UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Pesticide Registrations for Chlorpyrifos Products	)	
Gharda Chemicals International, Inc. and Red River Valley Sugarbeet Growers Association, et al.,	)	**Docket No. FIFRA-HQ-2023-0001**
Petitioners	)	

RESPONDENT'S MOTION FOR ACCELERATED DECISION

The U.S. Environmental Protection Agency ("EPA," "Agency," or "Respondent") hereby requests[1] that this Tribunal render an accelerated decision in favor of Respondent in this matter without further hearing pursuant to 40 C.F.R. § 164.91:

1. finding that there is no genuine issue of material fact regarding EPA's December 14, 2022 Notice of Intent to Cancel Pesticide Registrations ("NOIC");
2. finding that Respondent is entitled to judgment as a matter of law; and
3. issuing an order cancelling Petitioner Gharda Chemicals International, Inc.'s registrations for pesticide products containing the active ingredient chlorpyrifos, as proposed in the NOIC.

A Memorandum in Support of Respondent's Motion for Accelerated Decision is being filed with this motion.

[1] Pursuant to the Presiding Officer's June 5, 2023 Order Scheduling Hearing and Prehearing Procedures, Respondent contacted all other parties and determined that Petitioners object to the granting of the relief sought in this Motion for Accelerated Decision. Intervenors do not oppose.

Respectfully submitted,

FORREST PITTMAN

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Date: 2023.08.25 16:54:19 -04'00'

Dated: August 25, 2023

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MEMORANDUM IN SUPPORT OF
RESPONDENT'S MOTION FOR ACCELERATED DECISION

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I. SUMMARY OF THE ARGUMENT

The only facts that are material to this proceeding are whether necessary tolerances exist to cover residues of chlorpyrifos used on food and whether Gharda Chemicals International, Inc.'s ("Gharda") registrations bear labeling for use on food. EPA revoked all chlorpyrifos tolerances on August 30, 2021. JX 3, JX 2. Gharda's registrations continue to bear labeling allowing for use on food. JX 4, JX 5, JX 6. As there is no dispute as to these facts, Respondent is entitled to judgment as a matter of law that Gharda's registrations must be cancelled.

Nevertheless, Gharda and several grower groups ("Growers") (collectively with Gharda, "Petitioners") attempt to obfuscate the question before the Presiding Officer by raising irrelevant facts and unfounded complaints about the process. Their arguments primarily consist of attempts to challenge the propriety of EPA's decision to revoke all chlorpyrifos tolerances and seek to delay this proceeding while the challenge to that decision is pending before the Eighth Circuit Court of Appeals. These arguments have been resoundingly rejected by the Presiding Officer and the Environmental Appeals Board ("Board").

Petitioners also allege that EPA's issuance of the Notice of Intent to Cancel ("NOIC") Gharda's chlorpyrifos registrations was procedurally deficient, including claims that EPA failed to address economic impacts and interagency comments or provide sufficient due process. EPA fulfilled its statutorily mandated obligations in the issuance of the NOIC; the only "problem" is that EPA's determinations differ from what Petitioners desired.

Because Petitioners have not alleged any disputed issues of material fact, and because the pure legal question presented by this matter can easily be resolved by looking to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Federal Food, Drug, and Cosmetic Act ("FFDCA"), Respondent asks that the Presiding Officer enter an accelerated

decision pursuant to 40 C.F.R. § 164.91(a)(7), cancelling Gharda's registrations for pesticide products containing the active ingredient chlorpyrifos, as proposed in the NOIC.

II. LEGAL BACKGROUND

A. The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")

FIFRA provides for federal regulation of pesticide distribution, sale, and use. 7 U.S.C. §§ 136, *et seq*. Generally speaking, all pesticides distributed or sold in the United States must be registered (*i.e.*, licensed) by EPA. *Id*. § 136a(a). Before EPA may register a pesticide under FIFRA, an applicant must show, among other things, that the pesticide "labeling … compl[ies] with [FIFRA]" and that using the pesticide "in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id*. § 136a(c)(5)(B) and (D). On the first point, labeling that is misbranded[1] does not comply with FIFRA. *See id.* § 136j(a)(1)(F). On the second point, FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [Section 408 of the FFDCA]. . . ." *Id*. § 136(bb) (*citing* 21 U.S.C. § 346a).

B. FIFRA Section 6(b); Cancellation and Change in Classification

FIFRA Section 6(b), 7 U.S.C. § 136d(b), which sets forth the process by which EPA can cancel a pesticide product, provides in relevant part:

> (b) Cancellation and change in classification
>
> If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter

[1] "A pesticide is misbranded if [ ] its labeling bears any statement [ ] that is false or misleading." 7 U.S.C. § 136(q)(1)(A).

> or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent [ ]--
>
> (1) to cancel its registration . . . together with the reasons (including the factual basis) for the Administrator's action. . . .
>
> Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments . . . . The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request . . . , a decision [ ] issued after completion of such hearing shall be final. In 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.

C. 40 C.F.R. Part 164; Hearing

Hearings concerning cancellations of registration under FIFRA Section 6(b) are conducted pursuant to the rules of practice at 40 C.F.R. Part 164, subpart B. 40 C.F.R. § 164.3.

III. FACTUAL BACKGROUND

A. Chlorpyrifos

Chlorpyrifos is a broad-spectrum, chlorinated organophosphate insecticide that has historically been registered for a wide variety of food and non-food uses. In September 2007,

Pesticide Action Network North America and the Natural Resources Defense Council filed a petition ("2007 Petition") with EPA requesting revocation of all chlorpyrifos tolerances alleging that, among other things, the pesticide caused adverse neurodevelopmental effects in children at exposure levels below the Agency's regulatory endpoint (*i.e.*, 10% acetylcholinesterase inhibition). IX 1.

B. Ninth Circuit Litigation

On April 29, 2021, the Ninth Circuit Court of Appeals ruled against EPA in litigation involving the Agency's response to the 2007 Petition and the question of whether the chlorpyrifos tolerances should be revoked. *See League of United Latin Am. Citizens v. Regan ("LULAC")*, 996 F.3d 673 (9th Cir. 2021). In *LULAC II*, the Ninth Circuit found that the Agency had abdicated its statutory obligation to make a safety finding in its retention of chlorpyrifos tolerances and directed Respondent to issue a final rule in which the Agency would either revoke the tolerances or modify the existing chlorpyrifos tolerances, provided that the Agency concurrently issued a safety determination supporting the modified tolerances. The Ninth Circuit imposed a tight deadline for EPA to issue the final rule, explicitly requiring a "legally sufficient final response to the 2007 Petition within 60 days of the issuance of the [court's] mandate" and forbidding EPA from engaging in further factfinding. *Id.* at 703-04. Importantly, the Ninth Circuit also ordered EPA to "modify or cancel related FIFRA registrations for food use in a timely fashion . . . ." *Id*.

C. Final Rule Revoking Chlorpyrifos Tolerances and Final Order Denying Objections

Following the Ninth Circuit's order, EPA considered whether and how the Agency might modify tolerances by making a safety finding for a subset of uses. As part of that effort, EPA

initiated discussions with registrants of technical chlorpyrifos products,[2] including Gharda, to evaluate whether there might be a basis for EPA to make a safety determination for some uses within the time period imposed by the court. Verified Statement of Elissa Reaves ("Reaves Statement") at 7. In a series of approximately six meetings and several letter exchanges, Gharda proposed a number of restrictions on chlorpyrifos usage. *Id.* at 7-8. However, EPA could not accept any of the proposals due to, among other factors, Gharda's repeated attempts to include many additional food uses for which EPA had no basis to make a safety finding and very long phase-out schedules for other uses. *Id.* Respondent notes that Gharda's communications with the Agency prior to issuance of the Final Rule did not constitute enforceable "commitments"[3] (compared to, *e.g.*, requests for voluntary cancellation of certain uses), and thus EPA did not have a sufficient basis to conclude that aggregate exposures from registered uses would be limited in order to support a safety determination as to some subset of chlorpyrifos tolerances. Reaves Statement at 12.

Accordingly, in implementing the court's order within the mandated timeframe, EPA found that it could not make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under FFDCA Section 408(b)(2). 21 U.S.C. 346a(b)(2). Under the FFDCA, a tolerance may be left in place only if the Agency determines that the tolerances are safe; *i.e.*, that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. Because EPA found at the

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[2] Technical or manufacturing-use products are defined as "any pesticide product that is not an end-use product." 40 C.F.R. § 152.3. Technical or manufacturing-use products are intended for formulation into other pesticide products and often contain only the active ingredient. *See* EPA Pesticide Registration Manual, chapter 2, at https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

[3] *Cf.* Grower Objections at 6 (discussing "written commitments" from Gharda to make certain changes to its registrations).

time that it could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to chlorpyrifos residues, including all anticipated dietary (food and drinking water) exposures and all other exposures, EPA published the final rule revoking all tolerances for chlorpyrifos in the Federal Register on August 30, 2021. JX 3.

Pursuant to FFDCA Section 408(g)(2), EPA provided an opportunity for any person to file objections to the Final Rule and request an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2); *see also* 40 C.F.R. § 178.32(b). In response to the Final Rule, several objections, hearing requests, and requests to stay the Final Rule were filed by Petitioners in addition to other parties representing a wide variety of growers and pesticide users. On February 28, 2022, EPA published its order denying all objections, hearing requests, and requests to stay the Final Rule ("Denial Order") in the Federal Register. JX 2. EPA's publication of the Denial Order completed the Agency's administrative process for the Final Rule. Since the administrative objections process did not result in any changes to the Final Rule, all chlorpyrifos tolerances expired on February 28, 2022.

D. Eighth Circuit Litigation

Following Respondent's issuance of the Denial Order, Petitioners filed two petitions in the Eighth Circuit pursuant to FFDCA Section 408(h)(1),[4] which were subsequently consolidated by the court.[5] Prior to merits briefing and oral argument in that matter, the petitioners in that case, including Gharda, sought to stay implementation of the Final Rule "pending judicial review

[4] *See* Petition for Review, *Red River Valley Sugarbeet Growers Ass'n v. Regan ("RRVSGA")*, No. 22-1422 (8th Cir. Feb. 28, 2022), Entry ID 5131400, PX 18; Petition for Review, *RRVSGA*, No. 22-1530 (8th Cir. Mar. 14, 2022), Entry ID 5136561, PX 23. The Petitioners had also filed an earlier petition for review of the Final Rule prior to the issuance of the Denial Order, but that petition was dismissed for lack of jurisdiction. Judgment, *RRSVGA*, No. 22-1294 (8th Cir. Mar. 16, 2022).

[5] Order Granting Motion to Consolidate Cases 22-1422 and 22-1530, *RRVSGA*, Nos. 22-1422 and 22-1530 (8th Cir. Apr. 21, 2022), Entry ID 5149661, RX 52.

of that decision." PX 20 at 27. In its Eighth Circuit Stay Motion, Gharda made many of the same arguments as it does in this matter. *See, e.g., id.* at 27 (arguing irreparable economic harm from loss of use of chlorpyrifos) *and* at 30 (arguing due process violations from the Final Rule). The Agency responded that it would not be good public policy—and inconsistent with the FFDCA safety standard— to allow unsafe tolerances to remain in place while that litigation was pending.[6] The Eighth Circuit rejected the plaintiffs' stay request without elaborating upon its reasoning. RX 51. Oral argument took place on December 15, 2022, and this consolidated matter is currently pending before the Eighth Circuit. *See Red River Valley Sugarbeet Growers Ass'n v. Regan ("RRVSGA")*, Nos. 22-1422, 22-1530 (8th Cir. argued Dec. 15, 2022).

E. Notice of Intent to Cancel and Administrative Proceedings to Date

As a result of the Final Rule, no tolerances or tolerance exemptions exist to cover residues of chlorpyrifos in or on food. Thus, there is no basis in the law for allowing food uses to remain on chlorpyrifos registered products. *See* JX 1 at 3. Accordingly, in March of 2022, EPA issued letters to all registrants of chlorpyrifos products bearing labeling for food uses, confirming the revocation of tolerances and recommending that registrants either submit label amendments removing food uses from their products or submit voluntary cancellations of said products. RX 1. All chlorpyrifos registrants—with the sole exception of Gharda—submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels.[7] While Gharda submitted requests for voluntary

[6] *See*, *e.g.*, RX 48, *RRVSGA*, No. 22-1294 (8th Cir. Feb. 18, 2022) at 25 ("Petitioners have failed to demonstrate irreparable harm."), 29 ("[g]ranting Petitioners' stay request would also undermine judicial process and comity among sister circuits."), and 28 ("[t]he public interest and balance of harms also weigh strongly in favor of denying Petitioners' stay request."). This opposition contains essentially the same arguments in opposition to the stay motion filed in the consolidated second and third challenges petitioning for review of the Final Rule and Denial Order.

[7] The Agency has been working through and processing those requests since their submission. *See e.g.*, 87 FR 53,471 (Aug. 31, 2022); 88 FR 28,541 (May 4, 2023). The Agency published notice of Gharda's voluntary

cancellation for some uses and some label amendments, they also requested that EPA leave in place several modified food uses, noting that the company did not wish to voluntarily cancel those uses pending the litigation in the Eighth Circuit. Gharda's request would not result in the removal of all food uses as required by the revocation of chlorpyrifos tolerances. *Id.*

Given Gharda's express position to maintain food uses without tolerances in place and in order to continue efforts to comply with the Ninth Circuit's directive to cancel uses in a timely fashion, on December 14, 2022, EPA published the NOIC in the Federal Register, stating its intention to cancel the registrations of three pesticide products pursuant to FIFRA Section 6(b), 7 U.S.C. § 136d(b). JX 1. The NOIC identifies Gharda as the registrant for the products subject to the NOIC. JX 1 at 1. On January 13, 2023, Gharda and Growers filed with this Tribunal two Requests for Hearing and Statement of Objections and Request for Stay ("Gharda Objections" and "Grower Objections," respectively).

IV. STANDARD FOR AN ACCELERATED DECISION

Regulations pertaining to hearings arising under FIFRA Section 6, including hearings pertaining to cancellation and suspension of registrations, permit the ALJ to issue an accelerated decision similar to a summary judgment under the Federal Rules of Civil Procedure. Specifically, 40 C.F.R. § 164.91(a)(7) provides that an Administrative Law Judge, in their discretion,

> may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence such as affidavits as he may receive, . . . [by finding] that there is no genuine issue of material fact and that the [R]espondent is entitled to judgment as a matter of law.

cancellation request, 88 FR 37243 (June 7, 2023), but as noted, even granting Gharda's request in full would still leave several food uses not covered by tolerances on Gharda's registered chlorpyrifos products. *See* JX 9, 10, 11.

Many provisions of 40 C.F.R. Part 164, including 40 C.F.R. § 164.91, are analogous to those in the Federal Rules of Civil Procedure. *Cf*. Fed. Rul. Civ. P. 56(a) (providing for summary judgment where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law").[8]

Respondent has the burden to present an affirmative case for the cancellation of Gharda's registration. 40 C.F.R. § 164.80(a). However, "[o]n all issues arising in connection with the hearing, the ultimate burden of persuasion shall rest with the proponent of the registration." *Id.* § 164.80(b). Thus, Petitioners bear the burden of persuasion that the registrations at issue in this matter should continue. *Id.*; *see also AMVAC Chem. Corp.*, 18 E.A.D. 769, 774 (EAB 2022).

V. RESPONDENT IS ENTITLED TO JUDGMENT AS A MATTER OF LAW

A. Gharda's Chlorpyrifos Registrations Must be Cancelled as a Matter of Law

The NOIC clearly makes an affirmative case for cancellation of Gharda's products. Petitioners have not made any showing, much less met the burden of persuasion, that Gharda's chlorpyrifos registrations should continue. This motion turns on the dispositive and limited question of whether, as a matter of law, Gharda's chlorpyrifos registrations should be cancelled pursuant to FIFRA Section 6(b). There are no disputed issues of material fact; resolution of this matter is purely legal in nature. "[A] party opposing a properly supported motion for accelerated decision is required to 'provide more than a *scintilla* of evidence on a disputed factual issue to show their entitlement to a[n] . . . evidentiary hearing: the evidence must be substantial and probative in light of the appropriate evidentiary standard of the case.'" *B.W.X. Techs., Inc.*, 9 E.A.D. 61, 76 (EAB 2000) (citation omitted). Petitioners offer no such evidence. Their

[8] 40 C.F.R. Part 164 is also analogous to 40 C.F.R. Part 22, the regulations governing assessment of civil penalties and enforcement under FIFRA and other environmental statutes administered by EPA. *Cf*. 40 C.F.R. § 22.20 (authorizing accelerated decision where there is no genuine issue of material fact and party is entitled to judgment as a matter of law).

objections to the NOIC consist of inappropriate collateral attacks on the Final Rule, "factual" premises based only on a hypothetical future in which the Eighth Circuit vacates the Final Rule, and unsupported arguments that EPA was required to take action pursuant to FIFRA (*i.e.*, cancellation) before taking action under the FFDCA (*i.e.*, tolerance revocation).

The only facts that are material to this proceeding are whether tolerances exist to cover residues of chlorpyrifos used on food and whether Gharda's registrations bear labeling for use on food. All parties agree that there are no tolerances for chlorpyrifos on any food and that Gharda's current labels and requested label amendments bear labeling for use on food. *See* Gharda Objections at 6-7 (noting that "tolerance revocations made distribution or use unlawful"); Grower Objections at 18; JX 3; JX 4 at 4, JX 5 at 5, JX 6 at 4 *et seq*. (existing Gharda chlorpyrifos product labels); JX 9 at 6, JX 10 at 16 *et seq*., JX 11 at 6 *et seq.* (Gharda's requested chlorpyrifos product label amendments). There is no dispute as to these facts.

As explained in the NOIC itself, Gharda's chlorpyrifos products, which bear directions for use on food, must be cancelled because they do not meet the statutory standard for registered products and the labeling is misbranded. More specifically, "without a tolerance or an exemption from the requirement of a tolerance, pesticide residues in or on food are considered unsafe, as a matter of law." JX 1 at 2. "Because the FIFRA registration standard incorporates the FFDCA safety standard, a pesticide that results in residues in or on food that are unsafe, which includes residues not covered by a tolerance or tolerance exemption, does not meet the FIFRA registration standard." *Id.* Any registrations bearing labelling for food use may reasonably be expected to result in pesticidal residues on food. *Id.* Thus, pesticides bearing such labeling pose unreasonable adverse effects on the environment, simply because those residues, which are not covered by tolerances, are considered unsafe. 21 U.S.C. § 346a(a)(1). Furthermore, allowing food uses to

remain on the label would be misleading to users, since users might reasonably believe the pesticide could be used on those labeled food crops intended for sale without violating another law. *See id.* However, without appropriate tolerances or tolerance exemptions in place, any crops treated with the pesticide would be considered adulterated, and selling such food in interstate commerce would be a violation of the FFDCA. JX 1 at 4. Pesticides that contain misleading labeling are considered misbranded, and it is a violation of FIFRA to sell or distribute misbranded pesticides. 7 U.S.C. §§ 136(q)(1)(A), 136j(a)(1)(G). Therefore, "registrations bearing labelling for food use must be modified or cancelled, pursuant to FIFRA Section 6(b)." *Id.* at 2.

Stated plainly, Gharda's chlorpyrifos registrations may not continue to bear food use labelling. *Id.* Because Gharda declined to request registration amendments removing all food uses from its labels, those registrations must be cancelled because they "(i) pose unreasonable adverse effects on the environment under FIFRA Section 2(bb)(2), 7 U.S.C. § 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the FFDCA and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E)." JX 1 at 3. The substance of the Petitioners' objections is largely irrelevant to the simple legal matter presented by this NOIC: can food uses for which no tolerances exist remain registered? The answer is no. Accordingly, Respondent is entitled to judgment as a matter of law in this proceeding, and the Presiding Officer should grant this Motion for Accelerated Decision.

B. Cancellation is the Only Option Available to EPA

Cancellation in the instant case is the only possible outcome of the process initiated by the Ninth Circuit's order. The court directed EPA, once it addressed the chlorpyrifos tolerances, to modify or cancel related FIFRA registrations for food uses of chlorpyrifos "in a timely fashion." *Supra* section III.B. Because there are no chlorpyrifos tolerances in place under the

FFDCA, no food uses of chlorpyrifos can remain registered. JX 1 at 2; 40 C.F.R. § 152.112(g), FIFRA § 6(b). Both the Presiding Officer and the Board recognized that, pursuant to the Ninth Circuit's ruling, EPA must "proceed apace with any warranted cancellations" following the tolerance revocation. Order Denying Motion for Interlocutory Review at 6 (E.A.B. July 14, 2023); Order on Motion to Stay at 6, Dkt. #10.

Consistent with the Ninth Circuit's directive, EPA provided all registrants of chlorpyrifos products with the opportunity to remove food uses from product labels or to submit voluntary cancellation requests for their products. RX 1; JX 7; JX 1 at 3. However, Gharda did not seek to remove all food uses from its chlorpyrifos registrations; it sought to retain some food uses on its registrations despite the fact that no chlorpyrifos tolerances exist. JX 8. Thus, as it stated in the NOIC, EPA determined that said registrations

> must be cancelled because they each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products, bearing labeling for use on food crops, (i) pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the FFDCA and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

JX 1 at 3. Petitioners have failed to identify any other action that EPA could have taken with respect to Gharda's registrations that would comply with the requirements of FIFRA Section 6(b) and 40 C.F.R. § 152.112(g). Gharda's suggestion that EPA consider leaving some food uses in place based on the Agency's proposal in the Proposed Interim Registration Review Decision for Chlorpyrifos (PX 41) is not a viable alternative because no tolerances exist to support those uses. Consequently, the Presiding Officer should grant this Motion for Accelerated Decision and issue a cancellation order for Gharda's chlorpyrifos products as proposed in the NOIC.

VI. PETITIONERS DO NOT RAISE ANY GENUINE ISSUES OF MATERIAL FACT RELEVANT TO THIS PROCEEDING

All other material contained in Petitioners' objections is irrelevant. Petitioners attempt to obfuscate the question before the Presiding Officer by raising irrelevant facts and unfounded complaints about the cancellation process. Respondent addresses their arguments in this motion solely for the purpose of demonstrating that Petitioners do not dispute any genuine issues of material fact.

A. Pending Litigation in the Eighth Circuit Does Not Justify Continued Registration of Chlorpyrifos Products Labeled for Food Uses

Petitioners' arguments in the requests for hearing filed in this matter are—to a large degree—simply collateral attacks on the Final Rule itself. [9] To the extent the Petitioners raise factual arguments in their objections, they all concern the Final Rule, and thus are not appropriate for resolution through this proceeding. Gharda argues that the Final Rule "incorrectly revoked tolerances for the Safe Uses," and "was arbitrary and capricious and contrary to law in its revocation of tolerances for the Safe Uses." Gharda Objections at 5. Growers similarly argue that the Final Rule was "unlawful." Grower Objections at 4-8. As the Presiding Officer already stated:

[9] Gharda explicitly alleges that "the Final Rule [ ] incorrectly revoked tolerances" for chlorpyrifos (Gharda Objections at 5); that any action on the NOIC "should be delayed until after the Eighth Circuit decides Petitioners' challenge to the Final Rule" (*id.* at 6, 10-12); that there is "no reason that the NOIC cannot be delayed until after the Eighth Circuit's decision" (*id.* at 6-7); and various allegations of due process violations based on the same Final Rule-centric arguments (*id.* at 9-10). Thus, of the approximately seven pages of argument in the Gharda Objections, at most two constitute anything other than challenges to the Final Rule. *Id.* at 7-8, 12. The Grower Objections are likewise based on challenges to the Final Rule. *See, e.g.*, Grower Objections at 4-8 (arguing that the Final Rule was arbitrary and capricious).

> The FFDCA provides that once a petition for review of a final agency order revoking tolerances "or any regulation that is the subject of such an order" has been filed with the appropriate Circuit Court, "the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part." 21 U.S.C. § 346a(h)(1), (2). Lest there be any doubt that the FFDCA forecloses secondary review of such an order or regulation, the statute further provides that "[a]ny issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law." Id. § 346a(h)(5) (emphasis added). Here, the Eighth Circuit has exercised jurisdiction over the RRVSGA petitioners' challenge to the Final Rule. Agency Resp. Ex. 3. There may be, therefore, no overlap between the Eighth Circuit's review of issues related to the Final Rule and this Tribunal's review of the NOIC. This does not mean the case at bar conflicts with the Eighth Circuit's jurisdiction; it simply limits the issues the parties may raise here.

Order on Motion to Stay at 6, Dkt. #10. Thus, as Petitioners' various arguments challenging the Final Rule may not even be considered in the course of this proceeding to challenge the NOIC, the same arguments do not, and cannot, constitute genuine issues of material fact to be resolved through a hearing.

Petitioners assert that the NOIC cannot proceed based on what they allege is an "unlawful rule." This claim is premised on the fact that the Eighth Circuit has not yet ruled on the merits of Petitioners' challenge to the Final Rule. Petitioners' arguments presume that the Eighth Circuit will vacate the Final Rule and largely decline to address the actual record on which EPA has acted. Thus, this argument is simply a thinly veiled reassertion of their request to delay this proceeding until the Eighth Circuit issues its decision based on their presumption that the Eighth Circuit will vacate the Final Rule. Petitioners have already lost all their attempts to stay the Final Rule or this proceeding. Both the Presiding Officer and the Board rejected Petitioners' arguments concerning hypothetical rulings from the Eighth Circuit, especially in light of the affirmative steps required of EPA by the Ninth Circuit. *See* Order Denying Motion for Interlocutory Review at 5. As the Presiding Officer recognized, "[t]here may be [ ] no overlap between the Eighth Circuit's review of issues related to the Final Rule and this Tribunal's review of the NOIC."

Order on Motion to Stay at 6, Dkt. #10. Thus, the Eighth Circuit's ongoing review of the Final Rule "limits the issues the parties may raise" in the instant case and precludes challenges to the Final Rule itself. *Id.* Despite this, Petitioners' objections to the NOIC largely ignore the statutory requirement for EPA to cancel these registrations as a result of the tolerance revocations, and instead attempt to attack the Final Rule in this proceeding. *See* Gharda Objections at 5-6, 10-12; Grower Objections at 3-8, 10-11, 18-19, 20-21.

Petitioners are correct that the NOIC is ultimately based on the Final Rule, but the arguments that flow from that fact are wholly unsupported. The Presiding Officer has already rejected Petitioners' arguments concerning purported "conflicts" or "interfere[nce]" with the Eighth Circuit's jurisdiction over the challenge to EPA's Final Rule. Order on Motion to Stay at 6. Petitioners have conclusively failed to demonstrate anything about the litigation in the Eighth Circuit that would have any bearing on this case. Gharda maintains that the NOIC "is overly burdensome, unrealistic, [and] punitive." Gharda Objections at 10-12. However, this argument is premised on Petitioners' own unrealistic assertion—with no basis in the law—that EPA should, in essence, wait for all potential litigation on the Final Rule to resolve before taking any action on the chlorpyrifos registrations with food use. Such delay on EPA's part would clearly fail to comply with the Ninth Circuit's mandate. Petitioner Growers' argument that the NOIC is "premature" and has "no legitimate purpose" is likewise based on willfully ignoring both the Ninth Circuit's mandate and EPA's duty under FIFRA Section 6(b) and 40 C.F.R. § 152.112(g) to ensure that a pesticide product is not registered for any uses on food unless an appropriate tolerance for that pesticide is currently in place. Importantly, the Eighth Circuit declined to stay the Final Rule during the pendency of that litigation,[10] which means that the Final Rule is in

[10] RX 51.

effect, and there is no reason for EPA to delay proceeding with other related administrative actions, such as cancelling or amending registrations to remove food uses. Moreover, the Presiding Officer and the Board also declined to stay this cancellation proceeding while the Eighth Circuit litigation is pending.

B. Gharda's "Commitments" Are Not Relevant to This Hearing and Are Ineffective

Gharda makes a number of assertions concerning its "commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply." Gharda Objections at 6-7. While Respondent appreciates Gharda's recognition[11] that its chlorpyrifos products cannot be sold or distributed at this time and its assistance in working to ensure that users do not apply Gharda's products to food crops to avoid adulterated crops that cannot be sold without violating the FFDCA; however, such commitments are of no legal import to the NOIC. Petitioners make no legal showing that these "commitments" constitute a genuine issue of material fact that must be addressed by the Presiding Officer. Rather, Petitioners essentially assert that Respondent was required to demonstrate—in the NOIC—that unlawful application of chlorpyrifos to food crops was presently taking place in order to justify the cancellation. Gharda Objections at 7. Petitioners include no legal basis for this position, and plainly cannot do so. There is no requirement under FIFRA that EPA wait for evidence of unlawful or dangerous use actually occuring before issuing a NOIC; FIFRA Section 6(b) clearly states that any pesticide or labeling that is out of compliance with FIFRA is a sufficient basis for issuance of a NOIC. 7 U.S.C. § 136d(b). In any event, Petitioners' assertion that chlorpyrifos is not being used in a manner inconsistent with the

[11] Respondent notes that Growers may not share this recognition. In the Grower Objections, they imply that the actual impact on growers and consumers would be different if EPA did not cancel the chlorpyrifos products at issue in this matter but rather "amend[ed] chlorpyrifos registrations to restrict [certain] food uses and allow [other] food uses to continue." Grower Objections at 19. EPA reiterates that, even if the NOIC were never issued, application of chlorpyrifos to any food crop would still result in adulterated food that would be unlawful to distribute in the United States due to the lack of tolerances; there is no practical difference for growers or consumers.

Final Rule is unfortunately incorrect. EPA has been made aware of potential misuse. RX 63. While the details of this likely unlawful use of chlorpyrifos on food crops in 2023 are still being investigated, such incidents clearly heighten the need for EPA to remove all food uses from chlorpyrifos registrations.

C. EPA's Consideration of Economic Factors and USDA Comments Complied with the Requirements of Section 6(b)

Contrary to Petitioners' objections, there is no genuine issue of material fact with respect to consideration of economic factors or comments on the draft NOIC. The essence of Petitioners' argument is that EPA did not conduct the economic analysis required by FIFRA Section 6(b) and, relatedly, did not consider comments from the U.S. Department of Agriculture ("USDA")—which focused on the benefits of chlorpyrifos use on food crops—before issuing the NOIC. Gharda Objections at 7-9, 12; Grower Objections at 11-18, 19-20; JX 15. Contrary to Petitioners' assertions, EPA did consider the economic impact of the NOIC and USDA's comments in the NOIC itself. However, as explained in section V.B, above, after revocation of all chlorpyrifos tolerances by the Final Rule and Gharda's decision not to remove all food uses from its chlorpyrifos registrations, EPA was left with no other option than to issue the NOIC. *Supra* sections III.E, V.B.

Petitioners assert that EPA failed to consider before issuing the NOIC (and then failed to publish in the NOIC) the "impact of [cancellation] on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." Gharda Objections at 8 (quoting FIFRA Section 6(b)). Similarly, they also assert that EPA "did not give due consideration to the USDA's comments" on the proposed NOIC. Both arguments are easily debunked. The NOIC clearly considered the impact on the agricultural economy as required in FIFRA Section 6(b), finding that cancellation of Gharda's products "would have no economic

impact, beyond the impact already resulting from the revocation of the chlorpyrifos tolerances, since these products already cannot be used on food due to the lack of tolerances." JX 1 at 5. The NOIC also clearly responded to USDA's comments, noting that EPA could not consider economic impacts when determining whether to retain tolerances, and that the "NOIC itself does not actually result in any impact on agricultural commodities, retail food prices, or the agricultural economy." JX 1 at 5-6. EPA did consider the statutory factors and USDA's comment, but because "the same economic impact would result with or without this cancellation action," the cancellation would not have any economic impact. *Id.*

Thus, the apparent thrust of Petitioners' arguments is not that EPA failed to consider the statutory factors and USDA's comment, but rather that the sequence of actions for chlorpyrifos had the effect of not letting economic impacts drive the regulatory decisionmaking process as Petitioners seem to prefer, *i.e*., revoking tolerances first and then moving to cancel uses under FIFRA, instead of the other way around. However, there is no basis in FIFRA (or the FFDCA) requiring the sequencing of EPA actions desired by Petitioners. As EPA has previously explained:

> Section 408(l)(1) of the FFDCA provides that ''[t]o the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA].'' 21 U.S.C. 346a(l)(1). Nothing in this provision establishes a predetermined order for how the Agency is to proceed to resolve dietary risks. Nor does FIFRA include any provision that imposes a requirement that the Agency act first under FIFRA before it may act under the FFDCA in a situation [ ] where pesticide registrations and tolerances fail to meet the relevant legal standards of FIFRA and the FFDCA. Accordingly, there is no support for the notion that, as a matter of law, the Agency lacks the legal authority to revoke pesticide tolerances under the FFDCA that do not meet the safety standard of that statute unless the Agency has first canceled associated pesticide registrations under FIFRA.

74 Fed. Reg. 23,046, 23,069 (May 15, 2009) (Carbofuran; Final Tolerance Revocations). It is worth noting that, even if Petitioner's implied argument that FIFRA cancellation must precede FFDCA tolerance revocation were true, such an arrangement would change nothing about the outcome of this matter. In any FIFRA cancellation hearing, if it is determined that a use of a pesticide on food fails to meet the FFDCA Section 408 safety standard, the pesticide must be cancelled, irrespective of whether the benefits outweigh the risks because the pesticide would pose unreasonable adverse effects on the environment. *See* 7 U.S.C. § 136(bb).

In their economic impact arguments, Petitioners essentially assert that EPA should have either (1) considered the economic impact of revoking chlorpyrifos tolerances before issuing the Final Rule—an action that is not permitted under the FFDCA and would have been plainly at odds with the Ninth Circuit's mandate; or (2) conducted an analysis of the economic impacts of tolerance revocation before issuing the NOIC—although FIFRA Section 6(b) requires an assessment of the proposed cancellation's impact on the agricultural economy. The circuitous and speculative nature of Petitioners' desired analyses arises from the fact that all parties and USDA agree that the Final Rule is the action preventing user's ability to apply chlorpyrifos to food crops. Gharda Objections at 7 ("recogni[zing] that 'there can be no use, distribution, or sale of chlorpyrifos products for use on food'" due to the Final Rule); Growers Objections at 11 (outlining that growers currently cannot use chlorpyrifos on food crops); JX 15 (USDA recognizing that "revocation of tolerances for residues of chlorpyrifos in food makes any remaining registrations bearing labeled food uses of these products misbranded and out of compliance with FIFRA").

Similarly, Growers argue that EPA should have assessed the potential economic impacts of re-registering any uses cancelled as a result of this proceeding, under the presumption that the

Eighth Circuit will reinstate the tolerances. That argument would require EPA to presume facts not in existence at the time EPA issued the NOIC, and that are not relevant. Even at this time, it is unclear when the Eighth Circuit would issue its decision, whether that decision occurs before or after the conclusion of this proceeding or any appeals to the Board. Nor is there any clarity on how the Eighth Circuit might resolve the pending litigation; Respondent asserts that the court is likely to uphold the Final Rule, rather than reinstate tolerances as Petitioners speculate. Even assuming for purposes of this argument that tolerances are reinstated by the Eighth Circuit after the registrations are cancelled in this proceeding, it is still unknown whether re-registration would be pursued or how long that might take, what process for re-registering those cancelled uses would be required, or what fees might apply. *See* Verified Statement of Stephen Schaible, at 3-5. Hypothetical future economic costs for the variations of outcomes here are not relevant, since there is no dispute that at this time tolerances do not exist to cover the food uses that remain on Gharda's registered chlorpyrifos products.

D. Petitioners Have Been Provided All Required Due Process

Petitioners make a number of arguments alleging that EPA violated Gharda's rights to due process.[12] Gharda Objections at 9-10. The majority of these arguments—like the remainder of the Petitioners' objections—consist of attempts to inappropriately litigate the Final Rule in this forum. *E.g.,* Gharda Objections at 10 (discussing supposed due process violations created by EPA's failure to await a decision from the Eighth Circuit). Other purported "due process"

[12] Gharda also asserts, with no elaboration, that EPA's publication of the NOIC on December 14, 2022, was "burdensome, unfair, and unnecessary" because the 30-day period for Petitioners to request a hearing encompassed the 2022 holiday period. Gharda Objections at 12. Petitioners did not, and cannot, point to any principle that disallows a federal agency from taking an action with a response window encompassing a holiday. In any event, Gharda and Growers availed themselves of the statutorily provided due process and filed objections requesting a hearing in this proceeding. This argument patently presents no genuine issue of material fact that would preclude judgment as a matter of law in favor of Respondent.

arguments are merely restatements of arguments made elsewhere in Petitioners' objections. *E.g.*, Gharda Objections at 10 (alleging failure to consider USDA comments).

Leaving such restatements aside, the core of Petitioners' "due process" argument is that EPA failed to follow the statutorily-mandated process when issuing the NOIC.[13] Gharda Objections at 9. Here again, Petitioners are unable to point to any deficiency in EPA's process of seeking cancellation of the chlorpyrifos registrations. FIFRA requires that EPA provide a draft of the NOIC to the FIFRA Scientific Advisory Panel[14] and to the USDA 60 days prior to publication of the NOIC, which EPA did. JX 12; JX 14. Section 6(b) requires that EPA publish any response to USDA's comments in the published NOIC, which EPA did. JX 1 at 5. Section 6(b) requires an analysis of the impacts of the cancellation on the agricultural economy, which EPA performed. JX 1 at 6. Section 6(b) requires a consideration of alternatives in the final action taken pursuant to the notice, which EPA indicated it would consider in final action on the NOIC, although as noted in section V.B., such alternative needs to be a legally viable alternative. JX 1 at 5. Instead, Petitioners assert that their disapproval of EPA's conclusions in the NOIC is evidence of noncompliance with the FIFRA Section 6(b) process. Contrary to Petitioners' arguments, the statute does not require EPA to agree with USDA's comments nor does it require EPA to assign to the pending cancellation action any impacts that have already resulted from the revocation of the chlorpyrifos tolerances under the FFDCA. Finally, and most importantly, Section 6(b) also provides a due process opportunity to any registrant or any person adversely

[13] To the extent that Petitioners would argue EPA is depriving them of substantive due process—which is not directly alleged in their objections—Respondent asserts that no allegations have been made of "government action which is so arbitrary and irrational, so unjustified by any circumstance or governmental interest, as to be literally incapable of avoidance by any pre-deprivation procedural protections or of adequate rectification by any post-deprivation . . . remedies." *Syngenta Crop Protection, Inc. v. U.S. E.P.A.*, 444 F.Supp.2d 435, 447 (M.D. N.C. 2006).

[14] *See* FIFRA Section 25(d), 7 U.S.C. § 136w(d).

affected by the NOIC to request a hearing to contest the conclusions of the NOIC, of which Gharda and Growers have availed themselves.

Petitioners also assert a due process violation stemming from the sequence in which EPA took the multiple steps required to comply with the Ninth Circuit's mandate: to address the chlorpyrifos tolerances and then to address the chlorpyrifos registered food uses. As discussed in Section VI.C, above, there is no requirement for EPA to act first under FIFRA (*e.g.*, use cancellation) before acting under the FFDCA (*e.g.*, tolerance revocation). In any event, Petitioners have been provided all due process—of which they have fully availed themselves—to challenge the decision to revoke tolerances, first in filing objections to the Final Rule (PX 8, 12, 52-67) and then in challenging the Final Rule and Denial Order in federal court (PX 18, 23).

Petitioners correctly note that a pesticide registration conveys certain property interests to the holder of said registration. Gharda Objections at 9 (citing *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010)).[15] However, the instant matter is easily distinguished from *Reckitt*, a case in which EPA sought to force a registrant to make changes to its registrations and labels or face a "misbranding" enforcement action pursuant to FIFRA Sections 12, 13, and 14, 7 U.S.C. §§ 136j, 136k, 136l. *Id.* at 1134-35. On remand, the district court ultimately determined that EPA lacked authority to bring a misbranding action in lieu of a cancellation proceeding, and enjoined the Agency from bringing such a misbranding action until the registrant was provided with the due process afforded by the regulatory procedures of FIFRA Section 6. *Reckitt Benckiser, Inc. v. Jackson*, 762 F.Supp. 2d 34, 35 (D. D.C. 2011). The present matter, by contrast, is proceeding under precisely the procedures provided by Congress in FIFRA Section 6.

[15] It is important to note that such rights are limited, and that "there is no property interest in using property in a manner that is harmful to the general public. *American Vanguard Corporation v. United States*, 142 Fed.Cl. 320, 328 (Ct. Fed. Cl. 2019) (citing *Mitchell Arms, Inc. v. United States*, 7 F.3d 212 (Fed. Cir. 1993)).

Petitioners' due process claims must be rejected because they have not demonstrated why—or what—additional procedures are justified. *See Atochem N. Am., Inc. v. U.S. E.P.A.*, 759 F.Supp. 861, 869 (D. D.C. 1991) (citing *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976)). Petitioners have been afforded adequate procedural protections—including this ongoing administrative litigation specifically provided for in FIFRA Section 6(b)—and have made no legal argument as to why cancellation of pesticide registrations or uses must precede revocation of tolerances that are necessary to support registration of those uses.[16]

VII. Conclusion

As explained above, the NOIC clearly makes an affirmative case for cancellation of Gharda's products. The only facts that are material to this proceeding are whether tolerances exist to cover residues of chlorpyrifos used on food and whether Gharda's registrations bear labeling for use on food. All parties agree that there are no tolerances for chlorpyrifos on any food and that Gharda's current labels and requested label amendments bear labeling for use on food. Therefore, under FIFRA, because there are no chlorpyrifos tolerances in place, no food uses of chlorpyrifos can remain registered. Petitioners do not raise any genuine issue of material fact, but rather attempt to inappropriately challenge the Final Rule and obfuscate the question before the Presiding Officer. Consequently, the Presiding Officer should grant this Motion for Accelerated Decision and issue a cancellation order for Gharda's chlorpyrifos products as proposed in the NOIC.

[16] While it is not relevant to the instant matter, Respondent also notes that Petitioners were provided with all statutory due process provided under the FFDCA with respect to the Final Rule. *See* JX 2 at 37-38, 41-42 (EPA responding to comments asserting due process violations).

Respectfully submitted,

FORREST PITTMAN

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing MOTION FOR ACCELERATED DECISION, dated August 25, 2023, was filed electronically with the U.S. Environmental Protection Agency, Office of Administrative Law Judges E-filing system, with a copy via electronic mail to the following:

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