PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

January 17, 2017

U.S. Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave. NW.
Washington, D.C. 20460-0001

Submitted via Federal eRulemaking Portal

Re: Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment. Docket ID No. EPA-HQ-OPP-2015-0653-0402

The Pesticide Policy Coalition (PPC or "the Coalition") is pleased to submit comments to the U.S. Environmental Protection Agency (EPA) on its Notice of Data Availability (NODA) concerning the potential revocation of all tolerances for chlorpyrifos.

PPC is an organization of food, agriculture, forestry, pest management and related industries that support transparent, fair and science-based regulation of pest management products. PPC members include: nationwide and regional farm, commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators and distributors; pest-and vector-control operators; research organizations; and other interested stakeholders. PPC serves as a forum for the review, discussion, development and advocacy around pest management regulation and policy.

Chlorpyrifos is an active ingredient that is of critical importance to U.S. agriculture and pest management. Coalition members rely on chlorpyrifos products to protect crops vital to the production of food, energy, clothing, and countless other goods and services that benefit all Americans.

COMMENTS

The Coalition supports the long-established, rigorous, and science-based pesticide registration review process established under the Federal Insecticide Fungicide,

and Rodenticide Act (FIFRA). The FIFRA registration review process has historically provided for a transparent and science-based evaluation of pesticides with due process that affords opportunities for pesticide registrants and stakeholder to address concerns. Additionally, under the Federal Food, Drug and Cosmetic Act (FFDCA), proposed tolerance revocations must be grounded in relevant and reliable science-based factors, including valid, complete, and reliable study data.

EPA's regulatory decision-making for its proposed revocation of all tolerances represents a significant shift from the regulatory framework and statutory standards set forth in FIFRA and FFDCA. EPA's FIFRA Scientific Advisory Panel (SAP) raised troubling and unresolved questions around the biomonitoring data and analysis that are the core of EPA's regulatory decision-making for the proposed revocation of tolerances. For the reasons discussed in the following comments, the Coalition finds that the proposed revocation is based on flawed, unreliable, and incomplete data. The Coalition encourages EPA to deny the petition to revoke tolerances. If after following appropriate science review and policy development procedures, EPA concludes a need for any new regulatory actions, EPA should proceed with the established chlorpyrifos registration review process, using scientifically sound and credible assessment methodology.

1. EPA has failed to adequately address significant concerns with its reliance on the Columbia Children Center for Environmental Health (CCCEH) study findings.

EPA's own SAP raised significant concerns with the use of the CCCEH study in the human health risk assessment in the registration review for chlorpyrifos. The SAP cited numerous issues with EPA's reliance on the CCCEH study. The SAP's concerns included:

- Unavailable raw study data, which prevents important quality assurance assessment;
- Lack of study validation and replication of results;
- CCCEH researchers did not follow the laboratory practices that pesticide registrants are required to adhere to for studies that EPA will consider in the registration process;
- Issues related to the CCCEH approach to data analysis, including imputing values when many were below laboratory detection values, and the use of an unjustified formula based on unknown data that researchers used to generate missing data; and

- EPA's use of a single, umbilical cord blood measurement from the CCCEH study to establish a new point of departure (PoD), or regulatory health endpoint.

EPA has yet to address the majority of the issues raised by the SAP, and its attempts to follow SAP recommendations fall short. One example is that the SAP recommended that EPA base the PoD on blood concentrations at the time of exposure rather than cord blood at the time of delivery. In response, EPA derived a new exposure estimate based on an informal survey of pest control operators regarding their application practices at the time of study, almost two decades later. Applicators could not possibly recall their precise application practices after nearly 20 years, which means EPA's survey likely includes unreliable data. Overall, EPA appears to have selectively responded to the SAP's comments in an attempt to put a supportive gloss to a pre-determined outcome, which is not supported by a full analysis of the SAP review.

In light of these many unresolved concerns, EPA's use of the CCCEH study as the basis for its proposed revocation is not grounded in sound science.

2. EPA's drinking water assessment is incomplete and needs further refinement to account for local-scale exposure.

In the NODA, EPA provides drinking water exposure estimates which purportedly complete and combine the work of the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. However, EPA has failed to incorporate localized inputs that would further refine its drinking water assessment and ensure its estimates are as closely tied to real-world exposure scenarios as practically possible. Instead, EPA has settled with a regional-level assessment that results in overly conservative and less reliable exposure benchmarks. EPA's modeled simulations assume a single crop scenario at maximum rates and application on the same day across an entire watershed, which results in a grossly unrealistic worst-case estimate.

Nearly a year has passed since the registrant, Dow AgroSciences, submitted a local-scale drinking water assessment, which demonstrates it is feasible for EPA to further refine its assessment. The Coalition is concerned that EPA has yet to respond to or consider the registrant's more refined assessment in its regulatory decision-making.

The Coalition encourages the EPA to consider the registrant's study and approach,

and accordingly refine the drinking water assessment before finalizing its decision on whether to revoke all tolerances for chlorpyrifos.

3. EPA's departure from sound scientific principles threatens the use and availability of critical crop protection tools.

The PPC appreciates the EPA's role in ensuring the safe use of pesticide products, and recognizes the importance of risk assessments in protecting public safety. However, the Coalition is alarmed at EPA's abrupt divergence from accepted and credible scientific methodology in its assessment of chlorpyrifos. EPA's use of data and approaches taken in selecting a PoD and estimating drinking water exposures set a precedent that threatens the credibility of the FIFRA process that is relied on by pesticide registrants, the user community, and the public. Absent a more robust, independent peer review of the data and methodology, EPA should not base its regulatory decision on the analyses and novel approach used in the chlorpyrifos assessments.

CONCLUSION

The Coalition recognizes that EPA is under an impending court-ordered deadline to respond to the petition to revoke tolerances for chlorpyrifos. A decision to revoke all tolerances would effectively remove chlorpyrifos products from the marketplace. Process shortcuts, flawed science, and politics should have no place in a decision of this magnitude. In light of the significant concerns raised in the comments above, EPA does not have grounds to revoke all tolerances for chlorpyrifos and should continue with its ongoing chlorpyrifos registration review.

Sincerely,

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