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January 17, 2017

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

Re: Chlorpyrifos; Tolerance Revocations. Docket Number: EPA-HQ-OPP-2015-0653

We submit these comments in support of the U.S. Environmental Protection Agency's (EPA) proposal to revoke all chlorpyrifos' tolerances. According to the agency, its issuance of this proposal is in response to an August 10, 2015 order by the U.S. Court of Appeals for the Ninth Circuit in *Pesticide Action Network North America (PANNA) v. EPA*, No. 14-72794. The court decision directed EPA to respond by October 31, 2015 to PANNA and the Natural Resource Defense Council's (NRDC) petition to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations. After an extension, EPA must complete any final rule and fully respond to the PANNA and NRDC petition by March 31, 2017.¹

At issue are hazards associated with the widely used organophosphate insecticide, chlorpyrifos. Chlorpyrifos is a cholinesterase inhibitor that binds irreversibly to the active site of an essential enzyme for normal nerve impulse transmission, acetylcholine esterase (AChE), inactivating the enzyme. The scientific evidence of neurotoxic dangers associated with chlorpyrifos exposure is extensive and consistent. Epidemiological data also points to subpopulations that are 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 that the agency must not continue to ignore. These comments reiterate calls in previous comments by Beyond Pesticides to revoke the registration of chlorpyrifos and its food tolerances, given the serious toxicological issues associated with chlorpyrifos use and exposures, and EPA's failure to meet the standards set forth in Section 3(c)(5)(C) of the *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA).

Revised Human Health Risk Assessment

EPA's revised human health risk assessment now incorporates recommendations from the final report of a Scientific Advisory Panel (SAP). EPA states, "[The] revised analyses do not result in a change to the EPA's proposal to revoke all tolerances but it does modify the methods

¹ FR Notice. EPA-HQ-OPP-2015-0653; FRL-9954-65. Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment. November 17, 2016.

and risk assessment used to support that finding in accordance with the advice of the SAP.”² Under review was the use of the study by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University, which provides important information on the neurological outcomes of children exposed to chlorpyrifos. The study finds that children exposed to high levels of chlorpyrifos have mental development delays, attention problems, attention-deficit/hyperactivity disorder problems, and pervasive developmental disorders at three years of age.³ Concentrations of chlorpyrifos in umbilical cord blood also corresponds to a decrease in the psychomotor development and a decrease in the mental development in three year olds.⁴ A follow-up study in 2012 finds that children with high exposure levels of chlorpyrifos have changes to the brain, including enlargement of superior temporal, posterior middle temporal, and inferior postcentral gyri bilaterally, and enlarged superior frontal gyrus, gyrus rectus, cuneus, and precuneus along the mesial wall of the right hemisphere.⁵ Further, as a result of the CCCEH data, the EPA retained the 10X Food Quality Protection Act (FQPA) Safety Factor for all populations including infants, children and women of childbearing age.

Overall, the SAP agreed with the overall conclusion of the CCCEH study –that there is *an association between chlorpyrifos prenatal exposure and neurodevelopmental outcomes in children*, even though the panel did not believe there is enough data on the relationship between cord blood concentrations at birth to exposures at and around the time of chlorpyrifos application to support its use in quantitative risk assessment.

Also under review was the selection of the point of departure and its use in quantitative risk assessment. There is evidence that chlorpyrifos has effects below that which is observed for 10% red blood cell acetylcholinesterase (AChE) inhibition. Data has shown that chlorpyrifos alters neuronal function outside of, and unrelated to, the classical cholinesterase mechanism.^{6,7,8} However, regardless of the potential for multiple pathways of toxicity, there remains high confidence in the current available and quantifiable evidence of neurological impact. After review, EPA concludes that there is “sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for

² Ibid.

³ 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.

⁴ 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.

⁵ Rauh VA, Perera FP, Horton MK, et al. 2012. Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proc Natl Acad Sci U S A*. 109(20):7871-6.

⁶ Lee I, Eriksson P, Fredriksson A, et al. 2015. Developmental neurotoxic effects of two pesticides: Behavior and biomolecular studies on chlorpyrifos and carbaryl. *Toxicol Appl Pharmacol*. 288(3):429-38.

⁷ Androutsopoulos VP, Hernandez AF, Liesivuori J, Tsatsakis AM. 2013. A mechanistic overview of health associated effects of low levels of organochlorine and organophosphorous pesticides. *Toxicology*. 307:89-94.

⁸ Meijer M, Hamers T, Westerink RH. 2014. Acute disturbance of calcium homeostasis in PC12 cells as a novel mechanism of action for (sub)micromolar concentrations of organophosphate insecticides. *Neurotoxicology*. 43:110-6.

AChE inhibition,”⁹ and that EPA’s current approach for evaluating chlorpyrifos’ neurological impact is “not sufficiently health protective.”

Drinking Water Assessment

Previous agency drinking water assessments find that the chlorpyrifos oxon - transformed from the parent during chlorination in drinking water treatment - poses a threat to drinking water.¹⁰ The chlorpyrifos oxon persists through water treatment and thus remains in drinking water for at least 72 hours.¹¹ The conclusion from previous assessments has not changed, i.e., there is potential exposure risks from chlorpyrifos or chlorpyrifos-oxon in finished drinking water based on currently registered uses.

Responsibilities Under the Law

Section 408(b)(2)(A)(i) of the *Federal Food Drug and Cosmetics Act* (FFDCA) states that EPA can establish a tolerance for a pesticide chemical residue in or on food only if EPA determines that the tolerance is safe. “Safe” is then defined as 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.” Based on EPA data, chlorpyrifos’ registration does not meet this standard.

EPA states that its revised analysis indicates that “expected residues of chlorpyrifos on most individual food crops exceed the health-based “reasonable certainty of no harm” safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA).” Additionally, the agency also points out that “risk from the potential aggregate exposure does not meet the FFDCA safety standard.”

Based on this, and in light of the deleterious impact of chlorpyrifos exposure on children, the agency has no choice but to revoke chlorpyrifos tolerances. However, EPA presumably is leaving the door open for mitigation measures in order to make risk calculations conform to the set standards. EPA states that it “continues to seek comment on possible mitigation strategies, namely, use deletions, which might allow the EPA to retain a small subset of existing chlorpyrifos food uses.” We believe it is *inappropriate* for EPA to still seek to mitigate continued use of chlorpyrifos given the conclusions from its own assessment, SAP, and independent data demonstrating harmful impacts on children.

Conclusion

The path is clear for EPA to revoke tolerances for chlorpyrifos. The science is unequivocal. Chlorpyrifos exposures result in developmental delays, low birth weights, and

⁹ USEPA. 2016. Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

¹⁰ USEPA. 2014. Chlorpyrifos: Updated Drinking Water Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

¹¹ Kamel A, et al. 2009. Oxidation of selected organophosphate pesticides during chlorination of simulated drinking water. *Water Res*; 43(2):522-34.

other serious neurological health effects.¹² Chlorpyrifos is an incredibly neurotoxic organophosphate that has no place in modern agriculture as it poses dangers to farmworkers, farm families, especially vulnerable children,¹³ and others living near agricultural areas.¹⁴ There are alternatives available for farmers and other users that present a less risk, and ensure that there is no disruption in food production and practices once the revocation is final.

Given the serious risks involved, the agency must not delay on its proposal and act to eliminate this public health threat.

Respectfully,

A handwritten signature in blue ink, appearing to read 'NH' with a stylized flourish.

Nichelle Harriott
Science and Regulatory Director

¹² 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.

¹³ 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.

¹⁴ Harnly, ME, et al. 2009. Pesticides in dust from homes in an agricultural area. *Environ Sci Technol*;43(23):8767-74.