Minor Crop Farmer Alliance

Via Electronic Docket Submission October 29, 2021

Mr. Edward Messina
Director, Office of Pesticide Programs
C/O Office of the Hearing Clerk
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Objections to the Revocation of Chlorpyrifos Tolerances Final Rule (Docket No. EPA-HQ-OPP-2021-0523)

Dear Mr. Messina:

These objections are submitted on behalf of the Minor Crop Farmer Alliance ("MCFA") and its members in response to the final rule *Chlorpyrifos; Tolerance Revocations* published by the U.S. Environmental Protection Agency ("EPA" or "Agency") in the Federal Register on August 30, 2021 (86 Fed. Reg. 48315-36).

MCFA is an alliance of national and regional organizations and individuals representing growers, shippers, packers, handlers and processors of various agricultural commodities, including food, fiber, turf grass, nursery and landscape crops, and organizations involved with public health pesticides. MCFA advocates for use of sound science in government pesticide policies, so that our growers have access to crop protection tools that are safe for applicators, workers, the public and the environment. While our commodities are often called "minor crops" or "specialty crops," they play a major role in the public's health and wellbeing by supplying diverse and highly nutritious foods to the world's growing population, and safe and beautiful surroundings for our homes, schools, and places of business. These U.S. farmers grow more than 500 types of fruit, vegetable, tree nut, flower, ornamental nursery and turf grass crops. Specialty crop production accounts for more than $60 billion, or approximately 40% of total U.S. crop receipts.

On behalf of our members, MCFA objects to the revocation of the chlorpyrifos tolerances (40 CFR § 180.342) as specified in the final rule. These tolerances should remain in effect. Chlorpyrifos is an important pesticide used by many farmers in the production of their crops, including specialty crop producers who are members of MCFA, to address various insect pests. They and their customers rely on the chlorpyrifos tolerances to address any residues of the chemical that may be present in the commodities they produce and distribute. Consequently, MCFA members are adversely affected by the revocation of chlorpyrifos tolerances.

MCFA has three main objections to the final rule. In summary, first MCFA objects to the Agency relying on certain epidemiological reports as a basis for maintaining a ten-fold uncertainty factor in assessing whether the chlorpyrifos tolerances meet the statutory standard of safety, i.e., a reasonable certainty of no harm. It is clear that these epidemiological reports are the

central basis for the Agency not reducing the uncertainty factor. The epidemiological information on which the Agency is relying is unreliable and therefore inappropriate for use in the Agency's decision-making process. As such, MCFA believes the Agency has not conducted an appropriate weight-of-evidence analysis of the available reliable data and information as required.

Second, assuming *arguendo* that the ten-fold uncertainty factor is maintained, the Agency in the final rule acknowledges that there are at least eleven (11) current crop uses that would meet the required safety standard. However, the Agency indicates that because it is forced to deal with the entire label as currently constructed, it lacks the ability/flexibility to maintain the tolerances associated with these 11 crops. The Agency tries to disassociate itself from the consequences of the administrative regulatory path it has chosen to take, namely initiating tolerance revocation before completing a cancelation proceeding. If the Agency followed the sequence of taking the necessary tolerance actions only after first finalizing its registration decision in a cancellation action under Section 6 of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") as has been its historical approach, situations like that presented in the current action would be avoided. Consequently, MCFA objects to the tolerance revocations applicable to the 11 crops because these uses meet the required safety standard and the revocation of tolerance results because the Agency has failed to first initiate the applicable procedures under FIFRA before initiating this tolerance revocation action.

Third, MCFA objects to the October 29, 2021, effective date. The Administrator has the authority under the statute to stay the effective date, and he should exercise his discretion in this situation. Each of these objections are discussed in greater detail below.

I. The epidemiological reports which the Agency uses as support for not reducing the ten-fold uncertainty factor are not reliable and are inappropriate for use in the tolerance review process.

EPA should reconsider its approaches used in its revised chlorpyrifos human health risk assessment, particularly the reliance on three epidemiology reports[1], and more specifically the CCCEH report. The information in that paper underpins EPA's decision to maintain the Food Quality Protection Act (FQPA) ten-fold uncertainty factor. This additional uncertainty factor is central in determining whether chlorpyrifos exceeds the total aggregate/dietary risk under the FQPA. Essentially, the Agency is choosing to set aside the results of carefully conducted chlorpyrifos laboratory animal exposure studies and instead rely on these limited epidemiological reports. That approach does not appear to reflect the application of sound science or transparency, both of which the Agency has championed as cornerstones of its approach in implementing the provisions of the FQPA.

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[1] Mothers and Newborn Study of North Manhattan and South Bronx conducted by Columbia Children's Center for Environmental Health ("CCCEH") Columbia University; 2) Mount Sinai Inner-City Toxicants, Child Growth and Development Study; and 3) Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by University of California Berkeley researchers.

The chlorpyrifos toxicological database is very extensive, and the endpoints are well understood. In this instance, however, the Agency has decided to give undue weight to the "secret science" of these epidemiological papers, using the conclusions of those papers as the underpinning for the conclusion that there is uncertainty regarding the safety of the chemical residue. In fact, the Agency does not know whether the reported conclusions in the CCCEH reports are consistent with the underlying information/data associated with the report. Before relying on the conclusions of these reports, the Agency needs to validate them by determining : (1) whether the participants were actually exposed to chlorpyrifos, and if so, (2) at what dose, (3) over what time period, (4) whether the reported effects actually occurred, (5) that the measurements were accurate, and, (6) if the measurements were accurate, whether there were factors other than exposure to chlorpyrifos which caused the purported effect.

Consequently, the Agency is overriding the results of carefully constructed Good Laboratory Practices-compliant laboratory animal toxicology studies in favor of epidemiological studies, and all affected parties should be assured that the exposures to the pesticide are clearly documented and legitimate. Otherwise, the Agency is replacing scientific results with guesswork. By according these epidemiology studies such primacy in its decision making without having the raw data available and public consultation or discussion, EPA is reordering the hierarchy of information it uses to make regulatory decisions.

The administrative record is very clear. Despite the Agency making repeated reasonable requests to review the underlying data and information from the CCCEH study, the authors declined to share such information. Apparently, the researchers did not think they could trust the Agency to maintain the confidentiality of the information relating to the study's participants. Notwithstanding the researchers declining to provide the necessary access to demonstrate the reliability of the CCCEH paper, the Agency subsequently relied on the researchers' conclusions to justify maintaining the ten-fold uncertainty factor in its chlorpyrifos tolerances safety assessment. The reliance of the unsubstantiated information from these epidemiological reports is unjustified. Without the underlying information/data associated with the reports, they cannot be said to meet any reasonable definition of "reliable information" as contemplated by the FQPA.

Furthermore, the Agency has reliable, comprehensive and robust toxicity and exposure information for chlorpyrifos. The Agency recognizes that regulating chlorpyrifos on the basis of cholinesterase inhibition is sufficiently protective of infants and children. There is no available scientifically valid evidence that demonstrates that regulating chlorpyrifos based on cholinesterase inhibition is not sufficiently protective of infants and children from effects of potential exposure to the chemical, including neurodevelopmental effects. Further, as the Agency's record reflects, there are numerous other epidemiological publications and studies which are counter to the conclusions of the three reports in question.[2] Those other studies appear

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[2] In fact, a review of approximately 600 studies contracted by the EU European Food Safety Agency concluded that there is no evidence to suggest an association between pesticide exposure, including Chlorpyrifos, and neurodevelopment effects.

to indicate that at the measured levels of exposure, the evidence is insufficient to show causality between chlorpyrifos and adverse neurological effects in infants and children. As such, the Agency should re-initiate its analysis of whether, based on a weight-of evidence approach, the reliable available data demonstrate that the ten-fold uncertainty factor can be reduced. We believe that the data support such a reduction.

II. The Agency's current analysis demonstrates that even with no reduction of the ten-fold uncertainty factor, tolerances associated with 11 current crop uses would meet the required safety standard, and therefore should be maintained.

In its analysis, the Agency recognizes that 11 current crop uses would meet the required safety standard even if the ten-fold uncertainty factor is maintained.[3] However, the Agency indicates that because it is forced to deal with the entire label as currently constructed, it lacks the ability/flexibility to maintain the tolerances associated with these 11 crops uses. The Agency tries to disassociate itself from the consequences of the administrative regulatory path it has chosen to take, namely initiating tolerance revocation before completing a cancelation proceeding. If the Agency followed its traditional FIFRA/FQPA sequencing of taking the necessary tolerance actions only after first finalizing its decision in a cancellation action under Section 6 of the FIFRA, situations like that presented in the current action would be avoided. Consequently, MCFA objects to the tolerance revocations applicable to the 11 crops because the Agency has failed to first initiate the applicable procedures under FIFRA before initiating this tolerance revocation action.

It is not reasonable that Congress ever intended such a result in the application of the FQPA. Congress wanted to make certain that the Agency conducted the appropriate rigorous scientific analysis to be assured that residues associated with approved uses of a chemical met the required safety standards for maintaining the associated tolerance. However, Congress also recognized the important role pesticides play in agriculture production in producing the nation's food supply and maintaining national food security. Nowhere in the FQPA is there support for revoking a tolerance associated with a food use that met the reasonable certainty of no harm standard because of an administrative sequencing problem that the Agency itself controls. Revoking such tolerances in the instant situation merely serves to hurt the affected growers and their customers who rely on the foods they produce. It is not warranted from a safety perspective under the FQPA. The exposures are safe. What is missing is the Agency affording the registrant the opportunity to amend its registration to appropriately reduce the uses of the chemical to only the 11 crops. Additionally, canceling tolerances that meet safety standards undermines the scientific credibility of the Agency.

III. The Agency should exercise its discretion and stay the effective date of October 29, 2021.

The statute provides the Agency the authority to stay the effective date of the tolerance revocations. See 21 U.S.C. § 346a (g)(1). Under the current circumstances, the Administrator should exercise his discretion and extend the effective date, at least to allow the full

[3] These include alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry and wheat in specific areas of the country.

consideration of the objections and allow for the appropriate amendment of the registration to accommodate the uses associated with the above-referenced commodities so that the 11 tolerances are maintained.

Based on the foregoing, the Agency should modify the tolerance revocations decision for chlorpyrifos.

Respectfully submitted,

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