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Richard P. Keigwin, Director Pesticide Re-evaluation Division
Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington DC 20460-0001

**Re: Chlorpyrifos Registration Review: Preliminary Human Health Risk Assessment.
Docket Number: EPA-HQ-OPP-2008-0850**

Dear Mr. Keigwin,

Beyond Pesticides is pleased to submit comments for the Preliminary Human Risk Assessment for chlorpyrifos. The agency acknowledged its intent to issue this assessment in December 2010 as part of a response to a petition submitted by NRDC and PANNA in 2007. Beyond Pesticides submitted comments in December 2010 in support of efforts, regardless of legal stipulations, to complete chlorpyrifos' assessment and ban all chlorpyrifos uses. On analysis of EPA's 2011 preliminary human health risk assessment for chlorpyrifos, Beyond Pesticides identified some improvements to the agency's last assessment released in 2000. However, there are still many glaring data gaps and shortcomings that must be addressed. Most troubling is the proposal to reduce the Food Quality Protection Act (FQPA) safety factor to 1X for certain exposures. The agency notes that it would reevaluate the existing data to determine whether this reduction is appropriate. Beyond Pesticides would challenge that it is not appropriate for chlorpyrifos whose human health risk, especially to children, is associated with significant neurodevelopmental effects which the agency acknowledges. Further, the agency has admitted that it has not yet performed a comprehensive or integrated analysis of the neurodevelopmental risks posed to children. In light of this, it is imperative that the FQPA safety factor is not reduced for any route of exposure considered.

Given the serious toxicological issues associated with chlorpyrifos exposure, the agency must

not delay in evaluating the epidemiologic data that currently exists for chlorpyrifos. The evidence is clear and consistent that chlorpyrifos poses “unreasonable adverse effects” to human and environmental health. Beyond Pesticides would like to see this toxic chemical taken completely off the market, especially in light of safer alternatives currently available. At the end of this registration review for chlorpyrifos, the agency must deny its registration eligibility.

1. 2011 Preliminary Human Health Assessment

EPA states, “the focus of the 2011 preliminary risk assessment is on the cholinesterase inhibiting potential of chlorpyrifos.”¹ Chlorpyrifos is a cholinesterase inhibitor which binds irreversibly to the active site of an essential enzyme for normal nerve impulse transmission, acetylcholine esterase (AChE), inactivating the enzyme. Studies have documented that exposure to low levels of chlorpyrifos during pregnancy can impair learning, change brain function and alter thyroid levels of offspring into adulthood, especially females.^{2,3,4,5} The evidence of the neurotoxic dangers associated with chlorpyrifos’ exposure are extensive and consistent.

1.1 Epidemiological Evidence of Chlorpyrifos’ Neurotoxic Potential on the Most Vulnerable

EPA has identified recent epidemiological studies with mothers and their children, and states the agency “has not yet performed a comprehensive weight of evidence analysis on these studies.” While the independent literature is abound with epidemiological data for chlorpyrifos, the agency still lags behind in reviewing these studies. The studies identified were conducted at the School of Public Health at the University of California, Berkeley, the Mailman School of Public Health at Columbia University, and Mount Sinai School of Medicine. All involved cohorts of women enrolled during pregnancy. The Berkeley and Mount Sinai investigators measured organophosphate (OP) pesticide breakdown products in the pregnant women’s urine, while the Columbia investigators measured chlorpyrifos in umbilical cord blood. Intelligence tests were administered to children of these mothers between ages 6 and 9 years at Mount Sinai and at age 7 years at Berkeley and Columbia.

¹ USEPA. 2011. Chlorpyrifos: Preliminary Human Health Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC

² Haviland et al. 2009. Long-term sex selective hormonal and behavior alterations in mice exposed to low doses of chlorpyrifos in utero. *Reproduc. Tox.* 29(1):74-9

³ Abou-Donia MB, et al. 2006. In utero exposure to nicotine and chlorpyrifos alone, and in combination produces persistent sensorimotor deficits and Purkinje neuron loss in the cerebellum of adult offspring rats. *Arch Toxicol.*;80(9):620-31.

⁴ Abdel-Rahman A, et al. 2003. Increased expression of glial fibrillary acidic protein in cerebellum and hippocampus: differential effects on neonatal brain regional acetylcholinesterase following maternal exposure to combined chlorpyrifos and nicotine. *J Toxicol Environ Health A* ;66(21):2047-66.

⁵ Icenogle LM, et al. 2004. Behavioral alterations in adolescent and adult rats caused by a brief subtoxic exposure to chlorpyrifos during neurulation. *Neurotoxicol Teratol*;26(1):95-101.

Researchers at Columbia University in their series of ongoing prospective cohort studies in inner-city minority populations, linked exposure to chlorpyrifos to early childhood developmental delays. One study from this research group published in the *American Journal of Public Health* compared motor and mental development to levels of exposure to the pesticide at birth in 266 children born between 1998 and 2002 living in low income neighborhoods of the South Bronx and Northern Manhattan in New York City. The study found that concentrations of chlorpyrifos in umbilical cord blood correspond to a decrease in the psychomotor development and a decrease in the mental development in 3 year olds.⁶ Research by Rauh et al. finds that children exposed to high levels of chlorpyrifos had mental development delays, attention problems, attention-deficit/hyperactivity disorder problems, and pervasive developmental disorder problems at 3 years of age.^{7,8} The results of these cohort studies have consistently found that depressed cognitive development, birth weights and other neurodevelopmental end points are adversely impacted by chlorpyrifos and other pesticidal exposures.⁹

The Berkeley study, examining families in the intensive agricultural region of Salinas Valley, California, found that IQ levels for children with the most OP exposure were a full seven IQ points lower than those with the lowest exposure levels. The Berkeley team also found that every tenfold increase in measures of OPs detected during a mother's pregnancy corresponded to a 5.5 point drop in overall IQ scores in the 7-year-olds.¹⁰ Researchers from Mount Sinai School of Medicine also found that prenatal exposure to organophosphates is negatively associated with cognitive development, particularly perceptual reasoning, with evidence of effects beginning at 12 months and continuing through early childhood.¹¹ These studies are comparable and consistent with other chlorpyrifos studies and serve to demonstrate why this chemical should be removed from the market.

1.2 Retain FQPA Safety Factor

The purpose of the FQPA margin of safety factor is to “to protect infants and children, taking

⁶ Lovasi, GS, et al. 2011. Chlorpyrifos Exposure and Urban Residential Environment Characteristics as Determinants of Early Childhood Neurodevelopment. *Am J Public Health*;101(1):63-70.

⁷ Rauh VA. 2006. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics*;118(6):e1845-59.

⁸ Rauh V, Arunajadai S, Horton M, Perera F, Hoepner L, Barr DB, et al. 2011. Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide. *Environ Health Perspect* 119:1196-1201.

⁹ Perera FP, et al. 2005. A summary of recent findings on birth outcomes and developmental effects of prenatal ETS, PAH, and pesticide exposures. *Neurotoxicology*;26(4):573-87.

¹⁰ Bouchard MF, Chevri er J, Harley KG, Kogut K, Vedar M, Calderon N, et al. 2011. Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year-Old Children. *Environ Health Perspect* 119:1189-1195.

¹¹ Engel, S. et al. 2011. Prenatal Exposure to Organophosphates, Paraoxonase 1, and Cognitive Development in Childhood. *Environ Health Perspect* 119:1182-1188.

into account the potential for pre- and post-natal toxicity.” 21 USC §346a(b)(2)(C) It is known that children face unique hazards from pesticide exposure. Given the overwhelming evidence presented in the above mentioned research, it is inconceivable that EPA would consider reducing the FQPA safety factor for any route of exposure. EPA and industry may argue that the most important risks to children were eliminated with the decision to remove chlorpyrifos’ residential uses. However, what the data overwhelmingly indicates is that prenatal exposures are most important when it comes to the cholinesterase inhibiting potential of chlorpyrifos. Thus the FQPA safety factor must be retained for all routes of exposures since chlorpyrifos’ agricultural uses, golf course and public health mosquito spraying constituent the bulk of chlorpyrifos uses and the potential to affect pregnant mothers is great.

The epidemiological data also points to a sub-population that is disproportionately affected by chlorpyrifos exposures. Low income African-American and Latino families, including farmworker families, continue to suffer the most and this disproportionate impact creates an environmental justice issue. This represents a failure that is repeated over and over again in agency chemical regulation decisions. The risk assessment process does not force a consideration of those who suffer disproportionate risk or groups of people who are disproportionately affected. The FQPA safety factor must not be reduced for any exposures under any circumstances.

1.3 Inhalation/ Volatilization Exposures Put Farmworker Families at Risk

The Agency has developed a preliminary bystander inhalation exposure assessment for chlorpyrifos and found some exposure scenarios to exceed levels of concern while others did not. Beyond Pesticides commends EPA for including this assessment for chlorpyrifos. According to the preliminary assessment, (1) combined child exposure estimates (dermal and incidental oral) to turf following aerial mosquito treatment resulted in risk estimates of concern, (2) acute adult and child inhalation (spray drift) exposure following ground mosquito treatment exceeded levels of concern. Of the 24 acute ambient air concentrations assessed, 4 result in risk estimates exceeding levels of concern. Of the 5 acute application site air concentrations assessed, 3 resulted in a risk estimates of concern. Of the 5 short- and intermediate-term application site air concentrations assessed, 4 resulted in risk estimates of concern.

As mentioned before, certain subpopulations experience disproportionate impacts from chlorpyrifos exposure. Farmworkers and their families living in the vicinity of the fields they work are most at risk for chlorpyrifos exposures. The agency has found that dermal and oral exposures to aerial spraying, and inhalation exposures to ground spraying put people, especially vulnerable farmworkers and children, at risk. Many farmworker families reside in or in close proximity to chlorpyrifos application sites. Farmworkers' children have increased pesticide

exposure through inhalation, dermal absorption and non-dietary ingestion.¹² EPA's assessment of bystander exposures, based on a 24-hr air samples assumes that an individual is exposed to the same air concentration for 24-hours every day. The agency also believes that indoor concentrations may be equal to or lower than outdoor concentrations. However, studies from the University of California, Berkeley, find that pesticides are detected more frequently in house dust, surface wipes, and clothing than other media, including outdoor air. Pesticide residues on toddlers' socks and union suits were also found to be high¹³ This means that for farmworker families inhalation, dermal exposures and non-dietary oral exposures can in fact endure for 24-hr days for long periods of time. It is unforeseeable that any mitigation measures the agency recommends would serve to protect the public and vulnerable farmworker families from inhalation exposures. Due to the many exposure scenarios exceeding levels of concern, the agency must find an "unreasonable adverse effect" conclusion for chlorpyrifos and remove it from the market.

2. Drinking Water Assessment

The agency improved its drinking water assessment by addressing potential exposures to the transformation product chlorpyrifos oxon, which is more toxic than its parent, chlorpyrifos. According to EPA, "residues of concern in water include both parent chlorpyrifos and chlorpyrifos oxon." Even though little environmental data exists for chlorpyrifos oxon, it can persist through water treatment and thus remains in drinking water, for at least 72 hrs.¹⁴ EPA utilized models and water monitoring data to estimate the concentrations of chlorpyrifos and chlorpyrifos oxon in surface and drinking water. Many limitations were identified for the modeling and data used in the assessment, including the reliability of water monitoring data. EPA has proposed to incorporate targeted monitoring data in the future.

Among several concerning factors that arose from this drinking water assessment, including use scenarios for grapes and turf that yielded substantially high drinking water concentrations, EPA's modeling data reveals that chlorpyrifos uses result in high chlorpyrifos concentrations in surface waters and thus drinking water. Based on the data obtained by the agency's assessment, continued chlorpyrifos use proves to endanger drinking water, as well as contaminate surfaced waters and aquatic communities. Given that the oxon transformation product is more toxic than chlorpyrifos and persists through water treatment processes, the

¹² Beamer P.I., et al. 2009. Farmworker children's residential non-dietary exposure estimates from micro-level activity time series. *Environ Int*;35(8):1202-9.

¹³ Bradman A, et al. 2007. Pesticides and their metabolites in the homes and urine of farmworker children living in the Salinas Valley, CA. *J Expo Sci Environ Epidemiol.* 17(4):331-49

¹⁴ Kamel A, et al. 2009. Oxidation of selected organophosphate pesticides during chlorination of simulated drinking water. *Water Res*; 43(2):522-34.

agency must move to protect communities from contaminated waters and find an “unreasonable adverse effect” finding for chlorpyrifos.

3. Occupational Exposures

EPA’s 2006 assessment found that certain occupational exposures are of concern, even with all feasible personal protective equipment (PPE) or engineering controls. EPA was aware then that more PPEs will not significantly reduce exposure risks, yet the agency went forward with recommending the use of PPEs. For this 2011 assessment, the agency considered 305 exposure scenarios and found 80 to be of concern despite PPEs and 91 not of concern only when PPEs and engineered controls were instituted. Since certain exposure risks remain even with PPEs and other controls, these uses should be banned. Furthermore, according to Arcury and Quandt,¹⁵ despite federal regulations to reduce pesticide exposure (eg PPEs) among farmworkers, research conducted in farmworker communities show that such regulations are only partially enforced. High levels of pesticides continue to be detected among farmworker communities across the country as evidence that PPEs and other controls do not go far enough to protect these vulnerable population. This is a social and environmental justice issue that must quickly be addressed by the agency. EPA’s assessments continue to show that chlorpyrifos uses cannot be adequately mitigated by PPEs and thus these uses should be banned.

Conclusion

The agency’s recent human health risk assessment reveals that there are serious exposure risks associated with continued chlorpyrifos use that can only be mitigated with a complete revocation of chlorpyrifos registration. As mentioned in previous comments to the agency, Beyond Pesticides is concerned by EPA’s apparent focus on risk reduction strategies to come up with “acceptable” yet unnecessary rates of illness across the population. EPA continues to ignore the dangers to farmworkers, farm families, especially vulnerable children¹⁶ and others living near agricultural areas.¹⁷ Chlorpyrifos and its transformation product are frequent water contaminants, endangering drinking water supplies and communities that rely on those supplies. Prenatal and early childhood exposures to this neurotoxic chemical has been linked to developmental delays, low birth weights, and other serious health effects.^{18,19,20} Based on

¹⁵ Arcury, T. and Quandt, S. (eds). Latino Farmworkers in the Eastern United States. Chapter 5. Pesticide Exposure Among Farmworkers and Their Families in the Eastern United States: Matters of Social and Environmental Justice. DOI: 10.1007/978-0-387-88347-2_5. Springer Science +Business Media . LLC 2009

¹⁶ Beamer, PI, et al. 2009 Farmworker children's residential non-dietary exposure estimates from micro-level activity time series. *Environ Int* ;35(8):1202-9.

¹⁷ Harnly, ME, et al. 2009. Pesticides in dust from homes in an agricultural area. *Environ Sci Technol*;43(23):8767-74.

¹⁸ Haviland, J, Butz, D & Porter, W. 2009. Long-term sex selective hormonal and behavior alterations in mice exposed to low doses of chlorpyrifos in utero. *Reproductive Tox*. 29(1):74-9

these facts, EPA must not consider reducing FQPA safety factors for any use scenarios. Additionally, with many outstanding data still to be reviewed and collected by the agency, including epidemiological studies that confirm chlorpyrifos' high toxicity, EPA is failing in its duty to protect human and environmental health- a task it has been mandated to do. Given the serious risks involved, the agency must act to eliminate this public health threat and revoke chlorpyrifos' registration.

Sincerely,

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¹⁹ Venerosi, A et al. 2010. Gestational exposure to the organophosphate chlorpyrifos alters social-emotional behaviour and impairs responsiveness to the serotonin transporter inhibitor fluvoxamine in mice *Psychopharmacology*. 2010 Jan;208(1):99-107.

²⁰ Davis DL and Ahmed AK. 1998. Exposures from indoor spraying of chlorpyrifos pose greater health risks to children than currently estimated. *Environ Health Perspect.*;106(6):299-301.