January 17th, 2017

Comments to EPA from Environmental Health Scientists and Healthcare Professionals in support of EPA's 2016 Revised Human Health Risk Assessment and the 2015 proposed tolerance revocation for chlorpyrifos

Comments submitted to Docket EPA-HQ-OPP-2015-0653-0402
This letter is also available to the public at: https://www.nrdc.org/resources/letter-over-45-scientists-and-health-professionals-supporting-epas-2016-risk-assessment-0

We, the undersigned, write to express our support for EPA's 2016 Revised Human Health Risk Assessment for chlorpyrifos, and our support of EPA's 2015 proposal to revoke all food tolerances for this dangerous insecticide. We recommend that EPA finalize these two documents as soon as possible, and revoke all food tolerances of this toxic pesticide. This would prohibit the use of chlorpyrifos on food crops, protecting consumers in the U.S. that will otherwise continue to be exposed to chlorpyrifos through residues on produce (Bradman et al 2015; Lu et al 2006, Vogt et al 2012, EPA 2016 dietary risk assessment).[1, 2] Children especially experience greater exposure to organophosphate pesticides due to their increased hand-to-mouth action, and relative to adults they eat more fruits and vegetables, drink more, and breathe more.[3]

The new 2016 human health risk assessment has several important improvements over the earlier 2014 one. Both the 2014 and 2016 assessments use the PBPK model sponsored by Dow AgroSciences for deriving internal dosimetry measures.[4] However, whereas the 2014 assessment used a 10% red blood cell acetylcholinesterase inhibition (RBC AChEi) as a Point of Departure (PoD), in the 2016 assessment EPA followed the recommendations of its Scientific Advisory Panel to address the risks below 10% RBC AChEi because, "epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition" (EPA 2016; EPA SAP 2016).

[1] A dietary intervention study reported a 60% to nearly complete reduction in concentrations of two OP metabolites (malathion dicarboxylic acid (MDA), and 3,5,6-trichlor-2-pyridinol (TCPy), a metabolite of chlorpyrifos) immediately after starting the organic food diet.

[2] Residues and risk associated with imported produce, and other imported specialty crops ranging from herbs and spices to tea and coffee, also account for some of the highest risk servings of food and beverages in the U.S. food supply, yet because of EPA's lack of residue data, these residues and accompanying risk have not been rigorously accounted for in chlorpyrifos dietary risk assessments.

[3] Approximately 75% of the general U.S. population had detectable levels of TCPy in the National Health and Nutrition Examination Survey (NHANES) from 2001-2002. Results also showed children ages 6-11 years had concentrations of TCPy (geometric mean 3.48 μg/g creatinine) two times the concentrations detected in adults (geometric mean 1.49 μg/g creatinine) (DHHS 2009). Women living in an agricultural area of California (81% had a family member who was a farmworker) had significantly higher dialkyl phosphate (DAP) concentrations than the levels for women of similar age in the NHANES population (Bradman et al 2005)

[4] Comments submitted to EPA by Professors Whyatt, Slotkin and Hattis provide a detailed analysis of serious weaknesses in EPA's use of a model provided by Dow AgroSciences. Docket ID EPA-HQ-OPP-2008-0850-0510, EPA-HQ-OPP-2008-0850-0100, EPA-HQ-OPP-2008-0850-0092, EPA-HQ-OPP-2008-0850-0089

EPA summarizes these improvements as follows: "The 2014 revised human health risk assessment used dose-response data on acetylcholinesterase inhibition (AChI) in laboratory animals to derive a point of departure. However, the EPA believes that evidence from epidemiology studies indicates effects may occur at lower exposures than indicated by the toxicology database. The 2016 revised human health risk assessment uses neurodevelopmental effects as the critical effect, taking into account recommendations from the 2016 chlorpyrifos SAP on deriving a point of departure for risk assessment."[5] (EPA 2016)

We agree with EPA. Scientific evidence supporting the SAP statement comes from epidemiologic studies, laboratory toxicologic studies, and mechanistic studies demonstrating that chlorpyrifos is a powerful developmental neurotoxicant. Exposures to even very low doses of chlorpyrifos during critical windows of vulnerability during the nine months of pregnancy has been reported in epidemiologic studies to be associated with lower birth weight and adverse neurodevelopmental effects to children including diminished cognitive ability (lowered IQ) poorer working memory, and delays in motor development (Rauh et al, 2006, 2011, Whyatt et al 2005). In addition, chlorpyrifos has been associated with moderate to mild hand tremor in school age children (Rauh 2012) and with changes in brain structure in a pilot study using magnetic resonance imaging among children ages 6-11 (Rauh 2012).

Prenatal chlorpyrifos exposure from living in close proximity to agriculture fields is associated with autism spectrum disorders (Shelton et al., 2014). A recently published study of Costa Rican children living near banana and plantain farms showed a dose-dependent adverse impairment of working memory in boys, oppositional disorders, ADHD, decreased ability to discriminate colors, and an increased prevalence of cognitive problems in the parents (van Wendel de Joode et al 2016). Rural children and the children of farmworkers are exposed to chlorpyrifos through drift and volatilization (Coronado et al 2011; Bradman et al, 2005; Thompson et al, 2014; Wofford et al, 2014; Calvert et al, 2008). Certain subpopulations demonstrate greater susceptibility such as those who have reduced capacity to detoxify organophosphate pesticides like chlorpyrifos (Engel et al, 2015).

These disruptions in children's brain development appear to be permanent, irreversible and lifelong (Rauh et al 2015). The epidemiologic results are consistent with data from toxicological studies which found disruption in neuronal development, neurotransmitter systems and synaptic formation as well as behavioral and cognitive impairments in test animals following low-dose perinatal chlorpyrifos exposure (Slotkin 2004; Aldridge et al. 2004, 2005; Slotkin and Seidler, 2005, Levin et al 2001; Roy et al., 2004; Garcia et al., 2002).

Consistent with the SAP recommendations, EPA's 2016 assessment is much improved by using epidemiologic data from the Columbia Center for Children's Environmental Health (CCCEH) cohort to inform the derivation of time weighted average blood concentrations to be used as the Point of Departure (PoD) for risk assessment. We strongly support this approach. Making use of these epidemiologic data is essential if EPA is to ensure that its risk estimates reflect the reality of chlorpyrifos toxicity, particularly to nervous system development. As noted in EPA's 2010 Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment: "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." (EPA 2010) For example, epidemiologic data are used quantitatively in EPA's evaluation of risks from methylmercury and lead exposures.

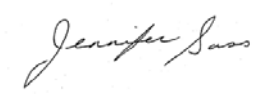
[5] https://www.epa.gov/ingredients-used-pesticide-products/revised-human-health-risk-assessment-chlorpyrifos

By using the CCCEH epidemiologic data to inform the PoD, the new 2016 risk assessment better addresses the elevated risks to vulnerable and sensitive populations from real-world exposures, including levels below those that trigger a 10% RBC AChEi. As EPA itself has concluded the adverse effects seen in epidemiologic research are occurring at doses below those that cause any measurable AChEi (EPA 2014, 2016).

With each year of delay in cancelling food tolerances and agricultural and other uses of chlorpyrifos, more children are unnecessarily at elevated risk for problems in learning, social skills, motor function, and other developmental domains (Raanan et al 2015). As the National Academy of Sciences (NAS) stated in its 2009 report *Science and Decisions* (page 72): "The design of a risk-assessment process should balance the pursuit of individual attributes of technical quality in the assessment and the competing attribute of timeliness of input into decision-making." Assessments must – in all but the most exceptional of circumstances – be based on the best available information already at hand. EPA's review of the risks of chlorpyrifos has already taken nearly a decade; protecting children's health requires expedient action to remove this pesticide from communities and the food supply.

We strongly urge EPA to finalize its assessment and cancel all remaining uses of chlorpyrifos as expeditiously as possible.

Respectfully,



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