United States Department of Agriculture
Office of the Chief Economist
Office of Pest Management Policy
1400 Independence Avenue, SW
Washington, D.C. 20250-3810

September 11, 2022

Edward Messina, Esq., Director
Office of Pesticide Programs Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: USDA Comments on the Draft Notice of Intent to Cancel Chlorpyrifos Registrations

Dear Mr. Messina:

Thank you for your August 11, 2022, letter and the opportunity to review and comment on EPA's draft notice of intent to cancel (NOIC) registrations of chlorpyrifos under Section 25(a)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). USDA acknowledges and recognizes that, in response to the April 29, 2021, order from the U.S. 9th Circuit Court of Appeals[1] EPA chose to revoke all tolerances[2] for residues of chlorpyrifos in food without canceling the associated products. We also recognize EPA's position that the February 28, 2022, revocation of tolerances for residues of chlorpyrifos in food makes any remaining registrations bearing labeled food uses of these products misbranded and out of compliance with FIFRA. As such, EPA considers this NOIC to be an administrative action. USDA disagrees, and has some overarching concerns with this action, as follows.

Under FIFRA, EPA is compelled to consider "the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." In addition, EPA is required to provide the Secretary of Agriculture with a 30-day comment period to review the notice (provided in your August 11, 2022, letter) and the Agency's analysis of the impact on the agricultural economy. As an analysis of impact, EPA states in its draft NOIC that this action produces no negative impacts to producers beyond those that were already imposed when EPA revoked chlorpyrifos tolerances. However, revocation under the Federal Food Drug and Cosmetic Act does not explicitly provide for analysis of the impact on the agricultural economy. As such, we have legal concerns around this action and would like to meet to discuss further.

In addition, USDA views this outcome as a harmful precedent. Processes exist for a reason and should be followed whenever possible. The regulatory certainty and transparency that result from predictable processes help to maintain public trust in the institutions responsible for regulating agricultural pesticides. This chlorpyrifos decision has left the significant agricultural impacts of the tolerance revocation unaddressed. Agricultural stakeholders are confused about the legality

[1] https://cdn.ca9.uscourts.gov/datastore/opinions/2021/04/29/19-71979.pdf
[2] https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0030

of use of labeled chlorpyrifos product in their possession, and both EPA and FDA have been forced to divert resources to improving clarity *post hoc*. The lack of a phase-out period caused a widespread disposal problem for existing stocks of chlorpyrifos products that can no longer be used. This divergence from normal procedures also caused confusion and concerns among international trading partners who look to the EPA as a model for consistent, risk-focused, and science-based pesticide regulatory processes that help to deliver a safe food supply. When U.S. stakeholders advocate for similar science-based policies and processes among international trading partners, examples of Agency actions that deviate from this model may undercut U.S. credibility in trade negotiations and other international regulatory venues. This can further harm the economic viability of U.S. producers in the long-term.

Lastly, EPA's 2020 proposed interim decision (PID) for chlorpyrifos[3] stated that a number of labeled food uses could be retained (with regional nuances) and still meet the Agency's safety finding under FFDCA and FQPA, even with the inclusion of a 10x safety factor. This list included alfalfa (including seed production), apples, asparagus, cherries (tart), citrus, cotton, peaches, soybeans, strawberries, sugar beets, and wheat. USDA also submitted comments[4] in response to this PID that includes an approach to exposure characterization that would allow the retention of other food uses that are important to growers. While EPA asserts that they had no choice but to revoke all tolerances because tolerances must be considered in aggregate under FQPA, other pathways could have been pursued to refine pesticide use patterns prior to tolerance revocations. A more practical, less disruptive pathway could have included negotiations with the registrants to narrow registration approvals and maintain safe uses, along with a transition plan for agriculture for uses for which the safety standard could not be met. This approach would have been consistent with past Agency practices: there are many examples of EPA taking such approaches and addressing risks while minimizing impacts to agriculture. Instead, the Agency chose to ignore its prior analysis and procedures and move forward with a wholesale and abrupt revocation of all tolerances based on the aggregate risk. In doing so, many agricultural stakeholders believe that the Agency put forth an outcome that created unnecessary chaos and confusion.

USDA recognizes the important and difficult work done by our EPA colleagues. We continue to support EPA as an international standard bearer in pesticide regulation. While we may sometimes disagree on specific regulatory outcomes, we continue to believe in the Agency's expertise and capabilities, and we strongly advocate for EPA as a credible and globally respected model for effective, science-based pesticide regulatory policy and decisions. We believe that the chlorpyrifos example is a deviation from this model. Rather than proceed with the NOIC under review, USDA would strongly support an Agency-initiated action to reestablish tolerances for and ultimately retain chlorpyrifos uses that meet the Agency's safety finding when considered as a subset of the aggregate (in accordance with the 2020 PID). We would be happy to provide input that could help inform EPA's analysis and risk/usage characterization.

On behalf America's agricultural producers seeking regulatory certainty, we also support EPA's typical decision-making process, the precedent for product cancellations and tolerance revocations established through the reregistration and registration review programs since the enactment of the Food Quality Protection Act in 1996, and the legal requirements for review by USDA. We are requesting that, in future actions, EPA follow historical precedent and legal

[3] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0964
[4] https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1101

procedures. We believe this will help to prevent unnecessary confusion among agricultural stakeholders and restore confidence in EPA's regulatory processes.

Please contact Clayton Myers at Clayton.Myers@usda.gov or me at Kimberly.Nesci@usda.gov if you would like to discuss our comments on this NOIC.

Sincerely,

Kimberly Nesci
Director, Office of Pest Management Policy

cc: Elissa Reaves, Ph.D., Director
Pesticide Re-evaluation Division, Office of Pesticide Programs
Environmental Protection Agency