



October 15, 2021

By Electronic Mail

U.S. Environmental Protection Agency  
Federal eRulemaking Portal (<http://www.regulations.gov>)  
Office of Administrative Law Judges (OALJ) E-Filing System (<https://www.epa.gov>)

RE: Objections, Request For Stay, Request For Guidance -- EPA-HQ-OPP-2021-0523

To Whom It May Concern:

CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) submit these objections to EPA's August 30, 2021 decision to revoke all chlorpyrifos tolerances under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a.<sup>1</sup> CLA and RISE request a stay of the effective date of this decision to permit time to address the concerns discussed here without harming the interests of our members and other stakeholders. To help provide greater clarity for our members and other interested members of the public, CLA and RISE also request that EPA develop and publish guidance on how it will implement its regulations at 40 CFR 180.32(b) concerning what constitutes "reasonable grounds" for a petition seeking to modify or revoke a tolerance or exemption from tolerance.

CLA is a non-profit trade association representing companies that develop, register, and sell pesticide products in the United States. CLA represents the interests of its member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. CLA's member companies produce most of the crop protection and pest management products regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. Section 136, et seq., and Section 408 of the FFDCA.

RISE is a national trade association representing manufacturers, formulators, distributors, and other industry leaders involved with specialty pesticides and fertilizers used by professionals and consumers. RISE promotes the safe and responsible use of pesticides to control pests and invasive species that are detrimental to our health and our environment.

EPA's decision adversely impacts CLA and RISE members who hold chlorpyrifos registrations by imposing an unnecessarily broad revocation of chlorpyrifos tolerances rather than a more appropriate tailored approach. The revocation also fails to provide sufficient time to adjust practices and lacks the guidance that growers, applicators and others in the supply chain need in order to comply when the tolerance revocations go into effect at the end of February 2022. In addition, EPA is vague on the manner in which its registration review under FIFRA will

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<sup>1</sup> Chlorpyrifos; Tolerance Revocations, Final Rule, 86 Fed. Reg. 48315 (August 30, 2021).



integrate with the tolerance revocation. CLA and RISE request that EPA stay the effective date of its decision to address these issues and others raised in the following seven sections.

**A. EPA Improperly Revoked Tolerances For The Eleven Crops That It Found Met The Safety Standard In Its 2020 Proposed Interim Decision**

EPA relies on the Ninth Circuit decision, *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673 (9th Cir. 2021) (*LULAC*), to justify its decision to revoke all food tolerances for chlorpyrifos without distinguishing among the variety of different food commodities affected by the Agency’s decision. The Ninth Circuit did not mandate that EPA revoke all tolerances. It allowed the Agency to revise tolerances based on existing information. The Court provided EPA with options, stating that:

such a final regulation could take one of two forms: either it could [1] revoke all chlorpyrifos tolerances or [2] it could modify chlorpyrifos tolerances *and* conclude that under the new tolerances there is a “reasonable certainty that no harm will result” due to “aggregate exposure to the pesticide chemical residue” that would result from such modified tolerances, including “to infants and children.”<sup>2</sup>

The Ninth Circuit made clear that EPA could “modify chlorpyrifos tolerances, rather than [] revoke them,” provided the decision included the required safety determination.<sup>3</sup>

EPA’s record contains sufficient information to determine that at least some tolerances and uses satisfy the safety standard and should not be revoked. For example, EPA’s December 2020 Proposed Interim Registration Review Decision (PID) identified eleven crops that met the safety standard and did not pose a risk from food residues or drinking water concentrations.<sup>4</sup> Chlorpyrifos tolerances apply to over eighty distinct food commodities and range from 0.01 parts per million (ppm) for apples to as high as 20 ppm for citrus oil. Each needs to be evaluated on its own merits.<sup>5</sup>

In the PID, EPA identified eleven commodities that could retain high-benefit agricultural uses in select regions, considering dietary exposure and impacts of drinking water on infants, children, and women of reproductive age. EPA made carefully considered and well researched findings to determine that these commodities would not pose potential risks of concern using the default 10X Food Quality Protection Act (FQPA) safety factor.<sup>6</sup>

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<sup>2</sup> *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 702 (9th Cir. 2021).

<sup>3</sup> *Id.*

<sup>4</sup> U.S. Environmental Protection Agency. December 3, 2020. Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100, EPA-HQ-OPP-2008-0850-097 (PID) at 40.

<sup>5</sup> See 40 C.F.R. § 180.342(a).

<sup>6</sup> PID at 19, 40.



EPA's revocation decision is internally inconsistent; it acknowledges the PID's safety finding with respect to these uses but nonetheless revokes them.<sup>7</sup> EPA did not revisit or reassess the PID safety finding for the eleven uses. Instead, the Agency suggests that it is bound to assess the aggregate exposure from all "currently registered" uses.<sup>8</sup> Nothing in the Ninth Circuit decision or the regulatory process requires that result. EPA can reconfirm its safety finding for these uses, can modify the tolerances if needed, and can undertake appropriate actions under FIFRA to allow registrations and labels to continue for certain food uses that meet the safety standard (as is planned for non-food uses).

EPA's chosen approach creates a procedural dilemma. Having delayed its decision regarding which chlorpyrifos registrations should be cancelled, EPA asserts it must consider aggregate exposure to *all* registered uses and must now revoke all tolerances. Moreover, when the Agency does address cancellation, there will be no basis to retain registrations as the corresponding tolerances have been cancelled. This approach to revoking all tolerances lacks scientific and legal justification. Instead, the Agency should either confirm or reassess its determination whether a subset of "highly beneficial" uses and tolerances satisfy the safety standard. At a minimum, EPA should differentiate the eleven crops that it concluded met the safety standard in the PID, finalize a safety determination for those crops and retain their tolerances, and take appropriate action under FIFRA to allow these limited uses to continue.

#### **B. EPA Should Revise Its Rule And Retain Import Tolerances As Needed For Commodities That Do Not Pose A Dietary Risk**

EPA's rule broadly revokes all tolerances for domestic and imported commodities, without distinguishing exposures from imported versus domestic commodities and without considering whether import tolerances are appropriate for certain commodities. Retaining certain chlorpyrifos tolerances as import tolerances is supported by EPA's guidance, by legal precedent, and by EPA's risk determinations in the August 2021 decision. The Agency should provide a process for the request, consideration, and approval of chlorpyrifos import tolerances.

EPA's guidance states that "as domestic uses are canceled during the pesticide reregistration process, or for any other reason (other than dietary risk), EPA will consider requests for modifying or maintaining the corresponding tolerance to allow the continued import of treated food into the U.S." provided EPA can make the required "safety finding."<sup>9</sup> The guidance explains that:

Registered pesticide uses may be canceled for a variety of reasons including internal business reasons, dietary risk concerns, or non-dietary risk concerns. In many cases, a tolerance is no longer needed after a registered use in this country is canceled, and EPA routinely proposes to revoke such tolerances. However, use in other countries may

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<sup>7</sup> 86 Fed. Reg. at 48333.

<sup>8</sup> *Id.*

<sup>9</sup> Pesticides; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food; Request for Comment, 65 FR 35069, 35072 (June 1, 2000).



continue and, unless a use was canceled due to dietary risk concerns, EPA will consider requests (normally by petition) to modify or maintain a tolerance as an “import tolerance.” EPA plans to use a variety of means to provide an opportunity for interested parties to support the modification or maintenance of a tolerance in these circumstances.<sup>10</sup>

EPA may allow for an import tolerance “provided that there is a need for the tolerance because the pesticide is used outside of the United States on commodities intended for the United States market and a proponent of the tolerance supplies sufficient data or information to demonstrate that a tolerance meets the food safety requirements of FFDCA.”<sup>11</sup>

In this case, EPA is proceeding with tolerance revocation before cancellation of any registered pesticide uses. However, EPA should nonetheless provide an opportunity to consider and approve requests for chlorpyrifos import tolerances where the data and risk assessments confirm that such tolerances would meet the safety standard. The D.C. Circuit Court of Appeals reversed a previous EPA decision to revoke all import tolerances along with all other tolerances for the product carbofuran, where the Agency agreed that exposure to carbofuran from imported foods alone met the safety standard.<sup>12</sup>

EPA’s risk findings in the August 2021 rule support the retention of import tolerances. EPA characterized the risks from aggregate exposures from dietary (food) exposure; non-occupational, non-dietary (residential) exposures; and drinking water. In the August 2021 decision, EPA found that “exposures from food and non-occupational exposures individually or together do not exceed EPA’s levels of concern.”<sup>13</sup> However, EPA found that, unless chlorpyrifos uses were limited to certain uses as discussed above, the calculated additional exposures from drinking water exceeded levels of concern.<sup>14</sup>

These findings indicate that potential exposures from imported commodities would not exceed levels of concern. Imported commodities have exposure profiles that differ from those of domestic commodities. Among other factors, drinking water exposure assessments consider the application of the pesticide product for certain uses and in certain geographic areas. In the August 2021 rule, EPA acknowledged not only that drinking water exposure depends on the scope of permitted use within the United States, but also that limiting the domestic food use of chlorpyrifos to the eleven uses discussed above would result in lower drinking water exposures and in aggregate exposure levels that do not exceed levels of concern.<sup>15</sup> If EPA’s decision to eliminate *all* domestic food uses remains in place, that would further reduce drinking water

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Nat'l Corn Growers Ass'n v. E.P.A.*, 613 F.3d 266, 275 (D.C. Cir. 2010); *see also* 40 CFR 180.254 (identifying retained import tolerances for carbofuran on certain commodities).

<sup>13</sup> *Id.* at 48332-33.

<sup>14</sup> *Id.* at 48333.

<sup>15</sup> *Id.*



exposures below levels of concern. In either case, allowing tolerances for imported commodities where needed should not create exposures above levels of concern.

### **C. EPA Should Provide A Clearer And More Practical Approach For Existing Stocks Of Chlorpyrifos Products Affected By The Tolerance Revocations**

EPA's decision revokes tolerances for residues of chlorpyrifos on food and food commodities, but it need not and should not be implemented in a way that unduly burdens non-food uses, such as use on golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products. FIFRA explicitly recognizes the importance of EPA addressing the disposition of existing stocks of pesticides when registrations are canceled (FIFRA Sections 6 and 19) and to that end EPA developed a policy in 1991 providing a framework to determine existing stocks provisions on a case-by-case basis (56 Fed. Reg. 29362). Yet EPA's August 2021 decision does not address cancellation or the issue of existing stocks, and in particular it does not provide a clear path forward for products labeled for both food and non-food uses after the tolerances are revoked.

Requirements for existing stocks are normally addressed in connection with a cancellation order, but the Agency has provided no timetable for acting on cancellation or issuing such an order, and that appears unlikely to occur before the tolerances are revoked. This creates confusion for registrants, distributors, applicants and the public regarding the appropriate uses of chlorpyrifos.

EPA's recently posted frequently asked questions guidance on this issue is ambiguous and unworkable. The guidance states that the tolerance rule "does not prohibit sale and distribution of registered pesticide products," but also that "sale and distribution of chlorpyrifos products labeled for use on food products would be considered misbranded" and a "violation of FIFRA once the tolerances are revoked"<sup>16</sup> In other words, according to EPA, the rule *does* effectively prohibit sale of registered products whose labels include food uses. The legal basis for this position is unclear. Courts have rejected other efforts by EPA to prohibit sale of a registered product by declaring it "misbranded."<sup>17</sup>

The guidance also acknowledges that there are labels and registrations that contain both food and non-food uses, and suggests that "[f]ollowing cancellation," such labels "will need to be amended to remove any food-uses that were cancelled." However, cancellation is unlikely to occur before the tolerances are revoked and future cancellation would not render an existing registered product "misbranded." Thus, the legal status of these products after the tolerances are revoked will remain unclear.

CLA and RISE request that the Agency revisit its approach and provide a clearer and more practical path forward for existing stocks that encourages compliance with the tolerance

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<sup>16</sup> Frequent Questions about the Chlorpyrifos 2021 Final Rule, available at <https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-10>.

<sup>17</sup> *Reckitt Benckiser Inc. v. E.P.A.*, 613 F.3d 1131 (D.C. Cir. 2010); *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 43 (D.D.C. 2011).



revocations while avoiding unnecessary marketplace confusion, needless legal jeopardy, wasted product and product disposal issues, excessive relabeling costs, and delays. The Agency could consider practical approaches short of full relabeling, such as stickers and point of sale notices, to allow existing stocks of registered products that are labelled for food and non-food uses to continue to be sold for uses that are unaffected by the tolerance revocation.

#### **D. EPA’s Decision Does Not Properly Respond To Comments And Fails To Provide Adequate Due Process**

The implementation challenges above highlight the lack of public involvement in this decision. EPA’s issuance of a final rule revoking all chlorpyrifos tolerances without providing a further opportunity for notice and comment, and without responding to prior comments, raises substantial due process concerns. The fact that the Ninth Circuit required “immediate issuance of a final regulation” “without further notice and without further period for public comment” limited the Agency’s options, but does not eliminate its due process obligations. If anything, this unusual posture calls for heightened attention and a more robust process going forward. Given the six-month window before the rule is slated to go into effect, the Agency must act promptly to respond to these objections and to other objections it receives and to revise the final rule as warranted.

Particularly troubling is the fact that EPA revoked all chlorpyrifos tolerances without responding to comments from the public on prior proposals that bear directly on whether tolerances should be retained or revoked in the final rule. Although EPA requested comments on its November 2015 proposed rule to revoke tolerances, the Agency never responded to the over 90,000 comments it received and explicitly declined to do so in this rule.<sup>18</sup>

To provide adequate due process, publishing a decision for notice and comment is insufficient. EPA must also respond to those comments. Without an Agency response, EPA denies the public a meaningful opportunity for involvement in the rulemaking. The claim that EPA need not respond to comments on a proposed rule to revoke tolerances in issuing a final rule revoking the tolerances renders the comment process irrelevant. EPA likewise contends that relevant comments received as part of the registration review process are “separate and apart from the procedural process of this final rule action.”<sup>19</sup> The Agency’s assertion that *all* such comments will be addressed as part of the “ongoing registration review process” is not adequate assurance as the Agency has already stated its intent to cancel registrations for uses corresponding to the revoked tolerances. EPA’s failure to respond to comments is inconsistent with the obligations of due process and transparency.

EPA’s lack of commitment to due process in this regulatory action is also evident in its statements regarding the process for handling objections to the August 2021 rule. The rule cautions that “EPA will not consider any legal or factual issues presented in objections, if that issue could reasonably have been raised earlier in the Agency’s review of chlorpyrifos relative to

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<sup>18</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0001>

<sup>19</sup> 86 Fed. Reg. at 48334.



this petition.”<sup>20</sup> However, without notice of the final rule, there was no opportunity for comments and objections targeted to the actual approach EPA has taken. There was also no notice to stakeholders of the proper forum among the many ongoing proceedings (petition to cancel, registration review, legal actions) in which objections must be lodged. Furthermore, EPA provides no timeline for responding to objections and has not committed to doing so before the tolerance revocations go into effect. The August 2021 rule states only that “objections of a purely policy or legal nature will be resolved in the Agency’s final order,” although the August 2021 rule itself purports to be final.

EPA should commit to responding fully to objections before the tolerance revocations go into effect, should extend the effective date if necessary to do so, and should make all warranted revisions and adjustments to the final rule in response to comments and objections before the tolerance revocations go into effect.

#### **E. EPA Has Not Identified How It Plans To Harmonize The Tolerance Revocations With FIFRA**

The FFDCA requires harmonization with FIFRA and EPA must coordinate tolerance revocations with FIFRA requirements.<sup>21</sup> EPA’s decision to revoke chlorpyrifos tolerances provides no explanation as to how and when EPA plans to complete this harmonization. As the tolerance revocation is effective at the end of February 2022 and EPA is not expecting to complete registration review by the time the tolerance revocations are effective, growers and others affected by this decision need guidance on how to proceed during the interim period. Among many issues, EPA’s failure to harmonize its tolerance and registration actions exacerbates confusion regarding label requirements and the status of existing stocks.

EPA should promptly provide information on how it plans to harmonize its tolerance rule with FIFRA registration decisions. CLA and RISE will comment further as needed once EPA announces its approach to FIFRA registrations related to this tolerance rule.

#### **F. EPA’s Decision Is Overly Conservative**

The challenges outlined above all arise from an overly conservative decision. EPA’s approach here is unnecessary given the available science, and appears to ignore the risk assessment undertaken by EPA’s own career scientists. The broad approach taken by the Agency is detrimental to the regulatory process and the public. Instead of basing its decision on the available science, EPA has taken an overly cautious approach and revoked all chlorpyrifos tolerances based on “uncertainty” raised by epidemiology data EPA was unable to fully evaluate. The Agency’s decision sends a disturbing message to other regulators around the world. EPA and the United States have long held a critical leadership role among countries implementing and defending evidence-based and risk-based regulation. The Agency should not allow this decision

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<sup>20</sup> *Id.* at 48316.

<sup>21</sup> *See* Section 408(l) of the FFDCA, 21 U.S.C. Section 346a(l).



to be seen as a step away from its long-standing defense of these pillars of scientific integrity and sound regulation.

**G. EPA Guidance On “Reasonable Grounds” Is Needed**

The Agency should take concrete steps to avoid further confusion over the standards that apply to EPA’s disposition of tolerance revocation petitions. The *LULAC* decision relied on EPA’s regulation at 40 CFR 180.32(b), which requires petitions to modify or revoke a tolerance or tolerance exemption to provide “reasonable grounds.” The Court confirmed that “[u]nder its regulations EPA may deny a petition when it finds that a petition is not supported by ‘reasonable grounds’ for revocation.”

For greater clarity, consistency and predictability, we respectfully request that EPA develop and publish guidance on what constitutes “reasonable grounds” under 40 CFR 180.32(b). The Agency has repeatedly expressed its commitment to scientific integrity and improved outreach to the public.<sup>22</sup> Clear guidance regarding how EPA will consider such petitions will help ensure that they are used for their intended purpose – to bring to the Agency’s awareness legitimate food safety concerns that may not be otherwise addressed through the pesticide regulatory process. Such guidance can assist the Agency in addressing future petitions in a timely and appropriate manner, applying rigorous scientific standards to them, and communicating outcomes to the public and the regulated community in a way that strengthens public confidence in the regulatory process.

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Thank you for your consideration of, and responses to, these objections, our request for a stay, and our request that EPA develop and publish guidance on how it will implement its regulation at 40 CFR 180.32(b) concerning what constitutes “reasonable grounds” for petitions seeking to modify or revoke tolerances or exemptions from tolerance.

Sincerely,

Chris Novak  
President and Chief Executive Officer  
CropLife America

Megan Provost  
President  
RISE

<sup>22</sup> See, e.g., *Draft FY 2022-2026 EPA Strategic Plan*, 86 Fed. Reg. 74448 (Oct. 1, 2021).