

October XX, 2021

Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted electronically via Federal eRulemaking Portal

RE: Formal Written Objections and Request to Stay Tolerance Revocations: Chlorpyrifos (EPA-HQ-OPP-2021-0523)

To Whom It May Concern:

We represent _____. We write concerning EPA's final rule issued on August 30, 2021, to revoke all tolerances for the insecticide chlorpyrifos (EPA-HQ-OPP-2021-0523). Pursuant to the Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(g) (21 U.S.C. 346a) we are writing to file formal objections regarding this action, as we believe it is inconsistent with federal statute, the Agency's own record on chlorpyrifos, and sound, science-based and risk-based regulatory practices. Based on these objections, we urge EPA to rescind the final rule revoking tolerances and consider continued agricultural uses of chlorpyrifos under its ongoing, normal-order registration review of chlorpyrifos. Furthermore, because this rule will cause significant and irreparable harm to food and agricultural stakeholders, we request the Agency stay implementation of the rule until these objections can be formally addressed and responded to by EPA.

Harm to Food & Agricultural Stakeholders, the Environment

As many of our organizations have commented regarding the ongoing registration review for chlorpyrifos (EPA-HQ-OPP-2008-0850), this chemistry holds a unique and significant value for many agricultural producers. Chlorpyrifos has more than 50 registered agricultural uses on numerous crops, many of which are high-benefit uses to protect against economically significant pests. We object to the tolerance revocation of all uses, as EPA's own risk assessments show some uses meet the legal standard under FFDCA. Additionally, this action will leave thousands of growers across the country defenseless to devastating pests, which is why we also request that EPA stay implementation of this rule until the Agency can thoroughly consider and respond to objections. To lose the ability to use chlorpyrifos, as would occur through implementation of the rule, would unnecessarily result in significant and immediate economic and environmental damage.

For example, Michigan cherry producers currently have no other effective control options besides chlorpyrifos for American Plum Borers and Peachtree Borers. These insect pests can bore into trunks of cherry trees ultimately leading to the tree's death.¹ What is worse, since fruit trees take years to reach maturity, growers who lose trees will be harmed for not just one growing season, but many years to come. Michigan State University (MSU) Economists estimated that a grower who loses a tree to borers would spend \$180 replacing it, as well as \$42 per year in lost income for the average of seven years it takes a tree to begin producing marketable fruit, ultimately costing the producer \$474 in lost revenue

¹ *Tart Cherry Pest Management in the Future: Development of a Strategic Plan*. June 2011. 23-24.
<https://ipmdata.ipmcenters.org/documents/pmsps/MITartCherryPMSP.pdf>

and replacement costs for every deceased tree.² Given that USDA estimates Michigan has more than 4.7 million cherry trees planted,^{3,4} this action would expose Michigan cherry producers to potentially tens to hundreds of millions of dollars in irreparable damage through the loss of chlorpyrifos.

U.S. sugarbeet growers will also face significant damages from this rule. These growers contend with sugarbeet root maggots (SBRM) – flies that lay their eggs at the base of sugarbeets, whose larvae then hatch, burrow into the plant, and feed on the sugarbeet. Chlorpyrifos is the most effective product available for treating emerged SBRM. The few other products registered can only suppress SBRM, not control it, or are only registered for use on adult flies, not larvae.⁵ Without chlorpyrifos, sugarbeet growers will be exposed to this damaging pest which can inflict up to 45 percent yield loss and \$500 in damages per acre.⁶ When considering more than 140,000 acres of sugarbeets are at risk of from SBRM,⁷ U.S. sugarbeet growers could be looking at tens of millions of dollars in irreparable damages annually should this rule take effect.

It is important to note that it is not just farmers, but also our environment that will be impacted should this rule take effect. For example, soybean growers use chlorpyrifos to control both two-spotted spider mites (TSM) and soybean aphid populations that have developed resistance to other insecticides, such as pyrethroids. These pests can inflict yield losses as high as 60 percent if left unchecked.⁸ For growers who face these pests, there is no one-to-one replacement for chlorpyrifos – it is the only option that will control both pests.⁹ Should this rule take effect, soybean growers who face TSM and pyrethroid-resistant aphids will now have to choose between applying twice as much pesticide active ingredient (which will also significantly increase their operational costs) or face serious crop damage. This results in an increase in pesticides used in the environment and additional sprays which unnecessarily increase the use of water and fuel.

These are just a few examples out of many where agricultural producers, supply chains, and our environment will face irreparable harm should this rule take effect. Wheat, asparagus, peach, apple, alfalfa, citrus, peanut, onion, and other producers will experience similar costly adverse impacts. We object to the rule on the basis that it will inflict significant economic damage to the tune of hundreds of millions of dollars to these farmers and many others. To ensure that this irreparable harm does not occur from this rule, which the Agency may yet modify or rescind based on public comment, we request

² Gordon, Julie and Kyle Harris. *Comments submitted by Cherry Marketing Institute to Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (EPA-HQ-OPP-2008-0850)*. February 26, 2021.

³United States Department of Agriculture. National Agriculture Statistics Service. 2019. *2018-2019 Michigan Fruit Inventory: Tart Cherries*. https://www.nass.usda.gov/Statistics_by_State/Michigan/Publications/Michigan_Rotational_Surveys/mi_fruit18/Tart%20Cherries.pdf

⁴U.S. Department of Agriculture. National Agriculture Statistics Service. 2019. *2018-2019 Michigan Fruit Inventory: Sweet Cherries*. https://www.nass.usda.gov/Statistics_by_State/Michigan/Publications/Michigan_Rotational_Surveys/mi_fruit18/Sweet%20Cherries.pdf

⁵ Franzen, David, Mark Boetel, Ashok Chanda, Albert Sims, and Thomas Peters. North Dakota State University. January 2021. "2021 Sugarbeet Production Guide." <https://www.ag.ndsu.edu/publications/crops/sugarbeet-production-guide>

⁶ Boetel, Mark. North Dakota State University. June 10, 2021. "NDSU Helping Control Sugarbeet Root Maggot." *Newsletter*. https://www.ndsu.edu/vpag/newsletter/ndsu_helping_control_sugarbeet_root_maggot/

⁷ Ibid.

⁸ Hodgson, Erin. Iowa State University Extension and Outreach. July 6, 2016. "Spider Mite Injury Confirmed in Soybean." *Integrated Crop Management*. <https://crops.extension.iastate.edu/cropnews/2016/07/spider-mite-injury-confirmed-soybean>

⁹ Koch, Robert, Theresa Cira, Raj Mann, Bruce Potter, Anthony Hanson. University of Minnesota Extension. August 19, 2021. "Environmental Protection Agency's Cancellation of Chlorpyrifos Tolerances: Alternatives for Management of Key Crop Pests." *Minnesota Crop News*. <https://blog-crop-news.extension.umn.edu/2021/08/environmental-protection-agencys.html>

that EPA stay implementation of this rule until it considers and formally responds to additional objections raised below and by other stakeholders.

Harm to Holders of Safe, Otherwise-Legal Foods

We also object to this rule on the grounds that its implementation will likely force the disposal of significant volumes of safe, legal food and feed products. EPA has indicated that detectable food and feed residues of chlorpyrifos after the February 28, 2022 implementation date will be subject to section 408(l)(5) of FFDCFA and FDA's channels of trade guidance. Under these provisions, FDA requires that:

"In order to avoid possible regulatory action against a food containing a residue of a pesticide chemical that is subject to the channels of trade provision, the party responsible for the food must, under section 408(l)(5) of the FFDCFA, demonstrate that the residue is present as a result of a lawful application or use of the pesticide chemical and that the residue does not exceed a level that was authorized at the time of that application or use."¹⁰

While this will not be an immediate issue, this provision is likely to become a significant concern once the rule takes full effect in February 2022. Since many finished food and feed products have extended shelf lives, there are almost certainly already foods in commerce with detectable residues from applications made prior to EPA's revocation rule and before applicators knew special channels of trade application records would be needed. Without these special records, products will likely be unnecessarily found adulterated and subsequently destroyed despite applications being made legally and residues not exceeding legal levels at time of application. This will potentially result in millions of dollars of additional food waste losses and further irreparable harm to agricultural supply chains. These significant food and feed losses do not seem to have been considered by the Agency in its issuance of the rule. We also object to the rule on this basis and, due to these additional economic harms that would occur should the rule take effect, request that EPA stay the rule's implementation until it can fully consider and respond to these objections.

Lack of Clarity on Continued Use, Existing Stocks

We are also greatly concerned with and object to EPA's approach to existing stocks of chlorpyrifos under the rule and in additional clarification guidance.¹¹ The Agency has effectively not taken a position on the matter or how it expects to responsibly wind-down use of the product. As very few growers are using chlorpyrifos this late into the 2021 growing season, millions of gallons remain in storage across the country and are unlikely to be used ahead of the rule's February 2022 implementation date. Most users will be effectively prohibited from using the product even if the registration has not been formally cancelled at that point, placing the financial and logistical burden on users and retailers to determine how to responsibly dispose of product. Without additional clarification from EPA on what to do with these existing stocks, it could inadvertently lead to inappropriate or mass disposal of product which could have significant environmental consequences.

¹⁰ United States Food & Drug Administration. *Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations*. Jeffrey Shuren. Federal Register 70, No. 95. (May 18, 2005): 28544. <https://www.federalregister.gov/documents/2005/05/18/05-9811/guidance-for-industry-on-channels-of-trade-policy-for-commodities-with-residues-of-pesticide>

¹¹ United States Environmental Protection Agency. Last Updated September 20, 2021. *Frequent Questions about the Chlorpyrifos 2021 Final Rule*. Accessed October 8, 2021. <https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule>

Significant Regulatory Action Subject to OIRA Review

We also take objection with EPA's determination that this rule is not an economically significant regulatory action as defined by section 3(f)(1) of Executive Order (E.O.) 12866, subject to review by the Office of Information and Regulatory Analysis (OIRA). By EPA's own analysis, the December 2020 proposed interim decision (PID) suggests this rule is likely to trigger the impacts threshold of an economically significant action. In the benefits section of the PID, EPA attests that the annual economic benefit of chlorpyrifos could be as high as \$130 million.¹² Many of our organizations provided comment to the PID in a letter dated March 6, 2021 demonstrating how we believe this assessment drastically undervalues chlorpyrifos' annual economic benefit, and that the actual value is likely to be much higher. The grower harm scenarios provided above for cherries and sugarbeets alone offer scenarios where harm might occur to individual crop groups in excess of the \$100 million threshold of an economically significant regulatory action, to say nothing of the dozens of other crop producer groups who also will be economically impacted by the loss of chlorpyrifos resulting from this action.

And this is only the impact on growers. As previously discussed, the economic damage from this action is likely to ripple across the agricultural supply chain as food holders may be required to discard millions of dollars in food and feed due to special channels of trade document challenges. It also does not factor in the costly paperwork burdens for stakeholders who may be capable of meeting the arduous channels of trade requirement, nor does it account for millions of gallons of existing stocks that may need to be discarded after the rule takes effect, and so on. When these factors are all considered, there is little doubt the annual impact of this rule will vastly exceed the \$100 million economically significant threshold.

If there continues to be any doubt that this rule is economically significant, the \$100 million threshold is only one factor of several that can trigger this status under section (3)(f)(1). If a rule is also likely to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities,"¹³ it is also considered economically significant. We have provided numerous examples how this rule is likely to adversely affect the entire agricultural economy, jobs, productivity, and our environment. At this point, there should be no doubt to the Agency that this action is in fact economically significant.

As an economically significant action, EPA should have provided OIRA with a copy of this draft regulatory action, required cost and benefit assessments, and other documents enumerated in sections (a)(3)(B) and (C) of E.O. 12866. However, the Agency conducted none of these requirements for this action. While we appreciate the Ninth Circuit Court of Appeals gave EPA a swift deadline for considering its order, E.O. 12866 also provides a mechanism for managing just such a scenario. Section (a)(3)(D) stipulates "for those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review...." We object to this action on the grounds that EPA had an obligation to conduct an OIRA review of this rule – a review which may have resulted in a significantly different regulatory outcome. However, EPA neglected to carry out this essential review function directed by E.O.

¹² United States Environmental Protection Agency. December 3, 2020. *Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100*. (EPA-HQ-OPP-2008-0850-0971). 39. <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971>

¹³ *Executive Order 12866 of September 30, 1993: Regulatory Planning and Review*. Clinton, William J. Federal Register 50, No. 98. (October 4, 1993). https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf, <https://www.epa.gov/laws-regulations/summary-executive-order-12866-regulatory-planning-and-review>.

12866 and as a result our organizations will be subject to significant harm from this rule. EPA should rescind the rule and, should it seek to advance it or another economically significant rule again, do so through appropriate regulatory review processes.

Revocation of Tolerances for High-Benefit FQPA 10X Uses

We also object to EPA's revocation of uses that the Agency describes as high-benefit and which EPA's career scientists and the record for chlorpyrifos indicate would be safe for continued use. In its April 29, 2021 decision which precipitated this rule, the Ninth Circuit ordered EPA to "issue a final regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA 'has determined that there is 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 for which there is reliable information' including for 'infants and children.'"¹⁴

Conveniently, the Agency has ample evidence instructing this matter from its ongoing registration review of chlorpyrifos. In the December 2020 chlorpyrifos PID, EPA identified 11 high-benefit agricultural uses that "the agency has determined will not pose potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X and may be considered for retention."¹⁵ These uses include or are similar to the ones described above where growers or the environment would be significantly harmed if access to chlorpyrifos were lost. The PID is clear that these 11 agricultural uses are protective from aggregate exposure to both food residues and drinking water concentrations. While we do not believe this 10X FQPA safety factor is necessary for the Agency to adopt, as we further discuss in our below objections, these uses clearly satisfy FFDCA standards and the criteria the Court gave to EPA.

Despite that EPA was given the option by the Court to modify chlorpyrifos tolerances, the Agency instead opted to arbitrarily revoke all tolerances in this rule, even those that EPA's own record supported retaining that could ensure the protection of human health. EPA supposes in the rule that it must consider "all currently registered uses" when determining aggregate exposure risks and whether tolerances can be maintained, but this is simply not true. The Court permitted EPA to modify tolerances in response to the ruling and the law clearly permits EPA to modify or revoke individual tolerances (21 U.S.C. 346(b)). We object to this rule in that it unnecessarily revokes tolerances to these 11 high-benefit agricultural uses that EPA's own scientific record establishes are safe, will protect human health from aggregate exposures, satisfies the orders given to EPA by the Court, and would otherwise help to minimize the rule's environmental and economic impact on stakeholders.

Import Tolerance Concerns

It is also concerning, and we take objection that the rule makes no accommodation for retaining import tolerances. Food residues are the only potential domestic exposure source from imports with chlorpyrifos residues, and the Agency has clearly stated those are not of concern. Since the Agency clarifies in the rule that "exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern," and since there are no domestic drinking water or environmental risks that could arise from foreign chlorpyrifos applications, there is no science-based reason for EPA to revoke these tolerances.

¹⁴ *League of United Latin American Citizens, et al. v. Michael S. Regan*, 996 F.3d 673. 67. (9th Cir. 2021).

¹⁵ United States Environmental Protection Agency. *Chlorpyrifos Proposed Interim Decision*. 40.

U.S. producers regularly face prejudice in export markets that impose restrictions on pesticide residues that are not aligned with CODEX standards or are otherwise scientifically unsupported. U.S. trade representatives constantly struggle convincing foreign governments to align their import tolerances with these international standards. However, when EPA takes steps mirroring the unscientific actions of foreign governments, it erodes the ability of U.S. trade negotiators and producers to seek appropriate regulatory treatment abroad. This is yet another reason why the Agency should have sought OIRA review of this rule, to ensure EPA's action would not undermine the mission of other federal agencies. We object to the rule on the basis that it does not permit import tolerances that are important to the U.S. agricultural trade strategy, as these residues pose no domestic dietary or environmental risks.

Uses on Non-Food Crops, Foods Not Resulting in Residues

Similar to our concerns with import tolerances, there are numerous domestic uses that are not intended for food purposes or will not result in food or feed residues, and thus pose little to no risk. Regardless, EPA has indicated it plans to revoke tolerances and will soon move to cancel these uses. We object to this aspect of the rule as well. For example, applications to fruit tree trunks where product is not directly applied to fruit will not result in residues and should not be cancelled. Sugarbeets are not sold as a raw commodity, but are highly refined, resulting in no residues in finished product. This use also should not be cancelled. We appreciate EPA may have concerns with drinking water exposures resulting from these uses, however we would point the Agency to additional comments below on new drinking water data that should be considered which EPA did not use in developing this rule. The Agency should carefully review these uses and not unnecessarily revoke tolerances or cancel uses that truly do not pose a dietary exposure risk and will only result in burdening producers.

Epidemiological, Drinking Water Data Concerns

Finally, as suggested above, we have numerous concerns with the underlying data and methodologies EPA has used to establish a 10X FQPA safety factor and ultimately reach the revocation decision in this rule. We continue to believe EPA's record on chlorpyrifos strongly supports use of a 1X FQPA safety factor. The primary driver of the Agency's decision to use the 10X safety factor is three epidemiological cohorts that supposedly identified links between chlorpyrifos or organophosphates generally and alleged neurodevelopmental effects from a potentially unknown mode of action (MOA) beyond the known acetylcholinesterase (AChE)-inhibition.

We object to EPA's use of this data for establishing the use of a 10X FQPA safety factor for numerous reasons. First, these cohorts – and most notably the Columbia Center for Children's Environmental Health (CCCEH) epidemiologic studies, which was specific to chlorpyrifos – have not to date provided raw study data to EPA, despite numerous requests from the Agency. Without this underlying data, it is impossible for the Agency to determine alleged exposure sources, exposure levels, and actual causes of neurodevelopmental effects. For these limitations and others, EPA's expert FIFRA Scientific Advisory Panel (SAP) on several occasions in recent years has cautioned the Agency against using these three cohorts as the basis for regulatory decisions.¹⁶

The weight the Agency should place on these studies is further diminished by other factors. In the years since these cohorts were released, several other epidemiological studies (which EPA has as part of its

¹⁶ United States Environmental Protection Agency. FIFRA Scientific Advisory Panel. "Meeting on Chlorpyrifos: Biomonitoring Data." (Meeting transcript: Arlington, VA; April 19-21, 2016). 644-646. https://www.epa.gov/sites/default/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf

record) have been released finding no link between organophosphates and alleged neurodevelopmental effects beyond known AChE-inhibition, to say nothing of decades of animal and other tests that also do not support the findings of these three cohorts. The results of these three studies have not been reproducible to date. Moreover, an additional, unknown MOA beyond the commonly-accepted AChE-inhibition that could have potentially caused neurodevelopmental effects to date has never been identified, for chlorpyrifos or any other organophosphate. Finally, even if an unknown MOA does exist, EPA's own career scientists at the Office of Research and Development (ORD) have developed data that indicates the mitigations the Agency has put in place to protect against AChE-inhibition would also be protective against the effects alleged in the epidemiological cohorts regardless of any unknown MOA.

In the rule itself EPA acknowledges that food residues and non-occupational exposures are not a concern, only ultimately raising issues with drinking water exposure risks. We believe these concerns can also be addressed, as in the rule EPA states of its 2020 drinking water assessment (DWA) that it "applied the new methods for considering the entire distribution of community water systems PCA [percent cropped area] adjustment factors, integrated state level PCT [percent crop treated] data, incorporated refined usage and application data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information" relative to its previous 2016 DWA. Using this improved DWA in its 2020 human health risk assessments for the registration review of chlorpyrifos, EPA sought to determine drinking water risks on the subset of 11 critical, high-benefit crop uses (the uses that the PID recommended retaining under the FQPA 10X scenario). The Agency found under the improved 2020 DWA none of the assessed uses exceeded drinking water levels of concern.

Confoundingly, the Agency contends it cannot use the 2020 DWA because it is not comprehensive across all currently registered uses. This is an inappropriate determination. In this rule, EPA has instead opted to revert to its cruder 2016 DWA for all uses, concluding it should throw out every use even when it has better data it could utilize. EPA has the opportunity and obligation to use the best available science where it can and can explore the appropriateness of modeling or extrapolation where there may be gaps. We strongly encourage EPA to reconsider its decision in this rule using the improved, best-available science in the 2020 DWA.

Conclusion

To summarize our concerns, FIFRA is a risk-benefit statute which directs the Agency to identify hazards of a pesticide use, determine the risks caused by that hazard, weigh those risks against the benefits of uses, and assuming they can be mitigated, reasonably mitigate those risks so the benefits of use outweigh the risks. In this instance, EPA has not even identified a hazard. The Agency has three limited, inconclusive studies which suggest a *potential* hazard, to say nothing of possible risks, the findings for which have never been confirmed or reproduced. There is also an abundance of additional human epidemiological and other evidence refuting the existence of this potential hazard. Even if a hazard exists and it presents a risk, EPA's own experts believe that risk can be mitigated using existing controls.

Despite all this, to mitigate the potential risks that may be posed by the alleged hazard, through this rule EPA is opting to eliminate hundreds of millions of dollars in agricultural benefits and inflict tens to hundreds of millions of dollars in additional costs to supply chains and the environment. We are very concerned about the precautionary precedent this rule poses to EPA's pesticide program and object on the grounds that it is fundamentally averse to the processes by which Congress directed the Agency to regulate pesticides, as well as commonly-accepted principles of modern science and risk-based regulation. We urge EPA to rescind this rule based on the above objections and to stay the rule's

implementation to avoid these irreparable harms from taking effect until the Agency can thoroughly review and respond to these concerns.

Sincerely,