April 30, 2015

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OPP Docket
Environmental Protection Agency Docket
Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Comments on Proposed Chlorpyrifos Revised Human Health Risk Assessment
EPA-HQ-OPP-2008-0850

Dear Mr. Keigwin,

We, the undersigned health professionals, write to express our support for withdrawal of all uses of the pesticide chlorpyrifos, and to comment on EPA's Revised Human Health Risk Assessment of Chlorpyrifos ("RHHRA").[1] The RHHRA recommendations will fail to protect children and adults who are regularly exposed to this hazardous pesticide.

While the current proposal acknowledges the risks of damage to the developing brain from chlorpyrifos exposure at levels well below those that EPA currently regulates to, it inexcusably fails to protect people from these unsafe exposures. We urge EPA to update the RHHRA to fully and adequately assess exposures and health harms from this neurotoxic insecticide, and to update and strengthen its recommendations.

We support withdrawal of all uses of chlorpyrifos because:

- EPA determined over 10 years ago that chlorpyrifos was too dangerous to be used around kids and cancelled all homeowner uses.[2]
- Chlorpyrifos remains one of the most widely used agricultural insecticides in the United States, at over 5 million pounds applied annually.[3]
- Across the country, rural families, farmworkers, and the families of farmworkers are regularly exposed to chlorpyrifos, resulting in poisoning incidents each year and medical problems from acute and chronic exposure to this hazardous insecticide.[4]
- Chlorpyrifos is linked to brain and neurodevelopmental damage in children in extensive peer-reviewed scientific studies.[5]

- EPA continues to leave rural children and the children of farmworkers in harms' way because they are exposed to chlorpyrifos through drift, volatilization, and take-home exposures from farmworker family members.[6,7,8]

EPA's risk assessment cannot be used to justify continued use. EPA used a flawed analysis unsupported by the science to estimate both exposure and health impacts on children, workers, and community members. The result is an assessment that does not meet federally mandated obligations to protect public health and vulnerable populations.

For example, EPA finally accepts the overwhelming evidence from animal studies, epidemiologic studies, and mechanistic data that demonstrate brain and neurodevelopmental impacts to children from exposure to chlorpyrifos during early life stages.[9] Yet, EPA continues to use cholinesterase inhibition of 10% as its allowable exposure limit even though EPA acknowledges that it does not protect against neurodevelopmental impacts. EPA finds that neurodevelopmental impacts from prenatal exposures occur at levels below those which cause 10% cholinesterase inhibition in the pregnant mother. EPA acknowledges this discordance, but claims to address it through use of the data completeness FQPA factor. Failing to regulate to protect against those acknowledged impacts is unacceptable.

In the RHHRA, EPA uses a model developed by Dow AgroSciences to set regulatory exposure limits so as not to exceed 10% cholinesterase inhibition in adults, rather than the real endpoint of concern, which is brain damage in children. In 2011, EPA's Scientific Advisory Panel found myriad flaws in the model, criticizing it as "problematic," "cursory," "overstated," "inadequate," "inaccurate," "imprecise," and "incomplete."[10] The model relies primarily on data from animal studies (either whole animal studies or *in vitro* tests in animal cells) as well as data from two studies of intentional pesticide exposures in human subjects. The human testing studies have a number of unresolved scientific and ethical deficiencies, including small sample sizes that raised concerns with the Human Studies Review Board.[11,12] EPA's own internal ethics officer found that one of the human studies (Kisicki et al 1999)[13] was ethically flawed and could not be used by EPA.[14]

EPA relied on the Dow model to eliminate (reduce to 1) the 10-fold factor meant to adjust for differences between animals and humans (inter-species), and to reduce from 10 to 4 for children the factor for differences among humans (intra-species). The result is that EPA allows chlorpyrifos exposures to be 10-fold higher for pregnant women, and 25-fold higher for children. This takes back and more the protections offered by its use of a 10X data completeness FQPA factor.[15] By also failing to invoke as required an additional FQPA factor for evidence of prenatal toxicity, EPA has further weakened its chlorpyrifos exposure limits for adult women including pregnant women, as well as for children.

Although EPA considered pesticide drift in its assessment and established no-spray buffers around school grounds, play fields, homes, day cares, hospitals and other occupied buildings, the small buffers EPA proposed will not protect kids from neurodevelopmental impacts because they are based on 10% cholinesterase inhibition. Likewise, EPA ignored direct pesticide drift onto people even though direct drift poisons people at alarming rates every year.[16] Moreover, EPA relied on only two flawed, unpublished, non-peer-reviewed industry-sponsored studies to completely discount volatilization[17]—a significant threat for which EPA had initially proposed buffers as large as 1000 feet. Because these harms disproportionately fall on farmworkers and their families, often low-income and people of color, this is a substantial failure to comply with principles of environmental justice and the environmental justice executive orders.

Further, EPA has not proposed any protections for infants and others who are at risk of unsafe exposures to chlorpyrifos through contaminated drinking water. EPA concluded that drinking water contamination will likely

exceed allowable concentrations of chlorpyrifos for many applications.[18] EPA should not allow continued contamination of drinking water.

EPA found that many uses of chlorpyrifos expose workers to dangerous levels of the pesticide. Even with the most protective gear and equipment it can require, EPA acknowledges that unacceptable risks would remain for 126 worker scenarios.[19] EPA should not allow continued harm to workers, particularly given EPA's complete failure to address the environmental justice concerns presented since farmworkers are disproportionately people of color and low income individuals.

We urge EPA to regulate pesticides so as to prevent health harms to children, rural communities and farmworkers. Such a review, if adequately conducted, will justify implementation of immediate and rigorously health protective measures for farmworkers and rural families, and a rapid withdrawal of all uses of the neurotoxic pesticide chlorpyrifos.

Sincerely,

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[1] US EPA. "Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review." Office of Chemical Safety and Pollution Prevention, December 29, 2014. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0195.

[2] http://www2.epa.gov/ingredients-used-pesticide-products/revised-human-health-risk-assessment-chlorpyrifos#EPA%20actions

[3] http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2012&map=CHLORPYRIFOS&hilo=L

[4] Calvert, Geoffrey M, Jennifer Karnik, Louise Mehler, John Beckman, Barbara Morrissey, Jennifer Sievert, Rosanna Barrett, et al. "Acute Pesticide Poisoning among Agricultural Workers in the United States, 1998-2005." American Journal of Industrial Medicine 51, no. 12 (December 2008): 883–98. doi:10.1002/ajim.20623.

[5] Reviewed in the RHHRA, Section 4.5, pg. 32-43

[6] Coronado, Gloria D., Sarah Holte, Eric Vigoren, William C Griffith, Elaine Faustman, and Beti Thompson. "Organophosphate Pesticide Exposure and Residential Proximity to Nearby Fields: Evidence for the Drift Pathway." Journal of Occupational and Environmental Medicine / American College of Occupational and Environmental Medicine 53, no. 8 (August 2011): 884–91. doi:10.1097/JOM.0b013e318222f03a.

[7] Bradman, Asa, Donald Whitaker, Lesliam Quirós, Rosemary Castorina, Birgit Claus Henn, Marcia Nishioka, Jeffrey Morgan, et al. "Pesticides and Their Metabolites in the Homes and Urine of Farmworker Children Living in the Salinas Valley, CA." Journal of Exposure Science and Environmental Epidemiology 17, no. 4 (May 31, 2006): 331–49. doi:10.1038/sj.jes.7500507.

[8] Thompson, Beti, William C Griffith, Dana B Barr, Gloria D Coronado, Eric M Vigoren, and Elaine M Faustman. "Variability in the Take-Home Pathway: Farmworkers and Non-Farmworkers and Their Children." Journal of Exposure Science and Environmental Epidemiology, March 5, 2014. doi:10.1038/jes.2014.12.

[9] RHHRA, pg. 43-49

[10] FIFRA SAP. "FIFRA Scientific Advisory Panel Meeting: Chlorpyrifos Physiologically Based Pharmacokinetic and Pharmacodynamic (PBPK/PD) Modeling Linked to Cumulative and Aggregate Risk Evaluation System (CARES)." US EPA, February 2011. http://www.epa.gov/osainter/hsrb/files/meeting-materials/apr-13-14-2011/appendix1.pdf

[11] HSRB June 2009 http://www.epa.gov/osainter/hsrb/files/june2009finalreport92609.pdf

[12] HSRB Apr 2011 http://www.epa.gov/osainter/hsrb/files/meeting-materials/apr-13-14-2011/appendix1.pdf

[13] Kisicki, J, C. Seip, and M. Combs. A Rising Dose Toxicological Study to Determine the NoObservable-Effect-Levels (NOEL) For Erythrocyte Acetylcholinesterase (AChE) Inhibition and Cholinergic Signs and Symptoms of Chlorpyrifos at Three Dose Levels. Dated April 15-19, 1999. Unpublished study prepared by MDS Harris Laboratories under Project No. 21438 and Dow AgroSciences Study No. DR K-0044793-284. MRID 44811002.

[14] Carley memo, May 2009. http://www.epa.gov/osainter/hsrb/files/1d6-ethics-rvw-kisicki-etal-060109.pdf

[15] The chlorpyrifos total uncertainty factors are 100X for adult females (10X FQPA SF and 10X intra-species extrapolation factor) and 40X for the other relevant populations (10X FQPA SF and 4X intra-species extrapolation factor). (RHRRA at page 8)

[16] Lee, Soo-Jeong, Louise Mehler, John Beckman, Brienne Diebolt-Brown, Joanne Prado, Michelle Lackovic, Justin Waltz, et al. "Acute Pesticide Illnesses Associated with Off-Target Pesticide Drift from Agricultural Applications: 11 States, 1998–2006." Environmental Health Perspectives 119, no. 8 (June 6, 2011): 1162–69. doi:10.1289/ehp.1002843.

[17] RHHRA, Section 6.3.2, pg. 83

[18] US EPA, "Chlorpyrifos: Updated Drinking Water Assessment for Registration Review," Office of Chemical Safety and Pollution Prevention. December 23, 2014.

[19] RHHRA, Section 9, pg. 97-108