rest" periods (see Figure 2). For both the acute (one-day exposure) and short-term (90-day exposure) chlorpyrifos studies, dosing occurred for six hours per day, five days per week. The rest periods during these studies provide an opportunity for the laboratory animals to replenish depleted cholinesterase and begin repairing damaged tissues.

Figure 2: Exposure pattern for laboratory animals exposed to methyl iodide via inhalation for a typical six hours per day, five days per week study.

Exposure patterns for people living near fumigant application sites are substantially different, with an exposure spike that may cause acute effects during the first day or two after the application, followed by a decreasing concentration over the next week or two (see Figure 3).

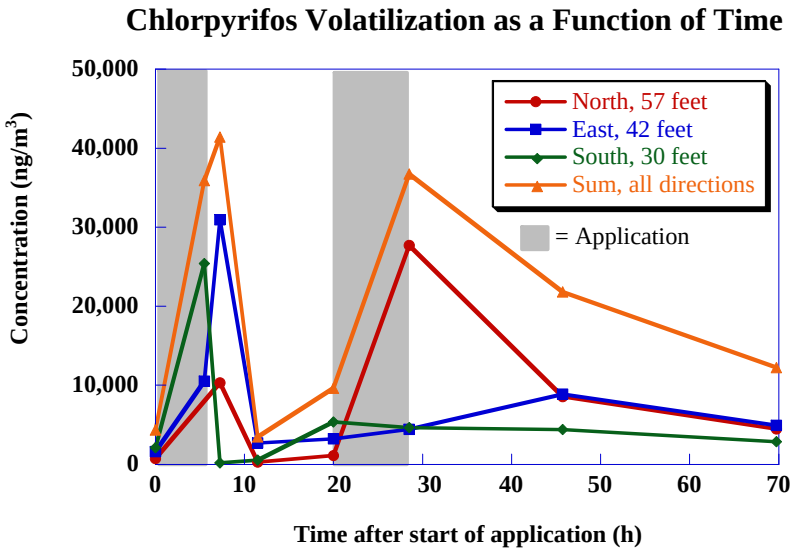

Figure 3: Exposure pattern for an actual application of chlorpyrifos (data from the California Air Resources Board monitoring study[2]) showing a spike in concentration after the application.

Real-world exposure can be continuous (assuming one stays at home and the wind direction is constant), with no opportunity for recovery. The high spike in concentration is likely to have a significantly different toxic effect than the constant exposure experienced by laboratory animals.

Because of the possibility of mixed acute and sub-chronic effects, this failure in inhalation exposure dosing is likely to be one of the most significant flaws in current reference concentration methodology that leads to an underestimation of the actual HEC, especially for toxicity arising from cholinesterase inhibition. Because the time course and duration of animal inhalation studies do not effectively mimic human exposures, the selected endpoints may not be protective of real-world exposures.

The risk assessment also states that data from California and Washington may not be representative of atmospheric concentrations in other areas of the country. Unfortunately, EPA has neither conducted air monitoring itself nor required registrants to conduct such air monitoring for chlorpyrifos, and thus there are no air monitoring data outside of California and Washington. Nonetheless, EPA's obligation under the FQPA is to conduct risk assessments based on "available information," 21 U.S.C. § 346a(b)(2)(C)(i)(I) – (III), and "EPA cannot reject the best available evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action -- a possibility that will *always* be present." *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000). Until EPA has evidence that children's exposure to chlorpyrifos in some parts of the country are lower than the exposures in the California and Washington air monitoring studies, EPA must act based on the data it has. Accordingly, it must use the air monitoring studies to reflect children's exposures and lower tolerances for chlorpyrifos to prevent the unacceptable aggregate exposures that result.

[2] CARB, *Report for the Application and Ambient Air Monitoring of Chlorpyrifos (and the Oxon Analogue) in Tulare County during Spring/Summer 1996*, Test Report #C96-040 and # C96-041 (1998), *available at* http://www.cdpr.ca.gov/docs/empm/pubs/tac/chlrpfs.htm

A. EPA's Consideration of Air Monitoring Data Should Further the Environmental Justice Goals Expressed in Executive Order 12898.

Under the terms of Executive Order 12898, each federal agency must pursue environmental justice "by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States." Executive Order 12898, § 1-101 (Feb. 11, 1994). In 2011, federal agencies, including EPA, signed a Memorandum of Understanding to implement the environmental justice goals expressed in Executive Order 12898.[3]

The majority of the air monitoring studies were conducted in Tulare County, California and Yakima County, Washington, and both counties have percentages of people of color and people living below the poverty level that exceed the national average.[4] Air monitoring studies indicate that poor people and/or people of color in rural communities where chlorpyrifos is sprayed are exposed to atmospheric concentrations of chlorpyrifos that exceed the atmospheric concentrations to which non-rural populations are exposed. Some of these concentrations exceed EPA's levels of concern. *Preliminary Risk Assessment* at 72. As a result, the effects of harmful atmospheric concentrations of chlorpyrifos are being borne by rural populations that are predominantly people of color and/or low income. In furtherance of the goals of the recent Memorandum of Understanding and Executive Order 12898, EPA must address these disproportionate health impacts by setting tolerances and imposing registration restrictions such that exposure to chlorpyrifos is limited to levels that are safe for all populations and do not leave people of color and low-income children disproportionately burdened by pesticide pollution.

B. Air Monitoring Studies Show That Some Rural Sites Have Levels of Atmospheric Chlorpyrifos That Are Not Safe.

EPA may establish a residue tolerance only if EPA establishes that a tolerance is safe, and must modify or revoke a tolerance if EPA determines the tolerance is not safe. 21 U.S.C. § 346a(b)(2)(A)(i). A tolerance is safe if EPA has "determined there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii).

As EPA recognizes, non-occupational exposure to atmospheric concentrations of a pesticide must be considered in the aggregate exposure analysis. For chlorpyrifos, there is reliable information, consisting of 15 air monitoring studies, indicating that applications of chlorpyrifos on many crops result in drift and/or field volatilization that create unsafe

[3] Memorandum of Understanding on Environmental Justice in Executive Order 12898 (2011), *available at* http://epa.gov/environmentaljustice/resources/publications/interagency/ej-mou-2011-08.pdf.

[4] According to the United States Census Bureau, in 2010, the percentage of people who identified as a race other than "White, non-Hispanic" in Yakima County was 61.5% and in Tulare County was 66.3%. These percentages exceed the nationwide percentage of 34.8%. Similarly, 22% and 23% of persons in Yakima and Tulare counties, respectively, were below the poverty level in 2009, compared to 14.3% nationwide.

atmospheric concentrations of chlorpyrifos. Therefore, EPA must modify chlorpyrifos use patterns or revoke residue tolerances for chlorpyrifos to reduce exposures to, or below, acceptable levels.

III. EPA Should Retain the 10X FQPA Safety Factor for Infants and Children in Light of Uncertainty Regarding the Effects of Chlorpyrifos on Endocrine Systems and Neurological Development.

The FQPA specifies that in the case of threshold effects, an additional tenfold margin of safety for the residue and other sources of exposure shall be applied for infants and children. 21 U.S.C. § 346a(b)(2)(C)(ii)(I). EPA can apply a different margin only if "on the basis of reliable data, such margin will be safe for infants and children." *Id*.

Congress intended "that EPA interpret the language of this section in furtherance of the . . . recommendations of the National Research Council's Study, Pesticides in the Diets of Infants and Children." H.R. Rep. No. 104-669 at 43 (1996). The National Research Council study recommended that EPA apply a tenfold uncertainty factor "when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete." *Id*.

Since the purpose of the FQPA safety factor is to account for uncertainty regarding the special vulnerability of infants and children to pesticides, Congress specified that EPA could apply a lower uncertainty factor only if EPA has reliable data showing that the alternative margin is safe. With respect to endocrine effects, EPA lacks reliable data that a 1X safety factor is safe for infants and children.

EPA recently placed chlorpyrifos on the first list of chemicals to undergo tier 1 screening in the endocrine disruptor screening program, and issued test orders requiring such screening. 74 Fed. Reg. 17,579 (Apr. 15, 2009). Under EPA's guidelines for the endocrine disruptor screening program, a chemical undergoes tier 1 screening only if there is uncertainty as to whether the chemical is capable of disrupting the endocrine system; if there is already data on this issue, then a chemical proceeds directly to tier 2 testing or to hazard assessment. 63 Fed. Reg. 71,542 (Dec. 28, 1998).

By issuing tier 1 screening orders for chlorpyrifos, EPA has acknowledged that the agency does not have adequate data to satisfy the tier 1 screening requirements, and that there is uncertainty regarding the endocrine disruption effects of chlorpyrifos. As a result, a 1X safety factor would not be based on reliable data indicating that the margin is safe for infants and children. If EPA lacks reliable data regarding the effects of chlorpyrifos on the endocrine systems of infants and children, then EPA is precluded from deviating from the 10X FQPA safety factor.

In addition, both the toxicity data and the epidemiological data indicate that the effects of chlorpyrifos on neurodevelopment both prenatally and in infant and juvenile animals are substantially greater than in adults. We refer EPA to the NRDC comment letter for a detailed analysis of these concerns, and note that in the absence of a no observed adverse effect level

("NOAEL"), the developmental neurotoxicity study provides no assurance that children will be protected if the FQPA 10X factor is not retained.

IV. In Its Final Tolerance and Registration Decisions, EPA Must Consider Data Showing That Cumulative Exposures to Chlorpyrifos and Other Organophosphates Are Not Safe.

Two subsections of the FQPA require EPA to consider cumulative effects when establishing a tolerance. In establishing, modifying, leaving in effect, or revoking a tolerance, EPA must assess the risk of a pesticide chemical based on "available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity." 21 U.S.C. § 346a(b)(2)(C)(i)(III). Similarly, for populations other than infants and children, EPA must consider "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity." *Id*. § 346a(b)(2)(D)(v).

Organophosphates were the first chemicals EPA identified as having a common mechanism of toxicity, based on their "ability to bind to and phosphorylate the enzyme acetylcholinesterase in both the central (brain) and peripheral nervous systems." EPA, *Organophosphorus Cumulative Risk Assessment -- 2006 Update* at 3 (2006) [hereinafter *Cumulative Risk Assessment*]. EPA interprets the FQPA to require the agency to find that the cumulative effects of exposures to organophosphates from all pathways are safe. *Id*. at 15.

A. Recent Epidemiology Studies Confirm Earlier Studies Indicating That Cumulative Exposures to Organophosphates are Associated with Neurodevelopmental Deficits.

Since the 2006 Cumulative Risk Assessment for organophosphates and associated re-registration determinations, at least three major epidemiology studies on chlorpyrifos and/or organophosphates have been published. The Columbia University studies have found an association between levels of chlorpyrifos in umbilical cord blood and negative neurological and behavioral outcomes in children at 3 and 7 years of age.[5] Statistical analyses confirm that the negative effects of chlorpyrifos are statistically significant and persist after controlling for other chemical exposures.

Two other epidemiology studies, conducted by researchers at the Mt. Sinai School of Medicine and the University of California at Berkeley, found that increased levels of urinary organophosphate metabolites are associated with certain negative neurodevelopment outcomes in children.[6] Unlike the Columbia study, the Mt. Sinai and UC Berkeley studies did not attempt to

[5] Rauh, V., et al., *Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First Three Years of Life among Inner-City Children*, 118 Pediatrics 6 (2006); Rauh, V. et al., *Seven-Year Neurodevelopmental Scores and Prenatal Exposure To Chlorpyrifos, a Common Agricultural Pesticide*, Environmental Health Perspectives 119 (8): 1196-01 (2011).

[6] Engel, S. et al., *Prenatal Exposure to Organophosphates, Paraoxonase 1, and Cognitive Development in Childhood*, Environmental Health Perspectives 119 (8): 1182-88 (2011) ("We found that prenatal maternal urinary

correlate outcomes with exposure to chlorpyrifos alone but instead correlated outcomes with exposure to organophosphate pesticides. EPA has stated that because the Mt. Sinai and UC Berkeley studies did not specifically measure exposure to chlorpyrifos, they are of limited use in the risk assessment for chlorpyrifos. *Preliminary Risk Assessment* at 31-32.

While the UC Berkeley and Mt. Sinai studies may not attribute the observed outcomes solely to exposure to chlorpyrifos, that does not mean the studies can be cast aside. Under the FQPA, EPA's risk assessment cannot be limited to aggregate exposures to chlorpyrifos. Instead, EPA must consider as well the cumulative effects of exposure to chlorpyrifos and other chemicals with a common mechanism of toxicity. 21 U.S.C. § 346a(b)(2)(C)(i)(III), 346a(b)(2)(D)(v). The UC Berkeley and Mt. Sinai studies are credible evidence that must be used in assessing the cumulative risk from organophosphates.

The UC Berkeley and Mt. Sinai studies indicate that from 1997 through 2001, children developing in the womb were exposed to actual levels of organophosphates that resulted in later developmental and behavioral harm. FIFRA Scientific Advisory Panel, *Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held September 16-18, 2008 on the Agency's Evaluation of the Toxicity Profile of Chlorpyrifos* at 37-38 (2008) [hereinafter *SAP Report*]. These studies show that, at a minimum, for the years 1997 through 2001, cumulative exposures to organophosphates were not safe. EPA's interpretation of these epidemiological studies must conform to the FQPA's mandate that EPA assess not just aggregate exposure to chlorpyrifos but cumulative exposures to organophosphates.

B. EPA's Cumulative Effects Analysis Should Account for Additive or Interactive Effects between Organophosphate Pesticides.

At the September 2008 meeting of the FIFRA Scientific Advisory Panel, the SAP suggested, after reviewing recent epidemiology studies on chlorpyrifos and other organophosphates, that the agency consider potential additive and synergistic effects of chlorpyrifos and other organophosphates. The SAP "supported the statement that exposures to all three AChE -inhibiting insecticides may act in combination to produce the observed effects. The Panel agreed that there may, in fact, be additive effects or effects generated by a mixture of the agents." *SAP Report* at 43; *see also id*. at 13.

In interpreting the Columbia studies, the SAP noted that diazinon, an organophosphate, and propoxur, a carbamate, were present along with chlorpyrifos. If the data are used to show the combined effect of diazinon and chlorpyrifos, "there is a slightly greater reduction in birth weight" than the effects of chlorpyrifos alone. "This may indicate that the effect of the combined chemicals is slightly greater than the individual chemicals alone and that there could

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dialkylphosphate metabolite concentrations were negatively associated with aspects of neurodevelopment at 12 and 24 months, and also at 6-9 years of age, in an urban, inner-city population."); Eskenazi, B. et al., *Organophosphate Pesticide Exposure and Neurodevelopment in Young Mexican-American Children*, Environmental Health Perspectives 115 (5): 792-98 (2007) ("[W]e report an adverse association of prenatal organophosphate pesticide exposure as measured by DAPs with mental development and pervasive developmental problems at 24 months of age."); Bouchard, M. et al., *Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year-Old Children*, Environmental Health Perspectives 119 (8): 1189-95 (2011).

be potential interaction between the two chemicals with respect to the association." *Id*. at 41. Indeed, the SAP notes that Rauh found that "the combination of chlorpyrifos and diazinon produced slightly greater effects for MDI than were seen for chlorpyrifos alone." *Id*. at 42.

The available evidence, including epidemiological studies and the recommendations of the SAP, suggest that there may be additive and/or synergistic effects from exposure to chlorpyrifos and other organophosphates. The agency should consider these potential additive and/or synergistic effects in assessing cumulative effects.

C. The Preliminary Risk Assessment Undermines Key Conclusions in the 2006 Organophosphate Cumulative Risk Assessment.

EPA completed the most recent cumulative risk assessment for organophosphates in 2006. If EPA relies on the 2006 Cumulative Risk Assessment in its forthcoming final decision on chlorpyrifos tolerances and registrations, EPA must account for more recent analyses that undermine key conclusions in the 2006 Cumulative Risk Assessment.

For example, in the preliminary risk assessment, EPA calculates that several subpopulations -- especially infants -- are exposed to levels of chlorpyrifos in drinking water that exceed levels of concern *Preliminary Risk Assessment* at 61. This directly contradicts the 2006 Cumulative Risk Assessment, which found that, individually and cumulatively, the levels of organophosphates in drinking water were safe. *Cumulative Risk Assessment* at 15 ("[T]he results of the OP CRA [cumulative risk assessment] support a reasonable certainty of no harm finding as required by FQPA and therefore EPA has completed reassessment of the OP tolerances."). EPA's Cumulative Risk Assessment conclusion is no longer tenable, in light of the preliminary risk assessment's calculation that levels of chlorpyrifos in drinking water are not safe.

Second, in the 2006 Cumulative Risk Assessment, EPA did not consider bystander exposures to chlorpyrifos. Recent air monitoring studies reveal harmful levels of chlorpyrifos in the air at many rural sites. Given that the air monitoring data show that some rural subpopulations are being exposed to harmful levels of chlorpyrifos through drift and field volatilization, the air monitoring data call into question the overall conclusion that cumulative exposures to organophosphates are safe.

A number of other currently registered organophosphate pesticides are also subject to spray drift and/or field volatilization. The California Air Resources Board has acquired air monitoring data for acephate, azinphos-methyl, DEF, diazinon, ethoprop, malathion, methamidophos, methidathion, methyl parathion, naled and phorate.[7] In all cases, measurable levels of the pesticide were found in air near application sites and in ambient air in areas of high use. EPA should account for these exposures when evaluating the filling of the "risk cup" and the cumulative risks associated with use of organophosphates.

[7] CARB, Toxic Air Contaminant Program Monitoring Reports (2011), *available at* http://www.cdpr.ca.gov/docs/emon/pubs/tac/tacstdys.htm.

The 2006 Cumulative Risk Assessment for organophosphates fails to account for unsafe drinking water and air exposures. EPA's revised drinking water assessment for chlorpyrifos, and recent data on atmospheric concentrations of chlorpyrifos, contradict EPA's 2006 conclusion that cumulative exposures to organophosphates are safe. Moreover, EPA has announced no plans to undertake a new cumulative risk assessment for organophosphates. At a minimum, to meet the FQPA safety standard, EPA should revoke all tolerances for chlorpyrifos to eliminate the unacceptable risks posed by chlorpyrifos specifically and to reduce the overall exposure of infants and children to organophosphates.

D. The Preliminary Human Health Risk Assessment Supports Canceling the Uses of Chlorpyrifos That Result in Unreasonable Risks to Farmworkers.

The preliminary human health risk assessment analyzes 305 occupational exposure scenarios. Eighty scenarios "resulted in risk estimates of concern . . . at all levels of personal protection and engineering controls considered." *Preliminary Risk Assessment* at 14. EPA should initiate proceedings to cancel the uses of chlorpyrifos that fit these 80 scenarios, unless EPA can substantiate formal findings that these occupational risks are not unreasonable adverse effects. To do so, EPA would have to find that the benefits of such uses outweigh the risks such that they are not unreasonable adverse effects within the meaning of FIFRA.

For other occupational exposure scenarios, EPA relies on personal protective equipment to reduce exposure below the level of concern. Personal protective equipment is often ineffective, for a variety of reasons, ranging from faulty equipment, to the failure of employers to provide equipment, to weather conditions that make wearing protective equipment not feasible. *See, e.g.*, Washington State Pesticide Incident Reporting and Tracking Review Panel, *2009 Annual Report* at 61-64 (2009). Risk estimates based on the use of protective equipment should incorporate real-world data on the adequacy of such equipment, or, in the absence of such data, should rely on realistic assumptions about the effectiveness of such equipment in reducing exposures.

Sincerely,

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