

EPA Issues Final Order Denying Objections to EPA's March 2017 Order Denying PANNA's and NRDC's 2007 Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos

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On July 18, 2019, the U.S. Environmental Protection Agency (EPA) issued a [pre-publication](#) version of a Federal Register notice announcing a final order denying the Pesticide Action Network North America's (PANNA) and the Natural Resources Defense Council's (NRDC) 2007 Petition requesting that EPA revoke all tolerances and cancel all registrations for chlorpyrifos (Order). This Order constitutes final Agency action denying all of the Petitioners' objections to EPA's previous refusal to revoke the tolerances for chlorpyrifos. This Order also constitutes final administrative action concerning all parts of the 2007 Petition that were not previously addressed by EPA. Given the previous extensive chlorpyrifos litigation, this latest action by EPA will likely lead to further litigation challenging EPA's decision to allow continued use of chlorpyrifos under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

Background

The FIFRA registrations and related tolerances for chlorpyrifos have a complicated regulatory and legal history, as discussed in previous blogs available [here](#).

EPA's new Order denies objections made by PANNA and NRDC under the FFDCA to EPA's March 29, 2017, order denying the request by PANNA and NRDC that EPA revoke all tolerances for chlorpyrifos and cancel all chlorpyrifos product registrations. In the Order, EPA begins by summarizing its prior responses to the 2007 Petition, in which EPA denied each of ten claims raised in support of the Petitioners' request that EPA revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations. The ten claims are:

1. EPA has ignored genetic evidence of vulnerable populations.

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2. EPA has delayed a decision regarding endocrine disrupting effects.
 3. EPA has ignored data regarding cancer risks.
 4. EPA's 2006 cumulative risk assessment (CRA) for the organophosphates misrepresented risks and failed to apply the Food Quality Protection Act (FQPA) 10X safety factor.
 5. EPA over-relied on registrant data.
 6. EPA has failed to address properly the exporting hazard in foreign countries from chlorpyrifos.
 7. EPA has failed to incorporate quantitatively data demonstrating long-lasting effects from early life exposure to chlorpyrifos in children.
 8. EPA has disregarded data demonstrating that there is no evidence of a safe level of exposure during pre-birth and early life stages.
 9. EPA has failed to cite or incorporate quantitatively studies and clinical reports suggesting potential adverse effects below 10 percent cholinesterase inhibition.
 10. EPA has failed to incorporate inhalation routes of exposure.

EPA's Order next focuses on the June 2017 objections to the March 29, 2017, Denial Order that were filed by several public interest groups and states. The three main objections, and EPA's response, are as follows:

- **Claims Regarding the Legal Standard for Reviewing Petitions to Revoke:** Objectors assert that EPA's Denial Order applied the wrong legal standard. Objectors assert that neither "scientific uncertainty" nor the **October 2022** deadline for registration review under FIFRA Section 3(g), nor the widespread agricultural use of chlorpyrifos, provide a basis for denying petitions to revoke. Objectors claim that EPA has unlawfully left chlorpyrifos tolerances in place without making the safety finding required by the FFDCA.
- **EPA Response:** In its Order, EPA denies the objections related to Petitioners' claims regarding neurodevelopmental toxicity, stating that the objections and the underlying Petition are not supported by valid, complete, and reliable evidence sufficient to meet the Petitioners' burden under the FFDCA, as set forth in EPA's implementing regulations. Specifically, EPA states that Objectors have not met their regulatory burden to provide "reasonable grounds" for revocation, including an assertion of facts to justify the modification or revocation of the tolerance (40 C.F.R. § 180.32(b)) or the initial evidentiary burden for persons seeking revocation to come forward with sufficient evidence to show that pesticide tolerances to be modified or revoked are not safe. After summarizing its review of available epidemiologic data, including feedback from the 2012 and 2016 FIFRA Scientific Advisory Panel (SAP) meetings, EPA states that "the epidemiologic studies are central to the Petitioner's claims regarding neurodevelopmental effects, yet the Petitioners and Objectors rely only on summaries in publications to present their case. Petitioners have not presented the raw data from the epidemiology studies for consideration of their claims." EPA "concludes that the information yet presented by Petitioners is not sufficiently valid, complete, and reliable to

support abandoning the use of AChE inhibition as the critical effect for regulatory purposes under the FFDCA section 408” and also that Petitioners have “failed to meet their initial burden of providing sufficiently valid, complete, and reliable evidence that neurodevelopmental effects may be occurring at levels below EPA’s current regulatory standard and no information submitted with the objections addresses this shortcoming of the Petition.”

- **Objections Asserting that EPA Has Found Chlorpyrifos to Be Unsafe:** Objectors assert that EPA has previously found that chlorpyrifos tolerances are unsafe and has not disavowed those findings. Specifically, they claim that EPA has found that chlorpyrifos results in unsafe drinking water exposures and results in adverse neurodevelopmental effects to children and that EPA must therefore revoke the tolerances.
- *EPA Response:* EPA denies making any regulatory findings that chlorpyrifos tolerances are not safe, stating that its statements in its 2015 proposed tolerance revocation was not a final action. EPA states: “Proposed rules are just that -- proposals; they do not bind federal agencies. Indeed, EPA made clear it was issuing the proposal because of the court order, without having resolved many of the issues critical to EPA’s FFDCA determination and without having fully considered comments previously submitted to the Agency.” Regarding those objections related to drinking water, EPA states that since the Petition did not identify drinking water exposure as a basis for seeking tolerance revocation, the Objectors cannot now raise that concern as a basis for challenging EPA’s denial of the Petition. EPA also states: “The mere fact that EPA is considering the potential impact of chlorpyrifos exposures in drinking water in the Agency’s FIFRA section 3(g) registration review does not somehow provide Petitioners and Objectors with a vehicle for introducing that topic in the objections process on the Petition denial.” EPA instead will continue its FIFRA Section 3(g) registration review and complete its evaluation of drinking water exposures to chlorpyrifos, and address these issues in its upcoming registration review decision.
- **Objections Asserting that the Denial Order Failed to Respond to Significant Concerns Raised in Comments:** Objectors argue that EPA’s Denial Order committed a procedural error by failing to address significant concerns raised in the comments on EPA’s 2014 risk assessment and 2015 proposed revocation that EPA’s assessment fails to protect children. In particular, the Objectors focus on concerns raised in comments asserting that (1) EPA’s use of 10 percent cholinesterase as a regulatory standard is not protective for effects to children’s developing brains; (2) EPA has not properly accounted for effects from inhalation of chlorpyrifos from spray drift and volatilization; and (3) EPA inappropriately used the Corteva physiologically based pharmacokinetic (PBPK) model to reduce inter- and intra-species safety factors because the model is ethically and scientifically deficient.
- *EPA Response:* EPA denies the objections claiming procedural error, stating it “has no obligation to respond to rulemaking comments in denying the Petition or responding to objections, both of which are adjudicatory actions that are not part of the rulemaking process. EPA also restated its prior response to the Petition that the “objections fail to meet burden of presenting evidence sufficiently valid, complete and reliable to demonstrate that chlorpyrifos results in neurodevelopmental effects that render its tolerances not safe.” EPA further

“believes it is lawful and appropriate for it to consider federally enforceable chlorpyrifos product labeling restrictions in assessing the extent of bystander risk from spray drift under both the FFDCA and FIFRA.”

Commentary

This latest EPA assessment appears to be more finely crafted than the earlier March 2017 response to the tolerance revocation Petition. EPA explains that it does not consider the epidemiology studies cited by the Petitioners to be persuasive sufficiently to change EPA’s fundamental approach to assessing chlorpyrifos risks. EPA notes that its current risk assessment utilizes the default 10X safety factor for infants and children specified by the FQPA, so any argument that it has not utilized this safety factor is moot. At the same time, EPA maintains that the epidemiology studies do not justify changing EPA’s point of departure for risk assessment, which remains the threshold for 10 percent acetylcholinesterase (AChE) inhibition. EPA states that there are significant problems with using the epidemiology studies for risk assessment, including lack of access to the underlying data, the absence of any known mechanism for neurodevelopmental effects below the threshold for AChE inhibition, and a lack of scientific consensus on a method for choosing an alternate point of departure based on the epidemiology studies. This interpretation of the epidemiology studies for chlorpyrifos will remain controversial and these studies will continue to be cited by those who seek to eliminate chlorpyrifos use.

EPA has also taken a position that the burden is on the Petitioners to support a petition to revoke tolerances with reliable data. What is less clear is “how much” evidence EPA considers sufficient to meet the threshold for tolerance revocation. Meanwhile, EPA will defer its assessment of possible neurodevelopmental effects of chlorpyrifos below the threshold for AChE inhibition pending completion of the registration review for chlorpyrifos. The deadline for EPA to complete registration review is **October 1, 2022**, although EPA states that it intends to expedite this process and to issue a proposed registration review decision by **October 2020**.

EPA also has included in its decision an intriguing discussion of some new animal studies for chlorpyrifos that purport to show low-level neurodevelopmental effects from chlorpyrifos. The California Department of Pesticide Regulation relied substantially on these new studies when it designated chlorpyrifos as a Toxic Air Contaminant. If these new chlorpyrifos studies are deemed credible, they could supplant efforts to use the chlorpyrifos epidemiology data in risk assessments and allow EPA to establish a new point of departure for chlorpyrifos that is not based on AChE inhibition. Rather than disregarding these new data, which were not submitted in support of the tolerance revocation Petition, EPA says affirmatively that it intends to review them in the pending registration review.

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