

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR**

**IN RE FIFRA SECTION 6(b) NOTICE)
OF INTENT TO CANCEL PESTICIDE)
REGISTRATIONS FOR CHLORPYRIFOS) DOCKET NO. EPA-HQ-OPP-2022-0417
_____)**

**GHARDA CHEMICALS INTERNATIONAL, INC.’S REQUEST FOR HEARING AND
STATEMENT OF OBJECTIONS AND REQUEST FOR STAY**

Gharda Chemicals International, Inc. (“Gharda”) hereby requests a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, “FIFRA”) to contest the proposed cancellation of the following of its pesticide product registrations:

- EPA Reg. No. 93182-3 Chlorpyrifos Technical¹
- EPA Reg. No. 93182-7 Pilot 4E Chlorpyrifos Agricultural Insecticide²
- EPA Reg. No. 93182-8 Pilot 15G³

These three registrations are referred to herein as the “chlorpyrifos registrations.” A Notice of Intent to Cancel was issued by the U.S. Environmental Protection Agency (“EPA” or “the Agency”) and published in the Federal Register on December 14, 2022. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022), Ex. 1. Copies of the approved labels for the chlorpyrifos registrations, and Gharda’s most recent proposed amendments to the labels (**submitted January 13, 2023**) for the chlorpyrifos registrations, are attached here. *See* Exs. 2 & 3.

¹ Product information on EPA Reg. No. 93182-3 can be found [here](#).

² Product information on EPA Reg. No. 93182-7 can be found [here](#).

³ Product information on EPA Reg. No. 93182-8 can be found [here](#).

In the NOIC, EPA is proposing to cancel the registrations of Gharda's chlorpyrifos products noted above. EPA alleges that the chlorpyrifos registrations should be cancelled because the Agency had revoked tolerances for all food uses of chlorpyrifos by way of a Final Rule dated August 30, 2021.⁴ In the NOIC, EPA also challenges the sufficiency of voluntary cancellations and label amendments Gharda submitted in March 2022 and June 2022, which brought its chlorpyrifos registrations and labels in line with the Final Rule as to all but a subset of uses that are the subject of ongoing litigation. Gharda and other affected parties urged EPA to immediately stay or withdraw the NOIC in correspondence dated January 6, 2023, but EPA denied this request.

The NOIC states that "the affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before January 13, 2023, whichever occurs later." 87 Fed. Reg. at 76,474, Ex. 1. Gharda notes that the address for Gharda identified in the NOIC is incorrect⁵ and states that Gharda has not received a copy of the NOIC from EPA. **Accordingly, Gharda submits that the 30-day time period for requesting a hearing on the NOIC has not yet begun to run and respectfully requests that EPA cure its defective notice promptly.**

While Gharda reserves all rights as to the ripeness of any further proceedings on the NOIC until it receives proper notice, Gharda hereby objects to the cancellation of the

⁴ See Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule"), Ex. 4.

⁵ Compare 87 Fed. Reg. at 76,474, Ex. 1 (identifying Gharda's address of record as 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238) with https://www3.epa.gov/pesticides/chem_search/ppls/033658-00026-20121220.pdf (Gharda submission of amended labeling to EPA identifying Gharda address as 4032 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238).

chlorpyrifos registrations and provides this notice of its objections and request for a hearing under 40 C.F.R. section 164.20(b) and request for a stay of the NOIC.

INTRODUCTION

This matter concerns the insecticide chlorpyrifos, a crop protection tool growers have relied upon for decades. After working with registrants in 2019 to identify key U.S. crop uses for chlorpyrifos, EPA used up-to-date science to determine that the tolerances for a subset of uses, on eleven crops in select geographic regions, meet the aggregate exposure safety standard in the Federal Food, Drug, and Cosmetic Act (“FFDCA”) (the “Safe Uses”). Despite that finding, which EPA announced in its Proposed Interim Decision (“PID”)⁶ in 2020 and reaffirmed in the Final Rule and several times since, EPA elected to revoke *all* food tolerances, including those the Agency found safe, at the expense of farmers across the country. EPA’s Final Rule disregarded Gharda’s written commitment *before* the Final Rule to modify its registration and product labels consistent with the Agency’s safety finding as to the Safe Uses. Indeed, Gharda was standing by before the Final Rule to submit amended labels to EPA narrowing uses to the Safe Uses, at EPA’s instruction, when EPA abruptly ceased discussions with Gharda. Gharda and others submitted objections to and requested a stay of the Final Rule (incorporated by reference here), which EPA denied.⁷

Nineteen grower groups (representing thousands of farmers around the country who rely on chlorpyrifos) and the sole remaining technical registrant of chlorpyrifos (Gharda) (collectively “Petitioners”) challenged the Final Rule as to the Safe Uses because it is arbitrary

⁶ Chlorpyrifos Proposed Interim Registration Review Decision, EPA-HQ-OPP-2008-0850 (Dec. 3, 2020) <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0971>, Ex. 5.

⁷ Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022), Ex. 6.

and capricious and contrary to the FFDCA in the lawsuit known as *Red River Valley Sugarbeet Growers Ass'n, et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir.) (the “lawsuit”). In the lawsuit, Petitioners seek vacatur of the Final Rule as to the Safe Uses. The lawsuit has been fully briefed, and oral argument took place on December 15, 2022. The parties’ principal briefs in the lawsuit are incorporated by reference here.⁸

As set forth below, the extreme and unprecedented action EPA has taken in issuing the NOIC is objectionable on numerous grounds. The NOIC is based on the Final Rule, which is arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses for all of the reasons set forth in Gharda’s objections to the Final Rule and briefing to the Eighth Circuit; the NOIC is accordingly itself arbitrary and capricious, even more so based on the current record before the Agency, in which there can be no doubt that EPA has all available tools and information at its disposal showing that the chlorpyrifos registrations are consistent with the Agency’s safety finding. EPA also improperly attempts to narrow the scope of the NOIC by contending that the propriety of EPA’s Final Rule—the sole basis for the NOIC—cannot be a topic for the NOIC. What is more, EPA’s NOIC blatantly disregards important FIFRA-mandated cancellation rights and processes. Indeed, EPA’s NOIC fails to comply with requirements established by FIFRA regarding consideration of alternatives to registration cancellation and input from the U.S. Department of Agriculture (“USDA”). Further, EPA ignores Gharda’s due process and property rights by, *inter alia*, failing to follow processes mandated by FIFRA for registration cancellation and failing to appropriately consider Gharda’s

⁸ Pet’rs’ Opening Br. (“Pet’rs Br.”), *Red River Valley Sugarbeet Growers Ass’n, et al. v. Regan, et al.*, Nos. 22-1422, 22-1530 (8th Cir. May 24, 2022), ID No. 5160660; Resp’t Br., *Red River Valley Sugarbeet Growers Ass’n*, Nos. 22-1422, 22-1530 (8th Cir. July 26, 2022), ID No. 5180922; Pet’rs’ Reply Br. (“Pet’rs Reply Br.”), *Red River Valley Sugarbeet Growers Ass’n*, Nos. 22-1422, 22-1530 (8th Cir. Sept. 6, 2022), ID No. 5195044, Ex. 7.

efforts to make its registrations and product labels align with EPA's Final Rule. Finally, EPA in large part ignores the lawsuit, which could be decided any day and could make the NOIC moot. EPA waited 15 months after the Final Rule—until the day before oral argument in the lawsuit—to publish the NOIC. Based on EPA's own conduct, there is no urgent need or other basis for EPA to proceed with the NOIC before the Eight Circuit's decision. Accordingly, Gharda respectfully submits that the Administrative Law Judge should dismiss the NOIC. At a minimum, the NOIC should be delayed until after the Eighth Circuit's decision.

GHARDA'S OBJECTIONS

OBJECTION 1: The NOIC is improperly based on the Final Rule, which incorrectly revoked tolerances for the Safe Uses. Contrary to EPA's contention in the NOIC (87 Fed. Reg. at 76,476, Ex. 1), comments and arguments challenging EPA's actions in the Final Rule are very relevant to the NOIC and scope of the NOIC.

- The primary basis for the NOIC is that in its Final Rule, EPA revoked all food tolerances for chlorpyrifos and, therefore, uses set forth in Gharda's registrations for food uses cannot stand and must be cancelled. Similarly, the NOIC contends that Gharda's product registrations and amended labels are not consistent with the Final Rule because they include the Safe Uses.
- For all the reasons set forth in Gharda's objections to the Final Rule and the Petitioners' briefing in the lawsuit (incorporated by reference here), the Final Rule was arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses. *See* Pet'rs Br. at 23–26, 42–54 (ID No. 5160660); Pet'rs Reply Br. at 14-22 (ID No. 5195044), Ex. 7; Gharda Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos (“Gharda Objs.”), EPA-HQ-OPP-2021-0523, at 9-11, 31-34 (Oct. 22, 2021), <https://www.regulations.gov/comment/EPA-HQ-OPP-2021-0523-0028>, Ex. 8. In the absence of a proper basis for revocation of tolerances for the Safe Uses, there is no basis for the NOIC, which seeks to cancel registered uses for the Safe Uses.
- The validity of the Final Rule as to the Safe Uses is currently under consideration by the Eighth Circuit. Oral arguments in the lawsuit occurred on December 15, 2022, and a decision is expected in the near future.
- If the Eighth Circuit vacates/remands the Final Rule as to the tolerances for the Safe Uses, the NOIC's purported basis for the cancellation action becomes moot.

OBJECTION 2: Action on the NOIC should be delayed until after the Eighth Circuit decides

Petitioners' challenge to the Final Rule.

- Taking action on the NOIC is contrary to the exercise of jurisdiction by the Eighth Circuit regarding the tolerances for the Safe Uses. *See* Pet'rs Br. at 1-5 (ID No. 5160660), Ex. 7.
- If registration cancellation occurs and the Eighth Circuit subsequently rules in Petitioners' favor by either vacating or remanding the Final Rule as to the Safe Uses, EPA would likely argue that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition process. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. EPA should not be allowed, through the NOIC process, to evade a potential Eighth Circuit invalidation of the Final Rule, especially when the lawsuit has been fully briefed and argued, and the Eighth Circuit's decision is forthcoming at any time.
- In addition, (1) challenging registration cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives prior to a decision by the Eighth Circuit would be overly burdensome and unfair and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit.
- In short, it would be improper and prejudicial to use the NOIC to circumvent judicial review and to force Gharda to pursue costly and time-consuming alternatives in parallel to the pending court proceeding. These inappropriate outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit's decision.

OBJECTION 3: The NOIC erroneously signals an urgent need for registration

cancellation. To the contrary, there is no urgency for the NOIC to address because there are currently no chlorpyrifos products used on food in the stream of commerce, as EPA knows, and therefore no reason that the NOIC cannot be delayed until after the Eighth Circuit's decision.

- The NOIC makes statements implying that chlorpyrifos is currently being sold, distributed and/or used for food uses. *See, e.g.,* 87 Fed. Reg. at 76,477 ("It is a violation of FIFRA to sell and distribute pesticides that are misbranded...because the aforementioned [chlorpyrifos] products would result in pesticide residues in or on

food...continued sale and distribution [of chlorpyrifos products] would not comply with the provisions of FIFRA.”), Ex. 1. This is misleading.

- In correspondence dated March 1, 2022, EPA asked Gharda to voluntarily cancel its food use registrations for chlorpyrifos. Gharda responded on March 30, 2022. *See Ex. 9.* Gharda’s response: (1) requested the voluntary cancellation of all of Gharda’s food use registrations for chlorpyrifos except for the eleven Safe Uses currently in litigation (consistent with Gharda’s commitment to the Agency well before the Final Rule); (2) recognized that “there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses”; and (3) “committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA’s revocation order remains under review by the Eighth Circuit.”
- EPA has never provided evidence contrary to Gharda’s commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA’s Final Rule remains under review by the Eighth Circuit.
- There is no evidence of or reasonable basis to believe that chlorpyrifos is being distributed, sold, or otherwise placed in the stream of commerce for use on food, necessitating registration cancellation at this time. EPA’s tolerance revocations made distribution or use unlawful. As noted above, in correspondence dated March 30, 2022, Gharda recognized that “there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses” and “committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA’s revocation order remains under review by the Eighth Circuit.”
- The NOIC alleges no facts inconsistent with Gharda’s commitments or otherwise demonstrating that chlorpyrifos products are being distributed, sold, and/or used in a manner inconsistent with the Final Rule.
- Oral argument in the lawsuit took place on December 15, 2022. For the Agency to wait nine months after Gharda’s commitment not to sell or distribute chlorpyrifos products to issue its NOIC and to do so one day before oral argument in the lawsuit, demonstrates an inappropriate attempt by the NOIC to create urgency where EPA’s conduct demonstrates none exists. In sum, there is no urgent need based on the facts for the NOIC to proceed with actions as extreme as cancellations before the Eighth Circuit’s decision.

OBJECTION 4: The NOIC violates FIFRA by ignoring several of the statutorily required steps that *must* precede registration cancellation, including the requirement to consider alternatives to cancellation, and by improperly attempting to narrow the scope of the Administrative Law Judge’s review.

- FIFRA Section 6(b) provides that “[i]n taking any final action under this subsection, the Administrator *shall* consider restricting a pesticide’s use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and *shall* include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.” 7 U.S.C. § 136d(b) (emphasis added).
- FIFRA does not permit EPA to ignore these statutory requirements simply because a tolerance action precedes a cancellation action. EPA is required to review the full record before the Agency in issuing a decision on a NOIC. *See* 40 C.F.R. § 164.90(b).
- EPA contends in the NOIC that only the Final Rule and the facts existing at the time of the Final Rule are relevant to the NOIC. The NOIC thus ignores FIFRA’s requirement that alternatives to registration cancellation *must* be considered *in taking any final action under FIFRA Section 6(b)* and improperly attempts to limit the scope of the Administrative Law Judge’s review.
- EPA did not consider the PID and the Safe Uses identified by the PID as an alternative to cancellation and therefore violated FIFRA’s registration cancellation requirements.
- EPA did not consider Gharda’s repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA’s registration cancellation requirements. *See* Decl. of Ram Seethapathi in Support of Gharda’s Objs. to the Final Rule Revoking All Tolerances for Chlorpyrifos (“Seethapathi Decl.”), EPA-HQ-OPP-2021-0523, ¶¶ 21–36 and Exhibits to Seethapathi Decl. A–H (Oct. 22, 2021), Ex. 8; *see also* Ex. 9.
- EPA has never provided evidence contrary to Gharda’s commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA’s Final Rule remains under review by the Eighth Circuit.
- EPA did not consider Gharda’s submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation as an alternative to cancellation and therefore violated FIFRA’s registration cancellation requirements.
- EPA did not consider Gharda’s submission of amended labels, which eliminated all food uses for chlorpyrifos except the Safe Uses as an alternative to cancellation and therefore violated FIFRA’s registration cancellation requirements.
- EPA did not consider the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA’s registration cancellation requirements.

- The Administrator of EPA did not publish in the Federal Register an analysis of the impact of cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and therefore violated FIFRA’s registration cancellation requirements.
- FIFRA Section 6(b) requires EPA to respond to USDA’s comments with respect to the NOIC.
- EPA gave no meaningful consideration to USDA’s request that EPA re-establish tolerances for the Safe Uses based on EPA’s own scientific findings and therefore violated FIFRA’s cancellation requirements. *See* Letter from Kimberly Nesci, Dir., Office of Pest Mgmt. Pol’y, United States Dep’t of Agriculture to Edward Messina, Dir., Office of Pesticide Programs (“USDA Comments Letter”), EPA, EPA-HQ-OPP-2022-0417 (Sept. 11, 2022) at 2, <https://www.regulations.gov/document/EPA-HQ-OPP-2022-0417-0002>.
- EPA gave no meaningful consideration to USDA’s comments that, *inter alia*, EPA was not following “historical precedent and legal procedures” with respect to the Final Rule and NOIC and that the EPA’s actions constituted “harmful precedent” and therefore violated FIFRA’s registration cancellation requirements. *Id.* at 1–3.
- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA’s comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 5: The NOIC violates Gharda’s due process rights.

- Once a pesticide registration is granted, it becomes the registrant’s property interest, *see, e.g., Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010), and cannot “be taken away without that procedural due process required by the Fourteenth Amendment,” *Bell v. Burson*, 402 U.S. 535, 539 (1971). FIFRA protects these due process rights by establishing an elaborate scheme for EPA to follow before cancelling a pesticide registration. *See, e.g., 7 U.S.C. §§ 136d(b)(1), (2); 136d(d); 136a(g)(1)(v); see also Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (FIFRA “establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration.”).
- Due process is denied when the statutorily mandated process for taking away a property right is not followed.
- EPA has failed to provide Gharda with due process by, *inter alia*: (1) instructing Gharda, before the Final Rule, to be prepared to submit a voluntary cancellation letter narrowing uses consistent with the PID and then abruptly terminating discussions; (2) not considering as an alternative to registration cancellation maintaining the Safe Uses as

registered uses in accordance with the PID and EPA's determination of Safe Uses; (3) not considering as an alternative to registration cancellation Gharda's repeated written commitment to the Agency before the Final Rule to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses; (4) not considering as an alternative to registration cancellation Gharda's commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's Final Rule remains under review by the Eighth Circuit; (5) not considering as an alternative to registration cancellation Gharda's submission of its request to voluntarily cancel all food uses of chlorpyrifos except the Safe Uses pending the outcome of the Eighth Circuit litigation; (6) not considering as an alternative to registration cancellation Gharda's submission of amended labels which eliminated all food uses for chlorpyrifos except the Safe Uses; (7) not considering the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (8) not publishing in the Federal Register an analysis of the impact of registration cancellation compared to the alternative of maintaining the Safe Uses on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; (9) failing to await the decision from the Eighth Circuit before issuing the NOIC when chlorpyrifos cannot be sold or used and there is otherwise no urgency for registration cancellation proceedings at this time; (10) overburdening Gharda and other adversely affected parties with the necessity to spend resources to defend the NOIC when an Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses would eliminate the need for the NOIC; (11) overburdening Gharda with the necessity to spend resources to challenge registration cancellation that may occur and be followed by a favorable Eighth Circuit decision vacating or remanding the Final Rule as to the Safe Uses; and, (12) failing to consider or meaningfully consider USDA's comments in response to the NOIC, including, as set forth above, that EPA should re-establish tolerances for the Safe Uses and did not follow "historical precedent and legal procedures" regarding the Final Rule and NOIC.

- EPA's actions in issuing the NOIC compound the Agency's due process violations in issuing the Final Rule. EPA violated the due process rights of Gharda and others by revoking all tolerances in disregard of the Agency's own scientific findings as to the Safe Uses and Gharda's written commitment in advance of the Final Rule to modify its registration in accordance with the Agency's safety finding. *See Gharda Objs. at 31–37, Ex. 8.*

OBJECTION 6: Under the circumstances of this matter, EPA's demand in the NOIC that Gharda amend its registration labels to voluntarily cancel food uses for the Safe Uses is overly burdensome, unrealistic, punitive, and improperly seeks to interfere with the exercise of jurisdiction by the U.S. Court of Appeals for the Eighth Circuit.

- As noted above, on March 30, 2022, Gharda submitted a letter to EPA seeking cancellation of all food uses of chlorpyrifos in Gharda's registrations except the eleven

Safe Uses. Gharda explained in its letter that EPA's revocation of tolerances for the Safe Uses was currently under review by the Eighth Circuit. Ex. 9. Gharda also submitted amended labels to EPA omitting all food uses but the Safe Uses on June 10, 2022. Ex. 10.

- The NOIC states that “[w]hile Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.*, it does not result in the removal of all food uses from those registered products); therefore, Gharda’s products identified [in the NOIC] are subject to this Notice.” 87 Fed. Reg. at 76,476, Ex. 1. The NOIC misleadingly omits that the only way Gharda’s registrations do not align with the Final Rule is as to the Safe Uses currently under review by the Eighth Circuit.
- To the extent Gharda’s prior commitments before the Final Rule and submissions to EPA after the Final Rule are somehow insufficient to satisfy EPA that label changes consistent with EPA’s safety finding can be accomplished (a position Gharda views as contrary to the law and facts, *see* Pet’rs Br. at 23–28 (ID No. 5160660)), Gharda has submitted amended labels to EPA (included with this submission at Ex. 3) that once again limit food uses to the Safe Uses in the permitted geographic regions (that are the subject of the ongoing litigation) and also add application rate changes consistent with the PID safety finding. Gharda submits these changes to further demonstrate its commitment to conform its registrations to EPA’s safety finding in the PID, despite that the changes proposed are based on information the Agency developed and has had in its possession for years. *See* Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-2008-0850-0941 at 33–34 (Sep. 22, 2020), <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941>, Ex. 11.
- The NOIC states that the cancellation proposed in the NOIC shall become final unless “the registrant makes the necessary corrections to the registrations” or a hearing is requested. 87 Fed. Reg. at 76,475, Ex. 1.
- Thus, EPA demands that Gharda voluntarily cancel all remaining food uses, the tolerances for which are currently under review by the Eighth Circuit. EPA’s actions appear to be punitive, and an attempt to undermine and thwart Gharda’s justified attempt to obtain judicial review of EPA’s Final Rule as to the Safe Uses.
- If registration cancellation occurs before an Eighth Circuit decision invalidating the Final Rule, EPA would likely contend that Gharda must nevertheless apply to EPA for a new registration as to the Safe Uses and proceed anew through the FIFRA registration and tolerance petition processes. In other words, EPA may claim that, even if the Eighth Circuit vacates or remands the Final Rule to the Agency as to the Safe Uses, if the registrations have been cancelled, the Eighth Circuit ruling is a pyrrhic victory because tolerances are meaningless for a cancelled registration. But (1) challenging cancellation through the FIFRA-established administrative and subsequent court process and/or (2) petitioning for a new registration are time consuming and expensive processes with uncertain outcomes. Forcing Gharda to undertake one or both of these alternatives would

be overly burdensome and unfair, and would abridge Gharda's right to have the tolerances for the Safe Uses decided in a meaningful way by the Eighth Circuit. These outcomes can be avoided simply by delaying the NOIC until after the Eighth Circuit decision.

OBJECTION 7: The NOIC does not give due consideration to the USDA's views, contrary to FIFRA.

- FIFRA Section 6(b) requires EPA to respond to USDA's comments with respect to the NOIC. 7 U.S.C. § 136d.
- EPA gave no meaningful consideration to USDA's request that EPA re-establish tolerances for the Safe Uses in accordance with its scientific findings and therefore violated FIFRA's registration cancellation requirements. *See* USDA Comments Letter at 2.
- EPA gave no meaningful consideration to USDA's comments that, *inter alia*, EPA was not following "historical precedent and legal procedures" with respect to the Final Rule and NOIC and that the EPA's actions constituted "harmful precedent" and therefore violated FIFRA's registration cancellation requirements. *Id.* at 1–3.
- As noted by USDA, it is unprecedented for EPA to ignore FIFRA-mandated cancellation rights and processes in a situation where tolerance revocation occurs first.
- It is illogical for EPA to contend in the NOIC that the Final Rule is irrelevant to the NOIC and then imply that it can ignore USDA's comments submitted pursuant to FIFRA because it did not submit objections to the Final Rule.

OBJECTION 8: Issuance of the NOIC with a response deadline shortly after the holiday period is burdensome, unfair, and unnecessary.

- As set forth above, there is no urgency or any other good faith reason to force Gharda and other adversely affected parties to respond to the NOIC during the holiday period and to prepare for and go through a potentially costly NOIC process in light of the circumstances set forth above. Accordingly, Gharda respectfully requests that the Administrative Law Judge stay action on the NOIC until after the Eighth Circuit's decision in the lawsuit.

REQUEST FOR STAY OF NOIC

Based on the foregoing, Gharda respectfully requests that the Administrative Law Judge delay any action with respect to the NOIC, including but not limited to the conduct of the hearing

requested herein, until after the Eighth Circuit's decision in the lawsuit. A stay of the NOIC proceedings is warranted because proceeding with a potential registration cancellation now would prejudice the rights of Gharda and others to obtain judicial relief from the Final Rule underlying the NOIC in the ongoing litigation. Should a potential cancellation of the chlorpyrifos registrations precede a favorable ruling by the Eighth Circuit invalidating the Final Rule, EPA may nevertheless take the position that Gharda must initiate the FIFRA registration and tolerance petition processes for chlorpyrifos anew—destroying decades of investment, causing the needless expenditure of Agency and registrant resources, and further delaying access to a crop protection tool critical to U.S. growers. As discussed above, as there are no chlorpyrifos products approved for use on food currently in the stream of commerce, there are no public health concerns with simply delaying further action on the NOIC until the Eighth Circuit rules.⁹

CONCLUSION

For the reasons set forth above, EPA's unprecedented NOIC is contrary to FIFRA in many respects, violates the due process rights of Gharda, and is otherwise deficient. Moreover, there is no urgent need or other basis for the NOIC to proceed before the Eighth Circuit's decision in the lawsuit. Forcing Gharda to defend the NOIC before the Eighth Circuit's decision would be unfairly burdensome and unnecessary and is contrary to the Eighth Circuit's exercise of jurisdiction over the tolerances for the Safe Uses.

⁹ In other administrative actions, EPA has applied the stay criteria set forth by the U.S. Food and Drug Administration at 21 CFR § 10.35(e)(1)–(4) ((1) petitioner will suffer irreparable injury; (2) petitioner's case is not frivolous and pursued in good faith; (3) sound public policy grounds support a stay; and (4) delay from a stay is not outweighed by public health or other public interests). For reasons outlined herein, Gharda has satisfied these criteria here.

Gharda respectfully requests a hearing on the NOIC and requests that the Administrative Law Judge find that the Administrator did not have a proper basis for issuing the NOIC and dismiss the NOIC. At a minimum, the Administrative Law Judge should delay action on the NOIC until after a decision from the Eighth Circuit in the lawsuit.

Respectfully submitted,

/s/ Donald C. McLean

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Date: January 13, 2023

CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, true and correct copies of the foregoing Request for Hearing and Statement of Objections and Request for Stay, and all associated Exhibits, were filed electronically with the EPA OALJ E-Filing System for the OALJ's E-Docket Database, with a copy (without attachments) via electronic mail to the following:

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/s/ Donald C. McLean _____

Donald C. McLean