Coalition of OP Registrants

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October 14, 2021

Via Electronic Submission

Hearing Clerk
Office of the Hearing Clerk (1900L)
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Written Objection on: Docket Number FFDCA-HQ-2021-0001; Chlorpyrifos; Tolerance Revocations Final Rule (Docket No. EPA-HQ-OPP-2021-0523)

Dear Sir or Madam:

The Coalition of Organophosphate (OP) Registrants ("the Coalition") appreciates the opportunity to submit comments and a formal objection to the referenced final rule issued by the U.S. Environmental Protection Agency (EPA) in the August 30, 2021, *Federal Register*.

Specifically, the Coalition objects to EPA's reliance on epidemiology data as the basis for a tenfold uncertainty factor in the chlorpyrifos assessment, and subsequently the use of these epidemiology data in any of the other OP risk assessments. The epidemiology data used to support the tenfold uncertainty factor in the risk assessment for chlorpyrifos are a driving reason EPA is proposing to revoke all the food tolerances. The Coalition, however, has filed numerous comments against the use of the epidemiology data as the basis for an uncertainty factor, as described in EPA's Health Effects Division (HED) 2015 Literature Review.[1] The Coalition believes that the overwhelming weight of evidence supports that use of the epidemiology data to apply a Food Quality Protection Act (FQPA) 10x uncertainty factor is not justified for any of the OPs.

[1] Memorandum from EPA Office of Chemical Safety and Pollution Prevention, "Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides" (Sept. 15, 2015) (Literature Review), available at file://lawbcfp00/data/bcdata/users/pberard/Downloads/EPA-HQ-OPP-2008-0440-0039_content.pdf.

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The epidemiology data that EPA relied upon in the Literature Review have serious flaws that make it inappropriate for use in a risk assessment, including the basis for reinstating an FQPA 10x factor for any of the OPs.

First, HED has acknowledged that there is no plausible biological explanation for the reported neurodevelopmental associations. In the absence of an experimentally demonstrable and accepted common mode of action/adverse outcome pathway, there is no basis for bridging any of the exposure outcomes alleged in the epidemiology studies from one OP to another. The only accepted common mode of action for the OPs is cholinesterase inhibition. The Coalition supports EPA's conclusion in the referenced rule that the appropriate regulatory endpoint for chlorpyrifos, and all OPs, is cholinesterase inhibition. There remains no scientifically valid evidence that demonstrates that regulating the OPs based on cholinesterase inhibition is not protective for all effects of concern, including neurodevelopmental effects. This was discussed again during the EPA Science Advisory Panel (SAP) meeting held in September 2020. Additionally, data generated by EPA's Office of Research and Development (ORD) related to non-animal testing methodology (NAM) further support the position that regulating OPs based on cholinesterase inhibition is protective of the effects alleged in the epidemiology data, and therefore an additional uncertainty factor would not be necessary. We do not believe EPA adequately considered this new information in issuing the referenced final rule, especially as additional NAM data generation is ongoing.

Second, despite numerous attempts, the researchers at Columbia University have refused to provide EPA with the information necessary to validate the studies and provide any credible evidence of neurodevelopmental effects that is sufficiently valid, complete, and reliable to meet the standards under the Federal Food, Drug, and Cosmetic Act (FFDCA).

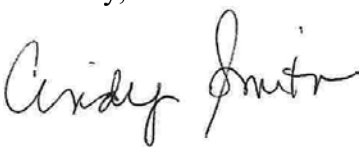
Third, in the Literature Review, the link to the OPs is very weak and not scientifically valid. It is based on spot samples of non-specific urinary metabolites. Reported associations that are based on nonspecific dialkyl phosphate (DAP) biomarkers are inappropriate for use in regulatory decision-making. There is no way to track the DAP biomarkers to any specific OP; moreover, the presence of the urinary DAPs may simply reflect exposure to preformed metabolites that can be present in foods and in the environment at higher levels than parent molecules and can seriously confound interpretation of the urinary DAP data. Because the reported urinary DAP data are not reliable, the reported association is also not reliable. EPA correctly recognized this deficiency with common urinary biomarker data in its review of epidemiological data for the pyrethroids.[2]

[2] EPA, Memorandum from the Office of Chemical Safety and Pollution Prevention (OCSPP), Apr. 30, 2019, Pyrethroids: Tier II Epidemiology Report (Apr. 30, 2019), available at https://www.epa.gov/sites/default/files/2019-08/documents/tier-ii-epidemiology-report.pdf.

Finally, EPA claims it is reapplying the 10x factor to OPs based on uncertainty; the database for the OPs, however, is quite robust and can give EPA great certainty. The studies and data that EPA has on file for the OPs meet the legal standard of reliable. The available epidemiology data have not been made available to EPA and therefore do not meet the legal standard. Additionally, data generated by EPA in ORD further support regulating OPs based on cholinesterase inhibition and are protective of the neurodevelopmental effects alleged in the epidemiology data. Therefore, the only uncertainty that exists is that imparted by the flawed epidemiology data.

Based on this objection and previous information provided to EPA, the Coalition believes that the epidemiology data described in the Literature Review should not be used as the basis for an additional uncertainty factor for any OP pesticide. Thank you for your consideration.

Sincerely,



Cindy Smith
Chair, Coalition of OP Registrants

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