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.	)	

INTERVENORS' MOTION FOR ACCELERATED DECISION

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INTRODUCTION

This proceeding involves the latest legally required action by Respondent U.S. Environmental Protection Agency ("Respondent EPA" or the "EPA") to protect people—and particularly infants and children—from serious health harms caused by chlorpyrifos. After years of scientific reviews documenting neurodevelopmental harm to children from low-level exposures to chlorpyrifos and numerous court rulings chastising EPA for unreasonable delay, EPA finally revoked all chlorpyrifos tolerances effective February 28, 2022, because EPA could not find chlorpyrifos safe under the applicable statutory standard. By starting the process of cancelling chlorpyrifos food-use registrations, EPA is taking the next step legally mandated by both the controlling statute and the Ninth Circuit in its order in *LULAC v. Regan*, 996 F.3d 673, 678 (9th Cir. 2021) ("*LULAC*").

Pursuant to 40 C.F.R. § 164.91(a)(7), Intervenors LULAC *et al.* (health, farmworker, civil rights, and labor advocacy organizations) hereby move for an accelerated decision because there are no genuine issues of material fact and Intervenors are entitled to judgment as a matter of law. The outcome of this proceeding turns on a single undisputed fact—EPA has revoked all chlorpyrifos tolerances because it could not find chlorpyrifos safe. Without such tolerances, the cancellation of chlorpyrifos food use registrations is legally foreordained. Issuing the Notice of Intent to Cancel Chlorpyrifos Registrations ("NOIC"), to initiate the cancellation process is also compelled by the court order in *LULAC*, which directed EPA to cancel chlorpyrifos registrations in a timely fashion after EPA revoked the associated tolerances. The NOIC makes out a prima facie case for cancellation, and Petitioners Gharda Chemical International, Inc., and the Petitioner grower organizations cannot meet their burden of proving that Gharda's chlorpyrifos products meet FIFRA's standards for continued registration. *See* 40 C.F.R. § 164.80(b) (proponent of registration bears burden of proof). Accordingly, this motion respectfully asks the

Tribunal to deny Petitioners' objections to the NOIC and enter an order cancelling Gharda's chlorpyrifos registrations.[1]

To avoid this legally compelled outcome, Petitioners' objections present issues that are beyond the proper scope of this proceeding. First, Petitioners repackage many of the arguments they have presented in their legal challenge to the Final Chlorpyrifos Tolerance Revocation Rule in the Eighth Circuit Court of Appeals. By filing that case in the spring of 2022, Petitioners availed themselves of the statutorily available mechanism for challenging the Final Rule and vested in the Eighth Circuit Court of Appeals exclusive jurisdiction over any challenges that can be presented to the Final Rule. Second, Petitioners also argue against cancellation based on economic impacts to growers and Gharda, but any such impacts stem from the tolerance revocation that has been in effect since February 2022 and are legally irrelevant under the stringent health-based standard governing food-use pesticide registrations. Finally, Gharda is being afforded the process due under the statutorily prescribed mechanisms for challenging the Final Rule and for contesting the NOIC. Accordingly, Intervenors are entitled to judgment as a matter of law, and this Tribunal should order cancellation of Gharda's chlorpyrifos registrations.

BACKGROUND

This motion begins by reviewing the controlling statutes, which Congress overhauled when it enacted the Food Quality Protection Act ("FQPA") in 1996, amending both the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). FQPA, Public Law No. 104-170, 110 Stat. 1489. The motion then walks through the administrative proceedings and court rulings that led to EPA's revocation of

[1] On August 25, 2023, Intervenors asked the other parties for their position on this motion. Respondent EPA has indicated it will not oppose, while both Petitioners have indicated they will oppose.

all chlorpyrifos tolerances. Finally, this motion describes the procedural history of this cancellation proceeding.

I. THE EVOLUTION OF THE HEALTH-BASED STANDARD GOVERNING FOOD USES OF PESTICIDES.

EPA regulates pesticides under two interconnected statutes: FIFRA governs the use of pesticides in the United States, and the FFDCA governs the allowable residues of pesticides on foods.

FIFRA requires EPA to register a pesticide before the pesticide can be marketed, sold, or distributed in the United States. 7 U.S.C. § 136a(a); *see also id.* § 136j(a). Under FIFRA, EPA cannot approve or maintain the registration of a pesticide unless it determines the pesticide will not generally cause "unreasonable adverse effects" to human health and the environment. 7 U.S.C. § 136a(c)(5); *see also id*. § 136d(b) (providing for cancellation of registrations of pesticide uses that cause unreasonable adverse effects). When EPA registers a pesticide, it approves a pesticide label, which must contain precautions and directions for use that will avoid unreasonable adverse effects to health and the environment. *Id*. § 136j(a)(2)(G).

Ever since Congress amended FIFRA in 1972 to contain stronger health and environmental safeguards, it has defined an "unreasonable adverse effect on the environment" as "any unreasonable risk to [people] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." *Id*. § 136(bb). Under this standard, once EPA identifies a risk of concern from using a pesticide, it weighs that risk against the benefits of using the pesticide and may approve the pesticide's registration if "the benefits outweigh that risk." *Env't Def. Fund v. EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976), *abrogated on other grounds by Dir., Off. Of Workers' Comp. Programs, Dep't of Lab. v. Greenwich Collieries*, 512 U.S. 267 (1994).

Under the FFDCA, EPA must establish a "tolerance" setting the maximum residue of a pesticide allowed on food for a pesticide to be permitted on that food imported or sold in interstate commerce. 21 U.S.C. § 346a(b). A food containing pesticide residues that exceed or lack a tolerance is deemed unsafe. *Id*. § 346a(a)(1). EPA must set tolerances at levels that ensure the food is safe. *Id*. § 346a(b)(2)(A)(i). Like FIFRA's risk-benefit balancing, EPA historically balanced safety against other considerations in deciding whether to set tolerances and at what levels. *See LULAC,* 996 F.3d at 692.

This changed when Congress overhauled our food safety laws in 1996 by passing the FQPA to prioritize health and children's health, in particular. The FQPA responded to a ground-breaking National Academy of Sciences ("NAS") report entitled *Pesticides in the Diets of Infants and Children*, which criticized EPA for treating children like "little adults" and failing to address the unique susceptibility of children to pesticide exposures based on the foods they eat, their play, metabolism, and sensitive stages of their development.[2] For example, infants drink seven times more per body weight than adults, inhale twice as much air, and put their hands in their mouths far more often than adults. Of particular relevance to chlorpyrifos, toxic chemicals can damage the child's developing brain during sensitive stages of development (*in utero*, infancy, and adolescence) at lower exposures than those that affect adults. *Id*. at 9, 60-63.

The FQPA revamped our food safety laws in three fundamental ways: (1) it strengthened the safety standard by basing it solely on risks to human health, providing enhanced protection to children, and requiring EPA to account for all the ways people are exposed to a pesticide that is used on food; (2) it unified the standards that apply to residues of pesticides on food and

[2] Available at Committee on Pesticides in the Diets of Infants and Children, National Research Council, *Pesticides in the Diets of Infants and Children* (1993)(ebook), https://www.ncbi.nlm.nih.gov/books/NBK236275/pdf/Bookshelf_NBK236275.pdf.

registrations of the pesticides under FIFRA; and (3) it established mechanisms for bringing old pesticides into compliance with the food safety standards as new scientific evidence of harm emerges.

More specifically, the FQPA amended Section 408 of the FFDCA to provide that EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). As amended, "safe" means "the Administrator has determined there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. § 346a(b)(2)(A)(ii). In making this determination, EPA must protect against aggregate exposures from all sources combined, whether from eating foods, drinking water, breathing air near the fields, or playing and rolling around on treated fields or carpets, in contrast to EPA's prior practice of considering each exposure separately. *Id.*; *Id.* § 346a(b)(2)(C)(i)(I), (D)(vi).

The FQPA further requires that EPA make specific safety determinations for each age group of infants and children and afford children additional protections when there are gaps in available data or when they have particular susceptibilities, including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id.* § 346a(b)(2)(C)(i)(II); *id.* § 346a(b)(2)(C)(ii)(I),(II).[3] Through these amendments, the FQPA

[3] The FQPA requires that "an additional tenfold margin of safety . . . shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Id*. § 346a(b)(2)(C), (D). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id*.; *Nw. Coal. For Alts. To Pesticides v. EPA*, 544 F.3d 1043, 1046, 1052 (9th Cir. 2008).

imposed an "assurance of safety for human health" as an uncompromising limitation on EPA's authority. *See LULAC*, 996 F.3d at 678, 692-93.

Of critical importance for this proceeding, Congress incorporated the FQPA's health-protective food safety standard into FIFRA's standard for registration of pesticides. The FQPA broadened the definition of "unreasonable adverse effect" to incorporate the new health-based standard for issuing tolerances. The FQPA did this by expanding the definition of "unreasonable adverse effect" to include "(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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a)." H.R. Rep. No. 104-669, pt. 1, at 30 (1996). This amendment incorporated the FQPA's reasonable certainty of no harm standard into FIFRA. It thereby created a unified, health-based standard governing both tolerances and registrations of pesticides for use on food. Accordingly, if a pesticide fails to meet this heightened health-based standard, it is not only ineligible for a food tolerance, but also cannot be registered for that food use.

II. EPA'S REVOCATION OF CHLORPYRIFOS TOLERANCES.

This proceeding grows out of EPA's revocation of chlorpyrifos tolerances, which was precipitated by a 2007 Petition, a series of EPA findings of serious harm to children from chlorpyrifos, and numerous court orders, including the Ninth Circuit's order in *LULAC*.

Chlorpyrifos is an organophosphate, a class of chemicals developed as nerve agents in World War II and later adapted for commercial pesticide use. It has been used on an extensive variety of food and feed crops, including foods eaten by children like apples, peaches, nectarines, pears, grapes, cherries, oranges, and strawberries. RX 23 at 398-447 (EPA 2014 Dietary Risk Assessment, Appendices 8 & 9).

Organophosphates have deleterious effects on people through inhalation, ingestion, eye contact, and absorption through the skin. They cause acute poisonings because they disrupt the proper functioning of the nervous system by suppressing an enzyme called acetylcholinesterase ("AChE") or cholinesterase. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, dizziness, difficulty breathing, vomiting, diarrhea, muscle spasms, seizures, skin rashes, and at very high exposures, convulsions, respiratory paralysis, and even death. IX 5 at 22.

The FQPA directed EPA to reregister old pesticides, including organophosphates, within ten years under the newly strengthened health-based standard. 7 U.S.C. § 136a-1. EPA prioritized the reregistration of organophosphates, including chlorpyrifos, because of their neurotoxicity and prevalence on foods children eat. In 2000, EPA ended chlorpyrifos use in and around homes, schools, daycares, parks, and hospitals because of acute poisoning risks to children. 65 Fed. Reg. 76,233 (Dec. 6, 2000); 66 Fed. Reg. 47,481 (Sept. 12, 2001). When EPA completed reregistration of the organophosphates as a class in 2006, it allowed dozens of agricultural uses of chlorpyrifos to continue. EPA based its 2006 safety determinations solely on acute poisoning risks, using a regulatory endpoint of 10% reduction of cholinesterase in red blood cells, a reduction that is a precursor to, but not believed to cause, acute poisonings. 86 Fed. Reg. 48,315, 48,318-19, 48,325 (Aug. 30, 2021) (JX 1, pgs. 1, 4-5,); 87 Fed. Reg. 11,222, 11,231-33 (Feb. 28, 2022) (JX 2, pgs. 1, 10-12).

A. EPA's Failure to Act on a 2007 Petition to Protect Children from Neurodevelopmental Harm from Chlorpyrifos Exposures.

In 2007, two Intervenor groups—Natural Resources Defense Council ("NRDC") and Pesticide Action Network North America ("PANNA")—filed a petition ("the 2007 Petition") asking EPA to revoke chlorpyrifos tolerances based on published, peer-reviewed studies

correlating low-level prenatal exposures with significantly elevated risks of autism, attention deficit hyperactivity disorder, and reduced IQ. IX 1. Based upon comprehensive reviews of the scientific evidence, EPA and its Scientific Advisory Panel ("SAP"), created by 7 U.S.C. § 136w(d), subsequently and repeatedly found that prenatal exposures to chlorpyrifos at levels far below those that would cause 10% cholinesterase inhibition result in learning disabilities and other neurodevelopmental harm to children. RX 25, 26 & 36; *LULAC*, 996 F.3d at 682, 686, 688 n.85, 701.

Based on these findings, EPA's 2014 revised human health risk assessment found that low-level exposures to chlorpyrifos cause permanent neurodevelopmental harm to children. RX 23 at 26, 48-49. The risk assessment further found that chlorpyrifos uses would result in exposures exceeding EPA's drinking water levels of concern, particularly in agricultural areas, and monitoring data confirmed that finding. *Id.* at 11, 88-91.

Despite these findings, EPA took no regulatory action on chlorpyrifos. Thus, Intervenor organizations pursued litigation challenging EPA's unreasonable delays, which resulted in court orders requiring EPA to act on the 2007 Petition. *In re PANNA*, 798 F.3d 809 (9th Cir. 2015) (writ of mandamus directing EPA to end "egregious" delays in addressing the "considerable human health interests" presented by chlorpyrifos); *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016) (2017 deadline to take final action on 2007 petition).

By a 2015 court deadline, EPA proposed revoking all chlorpyrifos tolerances. 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015) ("Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances."). The proposed rule indicated that EPA would continue reviewing the evidence of long-lasting neurodevelopmental harm to children from low-level exposures to derive an exposure level that

would be safe for children and would refine EPA's drinking water assessment. *Id*. at 69,080, 69,085, 69,104, 69,106.

In 2016, EPA released an updated risk assessment that derived a level of exposure sufficient to prevent learning disabilities and other neurodevelopmental harm to children. RX 33 (described in 86 Fed. Reg. at 48,319, 48,321 (JX 3, pgs. 5, 7); 87 Fed. Reg. at 11,235 (JX 2, pg. 14) Using that limit, instead of 10% cholinesterase inhibition, EPA found chlorpyrifos unsafe every way people are exposed. 87 Fed. Reg. at 11,233 (JX 2, pg. 12) (food and drinking water). Food-only exposures for chlorpyrifos were found to be unsafe for all populations, with toddlers facing risks of more than 14,000% of safe levels in food. *LULAC*, 996 F.3d at 687-89. And based on a refined drinking water assessment, EPA continued to find that most drinking water exposures continued to exceed safe levels. RX 34 (described in 87 Fed. Reg. at 11,237, 11,249, 11,257) (JX 2, pgs. 16, 28, 36). Meanwhile, California similarly derived an endpoint to protect children from neurodevelopmental harm based on animal studies and found chlorpyrifos unsafe. California initiated cancellation proceedings that culminated in Dow Agrosciences (now called Corteva Agriscience), the primary maker of chlorpyrifos at the time, agreeing to stop making chlorpyrifos by the end of 2020. IX 4 at 14 (citing California evaluations); Verified Written Statement of Ram Seethapathi ¶ 4 (July 14, 2023).

After a change in presidential administrations, EPA abruptly reversed course. Facing a March 31, 2017, court deadline to take final action on the 2007 Petition, the new EPA Administrator denied the petition because he wanted to continue studying the science before finalizing the tolerance revocation or taking another course of action. RX 56. Intervenors and several states challenged this denial by filing administrative objections and a lawsuit, which resulted in a 2019 court deadline for EPA to rule on their objections. *See LULAC v. Wheeler*, 922

F.3d 443, 445 (9th Cir. 2019) (en banc) (2019 deadline to rule on objections). By that deadline, EPA denied the objections preferring to address neurodevelopmental harm to children in the registration review process. RX 57. Intervenors and the states challenged EPA's denials in the Ninth Circuit Court of Appeals.

In December 2020, during the pendency of that lawsuit and in the waning days of the Trump Administration, EPA released for public comment a proposed interim registration review decision that concluded that aggregate exposures from currently registered chlorpyrifos uses are unsafe. PX 41 (Chlorpyrifos Proposed Interim Registration Review Decision (Dec. 2020), "2020 PID"). Even though the human health risk assessment underlying the 2020 PID identified neurodevelopmental harm to children as an effect of concern from chlorpyrifos, it reverted to the 2014 risk assessment's regulatory endpoint of 10% cholinesterase inhibition instead of using the more protective endpoints from its 2016 risk assessment or California's risk assessment. PX 38 at 2 (2020 Human Health Risk Assessment). Using this underprotective endpoint, the 2020 PID suggested that 11 chlorpyrifos uses might not exceed EPA's modified level of concern if used in only limited geographies and subject to substantial usage restrictions. 2020 PID at 40-41. The PID relied on a 2020 drinking water assessment that used untested methodologies that had never been used in EPA drinking water assessments, even though monitoring data documented chlorpyrifos concentrations above EPA's modified level of concern. 2020 PID at 17; PX 39 (2020 Updated Drinking Water Assessment). Because the proposal was predicated on far more limited usage than allowed under the current labels, EPA proposed label changes to limit use to certain watersheds, reduce application rates, and constrain application methods. 2020 PID at 16-17, 40-41, 64.

EPA solicited public comment on the 2020 PID and underlying assessments. Comments submitted by Intervenors, several states, and leading scientific experts revealed fundamental flaws in EPA's new drinking water assessment methodologies and in EPA's use of a regulatory endpoint that would not protect children from neurodevelopmental harm. IX 5 (Intervenors' Comments); IX 7 at 27-31 (Intervenors' Amicus Brief describing comments submitted by states and leading scientists). Under its regulations, EPA must address these public comments before finalizing or implementing the 2020 proposal. 40 C.F.R. § 155.58.

B. The Ninth Circuit Ordered EPA to Grant the 2007 Petition, Revoke or Modify Chlorpyrifos Tolerances, and Cancel Associated Registrations.

On April 29, 2021, the Ninth Circuit held that EPA could not lawfully deny the 2007 Petition and leave chlorpyrifos tolerances in place without making an affirmative finding that there would be a reasonable certainty of no harm to children. *LULAC*, 996 F.3d at 693-94. The court further concluded that EPA could not find chlorpyrifos safe based on the many EPA and SAP findings of neurodevelopmental harm to children from low-level chlorpyrifos exposures. *Id*. at 686-88, 700-01. Based on unbroken EPA and SAP findings that chlorpyrifos harms children's brains at exposures below those associated with 10% cholinesterase inhibition, the court concluded:

> On the present record, the only reasonable conclusion the EPA could draw is that the present tolerances are not safe within the meaning of the FFDCA. The EPA can find a tolerance safe only if there is "a reasonable certainty" of "no harm," and for nearly a decade, the EPA and its SAPs have concluded that there is *not* a reasonable certainty of no harm[.]

Id. at 700 (emphasis in original); *see also id.* at 701 ("EPA has not determined, and on this record reasonably could not determine to a 'reasonable certainty' that aggregate chlorpyrifos exposures under the current tolerances pose no risk of harm.").

The Ninth Circuit ordered EPA to grant the 2007 Petition and issue a final rule revoking all chlorpyrifos tolerances or possibly retaining some modified tolerances if it could, based on newly completed research, find the modified tolerances safe, in the aggregate, for infants and children. *Id*. at 703-04. EPA could modify tolerances, rather than revoke them, only if it could make an affirmative finding that reasonable certainty of no harm would result from aggregate exposures, including to children. *Id*. at 702. The court indicated that "it may well be that the EPA cannot make such a determination" given EPA's past findings, confirmed by the SAP, of neurodevelopmental harm to children from exposures below those allowed under EPA's tolerances. *Id*. at 702-03.

The court gave EPA an August 2021 deadline to revoke or modify chlorpyrifos tolerances to end the "egregious" multi-year delays that "exposed a generation of American children to unsafe levels of chlorpyrifos." *Id*. at 703. The court further ordered EPA to "modify or cancel the related FIFRA registrations for food use in a timely fashion consistent with the requirements of" the FFDCA standards incorporated into FIFRA. *Id.* at 704.

C. EPA Revoked All Chlorpyrifos Tolerances Because it Could Not Find Them Safe.

EPA issued the Chlorpyrifos Revocation Rule by that deadline because it could not affirmatively find reasonable certainty of no harm to children from all aggregate exposures to the pesticide. 86 Fed. Reg. 48,315, 48,317 (Aug. 30, 2021) ("Final Rule") (JX 3). The Final Rule reiterated the findings of the comprehensive scientific reviews by EPA and its SAP, which repeatedly and consistently found that chlorpyrifos causes learning disabilities and neurodevelopmental harm at exposures below EPA's tolerances. *See id*. at 48,320-21, 48,324-25. Because EPA could not find reasonable certainty of no harm to children from aggregate exposures to chlorpyrifos, it revoked all chlorpyrifos tolerances. *Id*. at 48,333.

Pursuant to 21 U.S.C. § 346a(g)(2), Petitioners filed objections to the Final Rule, making many of the same arguments they are making in this proceeding. PX 8-9, 12, 53-66. Intervenors also submitted feedback through the objections process, reminding EPA that it cannot retain chlorpyrifos tolerances without addressing Intervenors' longstanding objections to EPA's use of a regulatory endpoint that will not protect children from neurodevelopmental harm. IX 4.

EPA denied all objections and requests to stay the Final Rule. 87 Fed. Reg. 11,222 (Feb. 28, 2022) (JX 2). EPA considered Intervenor organizations' feedback unripe for consideration because EPA left the Final Rule in place and committed to address Intervenors' comments if faced with petitions to establish chlorpyrifos tolerances. 87 Fed. Reg. at 11,270-71 (JX 2, pgs. 49-50). Under the Final Rule, the tolerance revocations became effective on February 28, 2022. As of that date, chlorpyrifos cannot be used on food, chlorpyrifos products with labels authorizing food uses are misbranded because the label is false or misleading in violation of 7 U.S.C. §§ 136(q)(1)(A) & 136j(a)(1)(E), and applications of chlorpyrifos on food render the food adulterated and ineligible to be distributed in interstate commerce. Frequent Questions about the Chlorpyrifos 2021 Final Rule #3, at 2, # 10 at 6, #12 at 7 (RX 45).

D. Petitioners' Eighth Circuit Challenge to the Final Chlorpyrifos Tolerance Revocation Rule.

Pursuant to 21 U.S.C. § 346a(h)(1), Petitioners filed a petition for review of the Final Rule in the Eighth Circuit Court of Appeals, presenting many of the same arguments they press in this proceeding. *Red River Valley Sugarbeet Growers Assoc. v. Regan*, Nos. 22-1420, 22-1530 (8th Cir.) ("*RRVSGA*"). The filing of the petition for review gave that court "exclusive jurisdiction to affirm or set aside" the Final Rule, 21 U.S.C. § 346a(h)(2), and had the effect of precluding judicial review under any other provision of law for "[a]ny issue as to which review is or was obtainable" in that lawsuit. *Id*. § 346a(h)(5). Petitioners sought a stay of the Final Rule

pending appeal, which the Eighth Circuit denied. *RRVSGA* No. 22-1422 (8th Cir. May 15, 2022). As a result, the tolerance revocation has been in effect since February 28, 2022.

The parties have fully briefed the case. Intervenors submitted an amicus brief in support of EPA. IX 7. The case was argued on December 15, 2022, and is awaiting decision.

E. This Cancellation Proceeding.

After revocation of the chlorpyrifos tolerances, EPA asked chlorpyrifos registrants to request voluntary cancellation of their food-use registrations for chlorpyrifos. RX 1. All chlorpyrifos registrants have complied with this request, except one. 87 Fed. Reg. 76,474, 76,476 (Dec. 14, 2022) (JX 1, pgs. 1, 3). Gharda is the only holdout. *Id*. Gharda has requested voluntary cancellation of all food uses except for the 11 that the 2020 PID indicated might be safe. JX 9-11, 16, 88 Fed. Reg. 37,875 (June 9, 2023) (JX 16).

On December 14, 2022, EPA issued the Notice of Intent to Cancel Chlorpyrifos Registrations ("NOIC") to cancel Gharda's chlorpyrifos registrations. The NOIC explained that EPA issued the NOIC to comply with the Ninth Circuit's directive to cancel food use registrations "in a timely fashion" after it revoked the chlorpyrifos tolerances. 87 Fed. Reg. at 76,479 (JX 1, pg. 6). Because chlorpyrifos tolerances have been revoked, the NOIC expressly disallows any continued food uses of existing stocks or any movement of existing stocks, except for transporting stocks for lawful disposal consistent with state law or registrant return programs. *Id*. at 76,477-78. Gharda could have avoided this cancellation proceeding if it had voluntarily terminated all food use registrations and removed all food uses from the labels, but it refused. *Id*. at 76,478.

Instead, on January 13, 2023, both Gharda and the Grower Petitioners filed requests for a hearing and objections to the NOIC, thereby initiating this proceeding. Petitioners' merits-based objections largely repeat the arguments they presented in their Eighth Circuit challenges to the

Final Rule; they also assert that EPA failed to comply with the procedural steps for issuing an NOIC. Gharda Request for Hearing & Statement of Objections (Jan. 13, 2023) ("Gharda Obj."); Grower Petitioner Request for Hearing & Statement of Objections (Jan. 13, 2023) ("Grower Obj.").

Over Petitioners' objections, this Tribunal granted Intervenors intervention. Order Granting Intervention (May 22, 2023). The Tribunal denied Petitioners' request for a stay and denied certification of that denial to the Environmental Appeals Board ("EAB"). Order Denying Stay (Mar. 31, 2023); Order Denying Certification to EAB (May 22, 2023). The EAB denied Petitioners' request for certification of that denial for interlocutory appeal. EAB Order Denying Interlocutory Review (July 14, 2023).[4]

As required by this Tribunal's prehearing procedures, the parties have submitted prehearing exchanges. Although both Petitioners and Respondent have submitted sworn witness statements, the witnesses address either uncontested background facts or irrelevant issues. The pivotal issue is EPA's revocation of chlorpyrifos tolerances, which no one can dispute has occurred. This case can be resolved as a matter of law because, without tolerances in place, the remaining chlorpyrifos registrations legally must be cancelled.

ARGUMENT

Once EPA revoked all chlorpyrifos tolerances, cancellation of chlorpyrifos registrations for food uses became a foregone conclusion. When Congress incorporated the FFDCA food safety standard into FIFRA, it created a unified health-based system, eliminating any daylight

[4] These denials resolve Petitioners' objections alleging interference with the Eighth Circuit's jurisdiction and asserting harm from allowing this proceeding to continue before the Eighth Circuit challenge has been fully resolved. *See* Gharda Obj. at 6-7, 10-13; Grower Obj. at 3-4 10-11, 20-21.

between the standards governing pesticide registrations for food uses and tolerances for the pesticide on those foods. Under the amended laws, EPA can maintain tolerances and food-use registrations only if EPA finds reasonable certainty of no harm generally and specifically for children from aggregate exposures to the pesticide in food, drinking water, and residential exposures, including from spray drift. If EPA cannot make this finding, which it cannot for chlorpyrifos, the tolerances violate the FFDCA and the associated registrations violate FIFRA.

The Ninth Circuit recognized this interdependence when it ordered EPA to grant the 2007 Petition. It gave EPA a 60-day deadline to revoke or modify chlorpyrifos tolerances and directed EPA to cancel associated registrations in a timely fashion after it revoked tolerances. As required by that order, EPA issued the Final Rule upon finding aggregate exposures to chlorpyrifos unsafe. This finding and the revocation of the tolerances make cancellation of the associated registrations inevitable and dictate resolution of this proceeding in Intervenors' and EPA's favor.

The bulk of Petitioners' remaining NOIC objections repackage their challenges to the Final Rule. Thus, they argue that the Final Rule is arbitrary and capricious because it failed to allow 11 uses featured in EPA's 2020 proposal and is allegedly contrary to the scientific evidence. Gharda Obj. 5, 7-10; Growers' Obj. 4-10. However, Petitioners have challenged the Final Rule in the Eighth Circuit, which has exclusive jurisdiction over all challenges to the tolerance revocation. Accordingly, as this Tribunal has recognized, Petitioners cannot present their challenges to the Final Rule in this proceeding. *See infra* at 24-25. EPA issued the NOIC pursuant to FIFRA's required procedures and Gharda has been afforded due process as it has fully availed itself of the statutory mechanisms for challenging both tolerance revocations and the NOIC. It is entitled to nothing more.

I. CHLORPYRIFOS' FOOD USE REGISTRATIONS MUST BE CANCELLED AS A MATTER OF LAW BECAUSE CHLORPYRIFOS TOLERANCES HAVE BEEN REVOKED.

The outcome of this proceeding hinges on a single undisputed fact – EPA revoked all chlorpyrifos tolerances because it could not find reasonable certainty of no harm from chlorpyrifos as required to maintain tolerances under the FFDCA. That revocation has an additional legal consequence under both FIFRA and *LULAC.* It mandates cancellation of the associated registrations.

A. Congress Made Food-Use Registrations Dependent on Compliance with FFDCA Section 408.

When Congress overhauled our food safety laws in 1996, it expressly incorporated the new health-based food safety standard into FIFRA. EPA can register a pesticide only if it determines the pesticide will "not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). Before the FQPA, FIFRA defined "unreasonable adverse effects on the environment" as "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." The FQPA added a second definition that embedded the new food safety standard into FIFRA. Accordingly, "unreasonable adverse effects on the environment" now includes "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]." 7 U.S.C. § 136(bb).[5]

[5] Even before the FQPA expressly made FIFRA food-use registrations dependent on tolerances being in place, EPA's regulations authorized EPA to register a pesticide for food uses only if "all necessary tolerances [or] exemptions from the requirement of a tolerance . . . have been issued under FFDCA sec. 408[.]" 40 C.F.R. § 152.112(g). This regulation, which remains in effect, reflects the common-sense proposition that EPA cannot register a pesticide for use on food or approve labels representing that it can be used on food if it lacks the required tolerances and therefore cannot be used on food.

Section 408 provides that EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). To find a tolerance safe, the Administrator must find generally for adults and specifically for children "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. § 346a(c)(2)(A). Accordingly, where a pesticide fails to pass muster under Section 408's reasonable certainty of no harm standard, it is deemed to cause unreasonable adverse effects to health and is ineligible for registration under FIFRA.

Not only does FFDCA Section 408 establish this stringent, health-based safety standard, but it also prescribes how EPA is to determine whether a pesticide passes muster under this safety standard. Section 408 directs EPA, for example, to afford infants and children special protections based on their exposure patterns and gaps in data, to consider specific information in its pesticide risk assessments, including children's special susceptibility to neurodevelopmental harm from exposure to pesticides, and to ensure all aggregate exposures to a pesticide will be safe. *Id*. § 346a(b)(2)(C)(i), (ii). Based on its risk assessments and safety findings, EPA sets tolerances by promulgating tolerance regulations. *Id*. § 346a(d)(4)(A).

EPA issued the Final Rule because it could not find reasonable certainty of no harm from aggregate exposures to chlorpyrifos from uses on food. EPA's inability to make a safety finding for chlorpyrifos means the human dietary risks are inconsistent with Section 408 and constitute unreasonable adverse effects on health within the meaning of FIFRA. The Final Rule, therefore, predetermined the outcome of this cancellation proceeding as a matter of law.

B. *LULAC* Compels Cancellation of Chlorpyrifos Registrations for Food Uses that Lack Tolerances.

In *LULAC*, the Ninth Circuit recognized the inevitability of cancelling chlorpyrifos registrations for uses that no longer have tolerances. The 2007 Petition sought both revocation of chlorpyrifos tolerances and cancellation of the associated registrations. The court ordered EPA to grant the Petition and revoke or modify tolerances within 60 days to end EPA's incessant, unreasonable delays. It further ordered EPA to cancel the associated registrations because food uses are not permitted without tolerances in place. The court prioritized the tolerance revocations because they are the driver under both FFDCA and FIFRA and to ensure expeditious action to protect children from learning disabilities and other harm from chlorpyrifos exposures. The court gave EPA additional time to cancel the registrations because cancellation after tolerance revocation would require compliance with procedures, including the possibility of a hearing, that take longer than 60 days.

Acting on the directive from the Ninth Circuit, EPA revoked chlorpyrifos tolerances because it could not "make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA Section 408(b)(2). 21 U.S.C. § 346a(b)(2)."). 86 Fed. Reg. at 48,317 (JX 3, pg. 3). That finding and action dictate the outcome of the cancellation process because EPA determines consistency with Section 408 through the tolerance-setting process. EPA had no discretion to sit on this finding under *LULAC.* As the EAB recognized, "EPA *must* comply with the mandate of the Ninth Circuit Court of Appeals" to cancel related FIFRA registrations for food use in a timely fashion after revocation of the tolerances. EAB Order Denying Interlocutory Appeal at 1-2, 5. Accordingly, EPA issued the NOIC to comply with the Ninth Circuit's order to cancel the associated registrations "in a timely fashion." Issuing the NOIC was thus compelled by both FIFRA and *LULAC.*

C. The Incorporation of FFDCA Section 408 Into FIFRA Resolves Petitioners' Other Merits Arguments.

The integration of Section 408 into FIFRA's unreasonable adverse effects standard resolves Petitioners' substantive objections to cancellation. First, in establishing a purely health-based standard for allowing the use of pesticides on food, Congress made a concerted decision not to allow public health to be sacrificed to avoid the economic impacts of shifting to alternative pest control methods. Second, Congress directed that challenges to EPA's Section 408 determinations proceed through objections followed by judicial review in the courts of appeal and precluded review of the underlying issues in any other forum, including this one. These congressional determinations render Petitioners' objections based on economic impacts and the Final Rule's validity outside the scope of this proceeding.

1. Congress Prioritized Ensuring Pesticide Use on Food Would Be Safe, Even if Shifting to Alternatives Would Have Economic Impacts.

In enacting the FQPA, Congress established a single, health-based standard for all pesticides on foods, eliminating longstanding problems posed by the prior inconsistent standards. EPA had previously balanced health against other factors like economic considerations in setting food tolerances for pesticides. *LULAC*, 996 F.3d at 692 (before the FQPA, "the EPA interpreted the FFDCA to permit the balancing of safety against other considerations, such as economic factors"); *see also* H.R. Rep. No. 104-669, pt. 2, at 40 (1996) (EPA was authorized to consider "factors including the necessity for production of an adequate, wholesome, and economical food supply.")

In the FQPA, Congress "abrogated that approach" and "made the explicit decision to prioritize safety over all else." 996 F.3d at 692. By making reasonable certainty of no harm from aggregate exposures the uniform safety standard and requiring that EPA make an affirmative finding of safety, Congress conditioned pesticide use on food on meeting this strict health-based

standard, regardless of the costs of shifting to alternative pesticide control methods. *See* 142 Cong. Rec. H8127, 8143 (daily ed. July 23, 1996) (Statement of Rep. Waxman) ("The starting point for the FQPA was the creation of a single health-based standard that will apply to all foods"); *see also LULAC,* 996 F.3d at 678 ("EPA's discretion to set such tolerances is circumscribed, however, by an uncompromisable limitation: the pesticide must be determined to be safe for human beings"); *id*. at 693 ("EPA's obligations under the FFDCA are linked to a single issue, safety"); *id*. at 693-94 ("The FFDCA imposes an overarching obligation that the EPA protect human safety, and particularly the safety of infants and children").

Section 408 allows consideration of factors other than health only in limited circumstances that are inapplicable here. For cancer-causing pesticides where there is no known level of exposure at which no harm is anticipated (called "nonthreshold effects"), EPA may set a higher tolerance level than would be permitted for other pesticides as "necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B), (B)(iii)(II). However, the risks of harm cannot be significantly greater than what would be safe for the general populations and, importantly, EPA still must find aggregate exposures safe for children. *Id*. § 346a(b)(2)(B)(iv) (limits on extent to which the risks can exceed safe levels for the general population); *id.* § 346a(b)(2)(B)(vi) (the tolerance must be safe for infants and children); *see also LULAC*, 996 F.3d at 692 n.108, at 702 n.166. This provision shows that Congress knew how to allow EPA to consider significant disruptions to food production, but it limited that authority to cancer-causing pesticides and denied it to EPA when it is setting tolerances for other pesticides, like chlorpyrifos.

In setting such tolerances, Section 408 mandates a "singular focus on safety" and "explicitly prohibit[s] the EPA from balancing safety against other considerations, including

economic or policy concerns." *LULAC,* 996 F.3d at 693 n.112, 696. Nonetheless, Petitioners' objections ask this Tribunal to prevent cancellation of Gharda's chlorpyrifos food-use registrations based on the impacts of shifting to alternative pesticides. The Grower Petitioners argue that EPA erred by not considering the impacts of cancellation on growers, Growers Obj. at 11-19, and they have submitted eight witness statements describing the economic impacts to growers of various food crops if the Eighth Circuit rules in favor of Petitioners after chlorpyrifos registrations have been cancelled. Verified Written Statements of Michael Aerts, John Walt Boatright, III, Chris Butts, Neil Brodie Griffin, Luther Markwart, Peter Nelson, Ben Scholz, Jordan Scott. For its part, Gharda challenges the NOIC for failing to consider the economic harm to its business interests from not being able to continue selling chlorpyrifos products in the United States after it ramped up its production of chlorpyrifos in 2021 when Dow/Corteva left the market, and it has submitted witness statements elaborating on such impacts and on the costs it would incur to have its registrations reinstated should the Eighth Circuit rule in its favor. Gharda Obj. at 10-13; Verified Written Statements of Ram Seethapathi and Stephanie H. Stephens.

This evidence and the associated arguments are legally irrelevant because it is the tolerance revocations that have precluded sales and use of chlorpyrifos, not cancellation of the associated chlorpyrifos registrations. Both Gharda and the growers concede that chlorpyrifos sales and usage had to cease after the tolerance revocations became effective. Gharda Obj. at 6-7 (conceding "EPA's tolerance revocations made distribution or use unlawful" and reiterating its commitment "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"); *id.* at 13 ("there are no

chlorpyrifos products approved for use on food currently in the stream of commerce"); Growers Obj. at 8-9, 18 (same).

The economic impacts of cancellation are also immaterial because Congress decided to make the safety of our food the sole factor governing EPA's regulation of pesticides use on food. It is that congressional decision to prioritize the protection of our food supply and children's health that precludes consideration of the economic impacts of cancelling registrations of food-use pesticides that fail to meet the reasonable certainty of no harm standard. For this reason, Petitioners' economic impact arguments and evidence are immaterial and cannot change the outcome of the cancellation process.[6]

2. Petitioners' Objections to the Final Rule are Beyond the Scope of this Proceeding.

As explained above, FIFRA's unreasonable adverse effects definition expressly incorporates FFDCA Section 408, thereby creating a unified reasonable certainty of no harm standard governing tolerances and registrations. In addition to laying out the safety standard and the process for making safety determinations, Section 408 establishes the process for challenging tolerance revocation rules, allowing any person to file objections to the rule and to seek judicial review in a U.S. Court of Appeals after EPA rules on the objections. 21 U.S.C. § 346a(g)(2); *id.*

[6] While the impacts to growers of shifting to other pesticide control methods may be considered as part of the risk-benefit balancing for nonfood pesticides uses, Intervenors are aware of no precedent factoring a pesticide company's profits into food safety determinations. Before the FQPA, EPA considered whether limiting use of a pesticide would disrupt the domestic production of an adequate and wholesome food supply, not whether a foreign company could continue to reap profits from selling a pesticide that is harmful to human health or the environment. *Nat'l Coal. Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875 (D.C. Cir. 1987) (EPA could consider economic factors only to the extent related to public health and necessity for the production of an adequate, wholesome, and economical domestic food supply).

§ 346a(h)(1). By filing objections and thereafter seeking review in the Eighth Circuit Court of Appeals, Petitioners have availed themselves of these opportunities to challenge the Final Rule.

Section 408 gives the Eighth Circuit exclusive jurisdiction over all challenges to the Final Rule. It 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 under 21 U.S.C. § 346a(h)(1), that "court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part." *Id*. § 346a(h)(2). As this Tribunal explained: "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." Order Denying Stay at 6 (citing *id*. § 346a(h)(5) and adding emphasis). Accordingly, as this Tribunal stated, there can 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 Denying Stay at 6; *see also id*. (Section 408 "limits the issues the parties may raise here"). This Tribunal reiterated in granting intervention that "this Tribunal cannot now adjudicate any issues related to the Final Rule's legality" because it is currently the subject of an appeal before the Eighth Circuit. Order Granting Motion to Intervene at 3. Accordingly, any challenges to the Final Rule, along with any issues related to it, cannot be heard in this proceeding. *See Nat. Res. Def. Council v. Johnson*, 461 F.3d 164, 172-73 (2nd Cir. 2006) (noting Section 408(h)(1) is "quite expansive," extending to "[a]ny issue" that could be raised, rather than being limited to certain defined actions or decisions).

a. Petitioners' Objections Seeking Retention of 11 Uses Referenced in the 2020 Proposal Cannot be Heard in this Proceeding.

Despite this bar on duplicative litigation of the Final Rule's validity, Petitioners have filed objections arguing that the Final Rule is contrary to law and questioning the science underlying the Final Rule. Gharda Obj. at 5, 7-10; Growers' Obj. at 4-10. The central focus of Petitioners' objections is the 2020 proposal. They argue that EPA should have allowed retention of tolerances for 11 uses that the proposal suggested might be safe under dramatically altered use restrictions. *Id*. Petitioners have made the very same argument before the Eighth Circuit. PX 25 (Pet'rs 8th Cir. Opening Br. at 17-20). The Eighth Circuit has exclusive jurisdiction to decide these issues and Section 408 bars review of them in any other proceeding, including this one, as this Tribunal has recognized.

Petitioners seize upon Section 6(b)'s language requiring the Administrator to consider "restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for those restrictions[.]" 7 U.S.C. § 136d(b). The alternative they prefer is retention of the 11 uses featured in the 2020 proposal. Petitioners' argument is nothing less than a backdoor way to invite this Tribunal to review whether the Final Rule and cancellation should conform to the unfinalized 2020 proposal. This attempt to litigate the Final Rule and PID issues must fail because the Eighth Circuit has exclusive jurisdiction over such issues.

In yet another effort to bring the Final Rule and 2020 PID into this proceeding, the Grower Petitioners invoke a Section 408 provision directing EPA to coordinate tolerance revocation actions with related necessary actions under FIFRA "[t]o the extent practicable[.]." 21 U.S.C. § 346a(*l*)(1). Grower Obj. at 6-7. Petitioners have presented an identical argument to the Eighth Circuit and are barred from relitigating this challenge to the Final rule here. PX 25 at 63-69.

Moreover, EPA received objections making the same argument when EPA revoked carbofuran tolerances before cancelling its associated registrations. EPA explained that it chose to revoke tolerances first because it was "the quickest way to resolve acute dietary risks to children." Carbofuran Final Tolerance Revocations, 74 Fed. Reg. 23,046, 23,069 (May 15, 2009). Growers challenged the carbofuran tolerance revocation, but abandoned their argument that registrations had to be cancelled before tolerances could be revoked. *See National Corn Growers Assoc. v. EPA*, 613 F.3d 266 (D.C. Cir. 2010). Revoking chlorpyrifos tolerances has similarly protected children from harm from chlorpyrifos for two growing seasons, even as this cancellation proceeding is just getting under way.

Further, contrary to Petitioners' argument, Congress's direction to coordinate tolerance revocations and FIFRA cancellations "[t]o the extent practicable" does not eviscerate the "reasonable certainty of no harm" food safety standard. EPA must comply with that standard, and, under the Ninth Circuit's order, it had to do so in August 2021 for chlorpyrifos food tolerances, even though it could not cancel the associated registrations by that deadline. EPA acted in conformity with this direction by revoking chlorpyrifos tolerances because they are unsafe and thereafter initiating proceedings to cancel the associated registrations, as the Ninth Circuit ordered. By issuing the NOIC, EPA is now ensuring "that the substance of actions taken under FIFRA and the FFDCA are consistent," in accordance with the coordination direction. 87 Fed. Reg. 11,247 (JX 2, pg. 26).

b. Petitioners' Objections Based on the 2020 Proposal Lack Merit.

While Petitioners' objections based on the 2020 PID are not properly before this Tribunal, Intervenors offer this brief response for context, given how central the 2020 proposal is to Petitioners' challenge to the NOIC. As its name confirms, the 2020 proposed interim registration review decision was merely a *proposal* that was released for public comment

through the registration review process. The proposal could not form the basis of the August 2021 Final Rule for four reasons.

First, the PID suggested that 11 uses might possibly meet the safety standard only if significant amendments to their chlorpyrifos registrations and labels imposed substantial geographic and usage limitations. No such changes to the registrations or labels had happened by the time of the Final Rule. *See* 86 Fed. Reg. at 48,332-33 (JX 3, pgs. 18-19); 87 Fed. Reg. at 11,241, 11,244-46, 11,248 (JX 2, pgs. 20, 23-25, 27.).[7]

Second, as EPA's Objections Denial explained, "the findings in the proposed decision are just proposals and subject to change based upon public comment or other developments that may occur before the final decision is issued." 87 Fed. Reg. 11,244 (JX 2, pg. 23); *see also id.* at 11,246, 11,258 (JX 2, pgs. 25, 37,) The 2020 PID garnered extensive critical comments from scientists, states, and Intervenors, because it abandoned the regulatory endpoint designed to protect children from learning disabilities that was used in the 2016 risk assessment and its drinking water assessment used untested methodologies that had never been used in EPA's pesticide risk assessment. IX 5 at 30-33. EPA's regulations require that EPA solicit and respond to public comments on proposed registration review decisions and the underlying risk assessments. 40 C.F.R. §§ 155.56, 155.58. EPA has indicated that it will respond to the public comments later in the registration review process. 86 Fed. Reg. 48,315, 48,334 (JX 3, pgs. 1, 20);

[7] The 2020 PID lays out extensive protections that would need to be afforded workers who face unreasonable adverse effects from exposure to chlorpyrifos, including from the 11 uses. *See, e.g.,* 2020 PID at 42-49, 55-58, 64-79 (considering prohibiting aerial spraying and other common ground application methods and requiring more protective clothing or other equipment. *Id.* at 59, 85-106 (identifying the number of days workers must be kept out of fields after chlorpyrifos spraying to avoid unacceptable poisoning risks). The proposed labels EPA attached to its objections include some of the proposed mitigation but omit other mitigation needed to protect workers from serious risks of concern. JX 9-11.

see also 87 Fed. Reg. 11,234, 11,244-45 (JX 2, pgs. 13, 23-24) (objections denial order reiterates that EPA will respond to the comments prior to making an interim registration review decision). This acknowledgement is in keeping with well-settled administrative law principles that agencies must "consider and respond" to significant public comments. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015); *see also* 5 U.S.C. § 553(c) (agency must respond to relevant public comments in its justification for the final rule); *City of Portland, Oregon v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (agency must address comments that, if adopted, would change the decision); *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, 676 F. Supp. 2d 307 (S.D.N.Y. 2009) (vacating EPA pesticide registration because EPA violated notice-and-comment requirements). EPA has yet to fulfill its legal duty to address these public comments and, therefore, could not convert the 2020 PID into final tolerance decisions.

Third, Intervenors submitted objections to Final Rule arguing that the Final Rule, like the 2020 PID, is under-protective because it uses 10% cholinesterase inhibition as its regulatory endpoint. IX 4 (LULAC Petitioners Feedback to EPA Final Rule). In addition to the prior findings of EPA and the SAP, Intervenors relied on *LULAC* and on EPA's 2016 risk assessment and the California risk assessment, which used exposure levels that would protect children from neurodevelopmental harm and found all chlorpyrifos uses unsafe. IX 4 at 2-7, 9-14.[8] Because the

[8] Other public comments similarly criticized the PID for being underprotective. For example, fifty leading scientists and health professionals cited compelling evidence that "prenatal exposure at low levels is putting children at risk for cognitive and behavioral deficits and for neurodevelopmental disorders." Specifically, the scientists explained that reliance on cholinesterase inhibition "obscures the serious threat that chlorpyrifos poses to early brain development and represents an insensitive, unscientific and inadequate approach to health risk assessment." IX 7 at 27, quoting Comment submitted by Philip J. Landrigan, Director, Program for Global Public Health and the Common Good, Director, Global Observatory on Pollution and Health, Professor of Biology, Boston College et al. (Feb. 4, 2021), https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-1008/attachment_1.pdf at 1-2. Nine states that were

Final Rule retained no tolerances, EPA deemed Intervenors' objections irrelevant to the Final Rule, but committed to address them if it considered establishing any chlorpyrifos tolerances in the future. 87 Fed. Reg. at 11,270-71 (JX 2, pg. 49-50); *see also* 86 Fed. Reg. at 48,334 (JX 3, pg. 20) (EPA will respond to comments on the 2020 PID in the registration review process). EPA cannot retain tolerances (or associated registrations) without addressing Intervenors' objections.

Fourth and most fundamentally, EPA cannot, under the Ninth Circuit's decision in *LULAC*, finalize the 2020 PID and retain the 11 uses. One month after the close of the public comment period on the 2020 PID, the Ninth Circuit issued its decision in *LULAC,* concluding that using 10% cholinesterase inhibition is inadequate to protect children from learning disabilities. The court recited the numerous EPA and SAP findings that chlorpyrifos causes neurodevelopmental harm to children at exposures below those associated with 10% cholinesterase inhibition. *See, e.g., LULAC*, 996 F.3d at 691 ("EPA's own studies and pronouncements still in effect show that it regards chlorpyrifos as harmful at levels below existing tolerances."); *id*. at 685 ("EPA concluded that chlorpyrifos could cause harm even if exposure was below the AChE inhibition-related point of departure"). For example, the 2012 SAP report stated that "evidence suggest[s] that chlorpyrifos can affect neurodevelopment at

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also petitioners in the *LULAC* litigation submitted detailed comments criticizing EPA for reverting to an under-protective endpoint that is "manifestly insufficient" given "the body of evidence demonstrating that adverse brain impacts occur at much lower exposure levels of chlorpyrifos than those that cause 10% [cholinesterase] inhibition." IX 7 at 28, citing Comment submitted by Office of the Attorney General of New York et al. (Mar. 11, 2021), https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1077 at 2 , 15-16. The California Department of Pesticide Regulation ("CDPR") explained that EPA's 2020 risk assessment "does not adequately protect against the potentially profound and debilitating human health effects of exposure to this pesticide," which occur from exposures below those that cause 10% cholinesterase inhibition. IX 7 at 29, citing Comment submitted by the California Department of Pesticide Regulation (DPR) (Mar. 11, 2021), https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1067 at 1.

levels lower than those associated with [cholinesterase] inhibition[,]" the 2014 risk assessment explained that "chlorpyrifos likely played a role in the neurodevelopmental outcomes observed in these epidemiology studies . . . it is unlikely mothers enrolled in [those studies] experienced [cholinesterase] inhibition," the 2016 SAP report concluded " there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% [cholinesterase] inhibition," and the 2016 risk assessment found "there are neurodevelopmental effects occurring at chlorpyrifos exposure levels below that required for [cholinesterase] inhibition." *Id*. at 700-01. The Ninth Circuit did not believe EPA could continue to use 10% cholinesterase inhibition as its regulatory endpoint because "for nearly a decade, the EPA and its SAPs have concluded that there is *not* a reasonable certainty of no harm" at this level of exposure. *Id*. at 700 (emphasis in original).

It is a misnomer for Petitioners to call the 11 uses "safe uses" when the Ninth Circuit ruled that EPA could not find chlorpyrifos safe using 10% cholinesterase inhibition as the measure of safety. Instead, *LULAC* makes it clear that EPA's now-outdated proposal to find the 11 uses safe runs directly counter to the scientific evidence and the extensive findings of EPA and the SAP. Therefore, it would violate *LULAC* for EPA to base tolerance or cancellation decisions on the 2020 PID and drinking water and risk assessments that use 10% cholinesterase inhibition as the regulatory endpoint.

The merits of Petitioners' challenges to the Final Rule, however, are not before this Tribunal. What is before this Tribunal is the plain legal mandate for EPA to cancel chlorpyrifos registrations for food uses that are unsafe as a matter of law.

II. GHARDA IS OBTAINING ALL THE PROCESS IT IS DUE.

Petitioner Gharda alleges that the NOIC violates its due process rights (Gharda Obj. at 9-10), but EPA satisfied the procedural requirements for FIFRA Section 6 registration

cancellations. While the Grower Petitioners do not object to the NOIC on due process grounds, they argue EPA failed to comply fully with certain Section 6(b) procedures governing the issuance of an NOIC. Their argument fails for the same reason that Gharda's due process argument fails. Grower Obj. at 10, 19-20.

A. Compliance with FIFRA Section 6's Procedural Requirements Satisfies Gharda's Due Process Rights.

Petitioner Gharda's argument that EPA's issuance of the NOIC has deprived it of due process is without merit. FIFRA Section 6 establishes the process EPA must undertake when initiating cancellation of a pesticide registration and conveys a statutory right to a registrant and others to request further administrative proceedings when they oppose cancellation. Petitioners are assured of only the due process statutorily granted and, in the instant proceeding, are fully availing themselves of the opportunities FIFRA affords to challenge the NOIC.

A pesticide registration confers a right to use a pesticide—but that right is not unlimited. It is contingent upon EPA's determination that the pesticide, when used in accordance with widespread and commonly recognized practice, does not generally cause an unreasonable adverse effect on the health or the environment. 7 U.S.C. § 136d(b). Gharda's interest in its chlorpyrifos registrations is therefore subject to EPA's authority under FIFRA's comprehensive regulatory scheme. Gharda has no property interest in its chlorpyrifos registrations because "there is no property interest in using property in a manner that is harmful to the general public." *Am.Vanguard Corp. v. United States*, 142 Fed. Cl. 320, 328 (2019).

In *American Vanguard*, after finding that samples of a fungicide contained dioxin, which was not allowed under the registration, EPA issued a Stop Sale and Use order. *Id.* at 324. The registrant alleged that EPA's order violated its due process rights and the Fifth Amendment's prohibition on taking private property without just compensation. *Id*.

The court disagreed, explaining that Congress intended for EPA to closely regulate pesticides and the "right to sell [] pesticides domestically [] is controlled entirely by EPA" under FIFRA. *Id*. at 328. The court underscored EPA's pervasive regulatory control in the FIFRA statutory scheme, explaining that where EPA has found a pesticide to be harmful, the registrant retains no cognizable property interest because "without permission from the EPA, registrants cannot exercise their right to sell their pesticides." *Id*. at 327-28.

Here, EPA is pursuing cancellation through the process set out in FIFRA. This is in keeping with *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011), which reinforced the central role of FIFRA's cancellation process. There, EPA determined that a rodenticide, as labeled, would pose unreasonable poisoning risks to children and asked registrants to voluntarily amend their labels to incorporate measures to mitigate the risks. When Reckitt refused to do so, EPA launched a misbranding action. The district court held that EPA had side-stepped FIFRA's cancellation process by pursuing a misbranding action instead of cancellation.

Petitioner Gharda's argument that EPA has deprived it of due process fails because EPA is pursuing cancellation pursuant to FIFRA's cancellation procedures. EPA issued the NOIC after it found chlorpyrifos unsafe and revoked all chlorpyrifos tolerances. Given Congress's incorporation of FFDCA Section 408 into FIFRA's "unreasonable adverse effects" standard, EPA had more than an ample basis to issue the NOIC, which is subject to a low threshold given that it merely initiates an adjudicative proceeding. *See Env't Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 594 (D.C. Cir. 1971) ("[FIFRA's] legislative history and statutory scheme point[] to the conclusion that the FIFRA requires the [Administrator] to issue notices and thereby initiate the administrative process whenever there is a substantial question about the safety of a

registered pesticide."); *see also Nat'l Coal. Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 643 (D.C. Cir. 1989) (same). Moreover, the Ninth Circuit's order in *LULAC* instructed EPA to cancel associated registrations after revoking tolerances. Thus, EPA had no option but to issue the NOIC.

Finally, EPA followed Section 6's procedural requirements in issuing the NOIC. On August 11, 2022, EPA sent a draft of the NOIC, including an analysis of the impact of the proposed action on the agricultural economy to the Secretary of Agriculture for comment. The U.S. Department of Agriculture ("USDA") submitted comments on September 11, 2022, and EPA responded to USDA's comments in the NOIC. JX 14-15; 87 Fed. Reg. at 76,478 (JX 1, pg. 5). EPA also sent a draft of the NOIC to the SAP, which waived its right to review given the administrative nature of the cancellation. JX 12-13. Lastly, EPA's NOIC informed the public of the opportunity to file objections and requests for hearing, 87 Fed. Reg. at 76,480-81 (JX 1, pgs 7-8), which Petitioners did, initiating the instant proceeding. Gharda is owed nothing more to provide it due process.

B. EPA Satisfied its Obligation to Consider Impacts of Cancellation on Agriculture.

Petitioners assert that EPA failed to include in the NOIC an assessment of the impacts of cancellation "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy" and failed to respond to USDA's comments on that assessment, as required by Section 6(b). Petitioners are mistaken.

The NOIC includes an assessment of the cancellation's impacts on food prices, production, and the agricultural economy. Because the Final Rule revoked all chlorpyrifos tolerances and any food crop sprayed with chlorpyrifos cannot be sold or used, cancelling food-use registrations "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." 87 Fed. Reg. at 76,478 (JX 1, pg. 5).

EPA shared its assessment of the chlorpyrifos cancellation on the agricultural economy with USDA, received a response from USDA, and responded to USDA's comments in the NOIC. *Id*. EPA, therefore, fully complied with Section 6(b)'s procedural requirement to conduct the analysis, share it with USDA, and respond to USDA's comments.[9]

Petitioners seem to be faulting EPA for not adopting the positions presented in USDA's comments. As a matter of fact, however, Petitioners concede that the tolerance revocation caused sales and use of chlorpyrifos to end. *See* Gharda Obj. at 6-7, 13; Growers Obj. at 8-9, 18. Accordingly, they offer no factual rebuttal to EPA's conclusion that it is the tolerance revocation rather than the proposed cancellation that might be having economic impacts on food prices and production.

As a matter of law, Petitioners are trying to turn a purely procedural obligation into something more. A 1975 amendment to FIFRA added the requirement to include an economic assessment of a cancellation's impact on agriculture and the procedural obligation to provide the Secretary of Agriculture an opportunity to comment on that assessment. Congress rejected an amendment that would have given USDA concurrent decision-making authority partly because effectively giving USDA a veto would interfere with the adjudicative process governing cancellations, which requires that EPA cancellation decisions be based on the record developed at the hearing. The House Report explains that the amendment:

[9] Although not legally relevant under the health-based food safety standard, EPA released an assessment of the benefits of chlorpyrifos agricultural uses (PX 40) and a small business analysis (RX 47) along with the 2020 PID. USDA submitted comments on the 2020 PID, which addressed its agricultural impacts. PX 5.

> instead provides requirements for USDA's input before the administrative hearing is held, advertises it so that the public can amplify on the agricultural impact at the hearings, but preserves the authority of EPA to make a final decision, requiring the Administrator at the same time to provide and publish a detailed analysis of the impact on agricultural economy.

H.R. Rep. No. 94-497, at 7, (1975); *see also id*. at 6 ("By requiring EPA to seek Agriculture's comments, the substitute proposal assures that the impact on the agricultural economy of actions taken by EPA will be fully developed"); *id*. ("the amendment would afford an opportunity for public debate to be centered around any arguments offered by the Secretary of Agriculture for his objections to any change in classification of a pesticide or regulations issued under the Act. It would have much the same effect as the public exposure of an environmental impact statement").

EPA's assessment and USDA's comments were designed to inform EPA's balancing of risks and benefits under the "unreasonable adverse effects" standard then in effect. However, in enacting the FQPA and amending FIFRA's unreasonable adverse effects standard in 1996, Congress made it clear that protecting public health and the health of infants and children is required, even if it might have impacts on the agricultural economy. As the Ninth Circuit acknowledged, "when Congress unanimously passed the FQPA, the EPA interpreted the FFDCA to permit the balancing of safety against other considerations, such as economic factors . . . [but] the FQPA largely abrogated that approach. Congress made the explicit decision to prioritize safety over all else." *LULAC*, 996 F.3d at 692. EPA's assessment finding no agricultural impacts from cancelling food uses of chlorpyrifos is consistent with Congress' intent to prioritize health in Section 408 and abandon any risk-benefit balancing when setting food tolerances and authorizing use of pesticides on food. Accordingly, Petitioners' arguments that EPA failed to analyze the NOIC's impacts on the agricultural economy and include it in the NOIC are without merit.

CONCLUSION

This Tribunal should grant Intervenors' Motion for Accelerated Decision and Order Cancellation of Gharda's Chlorpyrifos Registrations.

Dated: August 25, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Motion for Accelerated Decision**, dated August 25, 2023, were sent this day in the following manner to the addressees listed below:

Original by OALJ E-Filing System to:
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U.S. Environmental Protection Agency
Office of Administrative Law Judges
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Dated: August 25, 2023

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