UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re:	)	
Revocation of All Tolerances for Chlorpyrifos	)	FFDCA-HQ-2021-0001 (EPA-HQ-OPP-2021-0523)
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GHARDA CHEMICALS INTERNATIONAL, INC.'S OBJECTIONS TO THE FINAL RULE REVOKING ALL TOLERANCES FOR CHLORPYRIFOS

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Chlorpyrifos Registrant

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

I. INTRODUCTION

On August 30, 2021, the U.S. Environmental Protection Agency ("EPA" or the "Agency") issued a final rule revoking all tolerances for the pesticide chlorpyrifos. *Final Rule for Chlorpyrifos Tolerance Revocations*, 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the "Final Rule"). Pursuant to Section 408(g)(2)(A) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(g)(2)(A), and 40 C.F.R. part 178, *et seq.*, Gharda Chemicals International, Inc. ("Gharda") submits these objections to EPA's Final Rule, together with the accompanying Petition to Stay the Effective Date of the Revocation of All Tolerances for Chlorpyrifos.

EPA issued the Final Rule in response to an April 29, 2021 order of the U.S. Court of Appeals for the Ninth Circuit in the lawsuit *League of United Latin American Citizens v. Regan*, 996 F.3d 673, 678 (9th Cir. 2021) ("LULAC"), instructing EPA to "either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "or to revoke all chlorpyrifos tolerances." Rather than modify tolerances consistent with the finding of its expert scientists that a subset of eleven key crop uses in select regions are safe, as set forth in the Agency's December 2020 Proposed Interim Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0971 ("PID"), EPA chose to revoke *all* tolerances for chlorpyrifos. EPA did so because it claimed that it is required under the FFDCA to assess aggregate exposure risks taking into account all "currently registered uses" and that, when taking into account potential drinking water exposures, it could not conclude that "the products as currently registered" are safe. Under the Final Rule, tolerances for all commodities will expire six months from the date of publication, on February 28, 2022. 86 Fed. Reg. at 48,336.

Gharda is challenging the legal and factual sufficiency of the Final Rule by exercising its right to file objections. Specifically, EPA has abused its discretion, acted arbitrarily and capriciously, and violated the due process rights of Gharda and others by revoking all

chlorpyrifos tolerances despite conceding in its own risk assessment that eleven key crop uses in select regions are safe, and in disregard of a written commitment from Gharda provided to EPA well in advance of the Final Rule to modify Gharda's registration in accordance with the Agency's safety finding.

Among other issues, the Final Rule is fatally flawed because it ignores relevant scientific data, including (i) comments on and proposed refinements to the 2016 drinking water assessment EPA relied on to revoke tolerances, (ii) the Agency's updated, more highly refined, and peer-reviewed 2020 drinking water assessment, and (iii) a drinking water study of chlorpyrifos oxon (the chlorpyrifos residue EPA believed to be of concern in drinking water) submitted by the registrants nearly a year ago that significantly undermines EPA's assumptions about drinking water risk concerns. EPA's failure to adequately consider and respond to highly relevant scientific data and comments that bear directly on the drinking water concerns EPA used to justify a revocation of all tolerances is arbitrary and capricious and raises significant due process concerns. EPA's Final Rule also improperly revoked import tolerances the Agency conceded in the PID are safe, and incorrectly applies a precautionary Food Quality Protection Act ("FQPA") safety factor of 10X to address "uncertainties" in epidemiology studies the Agency has acknowledged do not meet basic standards of reliability.

Apart from lacking any reasoned or logical scientific justification, the portions of the Final Rule objected to herein impose an unreasonable and effectively meaningless six-month implementation period. The six-month period for implementation ignores reality and allows no time for Gharda, distributors, and growers to phase out and exhaust significant stores of chlorpyrifos products that currently exist in the supply chain, and that will potentially cause the needless disposal of safe and nutritious food and feed. The disastrous consequences of the Final

Rule will ripple through the agricultural supply chain. EPA has also failed to harmonize the Final Rule with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), including by abdicating its responsibility to oversee the safe, lawful, and orderly phase-out of inventories and existing stocks of chlorpyrifos products. The Agency also disregarded cancellation procedures and interagency review processes intended to notify the public and other affected parties of actions like the one taken here that will significantly impact the agricultural economy.

Finally, EPA's decision followed months of discussions with Gharda concerning a voluntary cancellation of uses, during which Gharda committed to meeting each of EPA's continually increasing and scientifically or statutorily unjustified demands, in a good-faith effort to cooperate with the Agency. EPA led Gharda to believe it was close to finalizing a voluntary cancellation agreement with EPA that would allow key crop uses to continue—key crop uses that *EPA had found safe* in the PID—when the Agency abruptly withdrew from these discussions, without an explanation to Gharda, and revoked all tolerances. EPA's conduct and processes leading up to the Final Rule ignored its own science, are fundamentally unfair and demonstrate bad faith, further undermining the reasonableness of the Agency's decision-making.

For these reasons and as outlined more fully below, and because of the significant, immediate, and irreparable injuries Gharda has and will continue to suffer as a result of the revocation of all tolerances, the Final Rule should be summarily reversed or, at a minimum, stayed pending administrative review by EPA and any potential judicial review of the objections submitted by Gharda, growers, grower groups, and other adversely affected stakeholders.

II. SUMMARY OF OBJECTIONS

As set forth more fully herein, Gharda objects to the Final Rule on the following grounds:

1. EPA acted arbitrarily and capriciously by revoking all chlorpyrifos tolerances despite conceding in its own risk assessment that eleven key crop uses in select regions are safe. In

doing so, EPA ignored its PID and the updated, refined 2020 drinking water assessment on which the PID relied, claiming it is required by the FFDCA to assess risks based on exposures from all "currently registered uses." EPA's decision and reasoning is at odds with the statutory text, which is forward-looking and instructs EPA to assess "anticipated" exposures, not exposures based on uses the Agency *previously* approved, and would lead to the absurd result that EPA could never modify tolerances to limit use of a previously registered product based on new or updated scientific data. Consistent with its repeated commitments to EPA prior to the Final Rule, Gharda respectfully requests that, at a minimum, EPA retain the tolerances for the eleven key crops found safe in the PID.

2. EPA acted arbitrarily and capriciously in disregarding a written commitment from Gharda to modify its registration in accordance with the Agency's safety finding. The Agency disingenuously claimed that its "ability to make the safety finding" for a limited combination of uses in certain geographic areas "would be contingent upon significant changes to the existing registrations, including use cancellations, geographical limitations, and other label changes." EPA had at its disposal a commitment for these exact "use cancellations, geographical limitations, and other label changes" and decided for reasons unrelated to science or its statutory obligations not to act on it.

3. EPA acted arbitrarily and capriciously and in bad faith in negotiating a voluntary cancellation with Gharda, during which Gharda met each of EPA's continually increasing and scientifically unjustified demands, and during which EPA misled Gharda to believe that some key crop uses would survive, only to then abruptly and inexplicably revoke all tolerances. EPA added insult to injury in its misleading and prejudicial public messaging around the Final Rule, which cited reasons for revocation that are unsupported by science and at odds with the language

of the Final Rule itself.

4. EPA acted arbitrarily and capriciously and abused its discretion in failing to give adequate consideration to relevant scientific data and information. These include (i) comments on and proposed refinements to the 2016 drinking water assessment EPA relied on to revoke tolerances, (ii) the Agency's updated, more highly refined, and peer-reviewed 2020 drinking water assessment EPA discarded in the Final Rule, and (iii) a drinking water study submitted by the registrant nearly a year ago that demonstrates that chlorpyrifos oxon in drinking water is not a risk concern, nullifying EPA's prior assumptions concerning the effects of drinking water exposure. EPA's failure to consider relevant scientific data and information has damaged the Agency's global reputation as a fair, independent, and science-driven regulatory body.

5. EPA's failure to adequately consider and respond to highly relevant scientific data and information that bear directly on the drinking water concerns EPA used to justify a revocation of all tolerances violates Gharda's legally protectable property right in its registration and raises significant due process concerns.

6. EPA's Final Rule revoking tolerances without any reasoned or logical scientific basis deprives Gharda of the economic value of its registration, infringing Gharda's substantive due process rights.

7. EPA acted arbitrarily and capriciously by imposing an unreasonably short, off-season implementation period for the Final Rule, without an appropriate scientific basis for doing so. This will result in devastating economic and other harms to Gharda and its distributors, not to mention the growers who purchased Gharda's products in reliance on the registration and who depend on chlorpyrifos as their primary effective and affordable crop protection tool.

8. EPA acted arbitrarily and capriciously in failing to harmonize its decision with FIFRA,

including by abdicating its responsibility to oversee the safe, lawful, and orderly phase-out of inventories and existing stocks of chlorpyrifos products that will soon be rendered unusable as a result of the Final Rule. EPA must, at a minimum, revise the Final Rule to extend the expiration date of chlorpyrifos tolerances coextensive with a meaningful period for the exhaustion of existing stocks.

9. EPA acted in an arbitrary and capricious manner in revoking import tolerances. EPA conceded in its PID and underlying risk assessment that there are no dietary (non-drinking water) exposure risks associated with chlorpyrifos use in the United States or from imported foods.

10. EPA acted arbitrarily and capriciously and abused its discretion in failing to seek review of its revocation decision by the Office of Management and Budget's Office of Information and Regulatory Affairs ("OIRA"), given the significant impact the Final Rule will have on the U.S. agricultural economy.

11. EPA acted arbitrarily and capriciously in applying a precautionary 10X FQPA safety factor to address "uncertainties" in epidemiology studies of neurodevelopmental effects that do not meet basic standards of reliability.

III. GHARDA AND ITS ROLE IN THE CHLORPYRIFOS MARKET

Established in 1967, Gharda is a research-based company leading in the field of agrochemical manufacturing. Declaration of Ram Seethapathi ("Seethapathi Decl.") ¶ 5. Gharda was founded by Dr. Keki Hormusji Gharda, a prominent chemical engineer and chemist. *Id*. After obtaining a Masters degree and Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor, Dr. Gharda established Gharda Chemicals in a small rented shed. *Id*. More than four decades of innovation and investment in R&D transformed Gharda into a successful pioneer agrochemical company. *Id*. Gharda's product portfolio includes a wide range of insecticides and herbicides, including chlorpyrifos, for which it holds an EPA registration.

Gharda sells end-use chlorpyrifos products under the brand name Pilot™ as well as technical grade chlorpyrifos for manufacturing use. *Id*.

Chlorpyrifos is a vitally important agricultural tool, protecting over fifty valuable U.S. food crops from destruction due to insect pests, including alfalfa, cotton, soybeans, sugarbeets, and wheat. *Id.* ¶ 6. Crops protected by chlorpyrifos are worth upwards of over a hundred million dollars annually to the U.S. economy. *Id.* (citing EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos at 5, 7 , EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits")). Chlorpyrifos has value to growers in protecting their crops and income, as well as value to consumers who enjoy affordable, healthy, and high quality produce throughout the year. *Id.*

Chlorpyrifos's critical importance as an insect pest management tool is due to its broad-spectrum efficacy, favorable environmental characteristics, and affordability for growers. *Id.* ¶ 7. It is the leading active ingredient to control a broad spectrum of difficult-to-control insect pests, and for some destructive pests it is the only effective pest management tool available. *Id.* (citing Revised Benefits at 2). Because of its broad-spectrum effectiveness, chlorpyrifos is often the first tool growers employ to control new or unknown insect pests, a long-standing problem but one that will be exacerbated by climate change. *See id.* ¶ 8 (citing Revised Benefits at 12–13) (removal of "broad-spectrum materials such as chlorpyrifos . . . from pest management programs can result in unexpected outbreaks of previously minor pests or even the emergence of new pests"). Chlorpyrifos is also less harmful to beneficial insect populations than other insecticides. *Id*. It also requires fewer applications and avoids the use of multiple chemistries to control certain pests, reducing overall insecticide use. *Id*.

Gharda has long supported the registration of chlorpyrifos in the United States, including through an industry task force that provided financial and other support for comments, scientific data, and other materials submitted to EPA by Dow AgroSciences, LLC, now Corteva Agriscience. *Id.* ¶ 9, Appendix A. Gharda has invested over CBI in the development of data and other information to support the registration of chlorpyrifos in the United States.

In February 2020, Corteva announced that it would end production of chlorpyrifos by 2021. *Id.* ¶ 10. At that time, chlorpyrifos continued to be a critically important agricultural tool for many growers. *Id*. As a result, many distributors and farm input suppliers began looking to Gharda to meet the market demand for chlorpyrifos. *Id*. In response to this increase in demand, Gharda significantly increased its production of chlorpyrifos. *Id*. Immediately prior to the Final Rule, Gharda was the primary supplier of chlorpyrifos for agricultural use in the United States. *Id*.

Chlorpyrifos is one of Gharda's most important products. In 2020, Gharda's annual U.S. revenues of chlorpyrifos were approximately CBI. *Id.* ¶ 11. Revenues from sales of chlorpyrifos comprise a significant portion of Gharda's overall U.S. business, which prior to the Final Rule was only expected to increase. *Id.* In 2020, Gharda's annual U.S. revenues from chlorpyrifos were approximately CBI. *Id.* 2021 U.S. revenues from chlorpyrifos total CBI to date and prior to the Final Rule were expected to increase to CBI by year end. *Id.* In 2022 and beyond, Gharda's annual U.S. revenues from chlorpyrifos were projected (before the Final Rule) to be approximately CBI annually. *Id.*

Gharda's position in the U.S. agrochemical industry is unique. *Id.* ¶ 12. Unlike many other registrants and leading suppliers of crop protection tools in the United States, Gharda does not have U.S.-based manufacturing facilities, which adds an additional level of complexity to the

supply chain not encountered by U.S.-based manufacturers. *Id*. Gharda ships materials to the United States and then uses tolling companies to package and label the technical and end use chlorpyrifos products for sale to U.S. distributors, creating significant employment opportunities. *Id*. The pandemic has exponentially increased the costs and time required to ship Gharda's materials to the U.S. for formulating, packaging, and labeling. *Id*.

Currently, Gharda has a significant volume of raw materials on hand at its manufacturing facility in India. *Id.* ¶ 13. Gharda also has inventory of U.S. labeled chlorpyrifos product on hand at its India facility valued at CBI. *Id.* In addition, Gharda has inventories of chlorpyrifos product ready for distribution in the U.S. valued at CBI. *Id.* If Gharda is unable to formulate, sell, and distribute these products for use in the 2022 growing season and beyond, Gharda will suffer CBI economic losses. *Id.* These losses are in addition to the CBI loss in its investment in chlorpyrifos and future annual lost sales of approximately CBI annually. *Id.* There are also significant stores of U.S. labeled chlorpyrifos products in the hands of distributors, retailers, and growers, estimated to be valued at approximately CBI. *Id.* ¶ 14. (Gharda has been specifically informed by some of its major customers that they currently have inventories of chlorpyrifos product on hand valued at approximately CBI. *Id.*)

IV. LEGAL STANDARDS

A. Tolerance Revocations Under the FFDCA

The FFDCA requires EPA to set food safety "tolerances," which are maximum levels of pesticide residue allowed in or on food. FFDCA § 408, 21 U.S.C. § 346a. EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe." FFDCA § 408(b)(2)(A)(i), 21 U.S.C.

§ 346a(b)(2)(A)(i). Food containing pesticide residues that exceed an established tolerance level is deemed "adulterated" under the FFDCA and may not be moved in interstate commerce. FFDCA §§ 301, 402, 21 U.S.C. §§ 331, 342. In considering whether to establish, modify, or revoke a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." FFDCA § 408a(b)(2)(D), 21 U.S.C. § 346a(b)(2)(D)(i).

In 1996, Congress amended the FFDCA with the passage of the FQPA, which, among other things, established a new safety standard for pesticide tolerances covering pesticide residues in or on raw agricultural commodities. A tolerance is deemed "safe" under the FFDCA if "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." FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii). This includes exposure from food, drinking water, and in residential settings, but does not include occupational exposure. In assessing reasonable certainty of no harm, EPA is to apply an additional tenfold margin of safety "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" but EPA has discretion to apply a different margin of safety if there is "reliable data" to support that determination. FFDCA § 408(b)(2)(C)(i)(II) and (III); 21 U.S.C. 346a(b)(2)(C)(i).

While application of "reasonable certainty of no harm" to tolerances for raw agricultural commodities was new to EPA when the FQPA was passed, the same standard had been used for decades by EPA when establishing tolerances for processed foods and by the Food and Drug Administration ("FDA") in approving food additives, in both cases under FFDCA § 409. In the 1958 Food Additives Amendment to the FFDCA, Congress made clear that a safety

determination under the "reasonable certainty of no harm" standard does not require absolute proof of safety: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rep. No. 2422, 85th Cong., 2d Sess. 6, *reprinted in* 1958 U.S.C.C.A.N. 5300, 5305; *see also* H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4-5 (1958). Thus, Congress did not intend the reasonable certainty of no harm standard to be based on the precautionary principle, under which all doubt must be exhausted before a tolerance may be established or left in effect.

Consistent with this standard, tolerances cannot be revoked without valid and reliable data because registrants have a legally protectable property interest in their registration, which cannot be taken away without due process of law. *See Indus. Safety Equip. Ass'n v. EPA*, 656 F. Supp. 852, 856 (D.D.C. 1987), *aff'd*, 837 F.2d 1115 (D.C. Cir. 1988) ("It is well settled that an agency license can create a protectible [sic] property interest, such that it cannot be revoked without due process of law."); *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) ("A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute."); *Ctr. for Biological Diversity v. EPA*, No. 11-cv-00293, 2013 WL 1729573, at *6–7 (N.D. Cal. Apr. 22, 2013) ("[O]wners of the pesticide registrations . . . have property and financial interests in the registrations."); *Mem. & Order, Pesticide Action Network N. Am. v. EPA*, No. C 08-01814, at 4 (N.D. Cal. July 8, 2008), ECF No. 43 ("The registrations involved here are essentially government licenses to produce, distribute and sell pesticides . . . [and] therefore constitute property[.]"). It is therefore essential that the Agency have valid and reliable data and conduct a thorough, science-based assessment before making a decision to modify or revoke tolerances.

B. Objections Under the FFDCA

Under Section 408(g) of the FFDCA, "[w]ithin 60 days after a regulation or order is issued" by EPA, "any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefore." 21 U.S.C. § 346a(g)(2)(A). Objections must (1) "[b]e in writing"; (2) "[s]pecify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought"; (3) "[b]e signed by the objector"; (4) "[s]tate the objector's name and mailing address"; (5) "[b]e submitted to the hearing clerk"; and (6) "[b]e received by the Hearing Clerk not later than the close of business of the 60th day following the date of the publication in the Federal Register of the order to which the objection is taken …." 40 C.F.R. § 178.25.

V. RELEVANT BACKGROUND AND REGULATORY HISTORY

A. EPA's 2020 Proposed Interim Decision

On December 7, 2020, as part of EPA's Registration Review of chlorpyrifos, EPA published its PID. *See* 85 Fed. Reg. 78,849 (Dec. 7, 2020). The PID is supported by analyses included in EPA's September 21, 2020 Third Revised Human Health Risk Assessment, EPA-HQ-OPP-2008-0850-0944 (the "2020 RHHRA"), which in turn relies on, among other documents, a September 15, 2020 Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-0850-0941 (the "2020 DWA"). EPA's PID and 2020 DWA reflected a fulsome, measured, and well-reasoned assessment of the human health and drinking water risks of chlorpyrifos by EPA's expert scientists.

In its 2020 RHHRA and PID, EPA continued to use 10% red blood cell acetyl cholinesterase inhibition ("RBC AChE") as a regulatory endpoint or point of departure for human health risk assessments for chlorpyrifos. *See* 2020 RHHRA at 2. This conservative and

health-protective endpoint is supported by decades of scientific study. EPA stated that it "remains unable to verify the reported findings" of epidemiology studies claiming links between prenatal exposure to chlorpyrifos and neurodevelopmental effects. *Id.* at 89–90.

EPA's PID relied on the 2020 DWA, which updated and refined the Agency's 2016 DWA. The 2020 DWA is one of the most sophisticated drinking water analyses EPA has conducted, and relied on EPA's most cutting edge and highly refined methods for assessing drinking water risks. *See* Declaration of Rick Reiss ("Reiss Decl.") ¶¶ 9–11. EPA subjected the 2020 DWA to peer review by nine EPA expert scientists, an unprecedented level of peer review for an assessment of its kind. *Id.* ¶ 12. In the 2020 DWA, EPA focused on eleven uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat) that EPA determined to be high-benefit, critical crop uses. *Id.* ¶ 8. The 2020 DWA focused on select regions of the country where estimated drinking water concentrations are below the drinking water level of concern. *Id*.

In the 2020 RHHRA and PID, EPA conducted an assessment of potential risk to human health from aggregate exposure to chlorpyrifos residues, taking into account all anticipated dietary exposures from food, drinking water, and residential sources, pursuant to FFDCA Section 408(b). EPA determined that there were *no* potential risks of concern from exposure to chlorpyrifos in food or residential uses alone. 2020 RHHRA at 12; PID at 14, 18. EPA determined that risks from drinking water exposure exceeded safe levels taking into account *all* registered uses but, relying on its 2020 DWA, EPA found that risks were *below* the drinking water level of concern benchmark anticipating use only on the eleven high-benefit crops set forth above in certain identified regions of the country. PID at 18.

In its 2020 RHHRA and PID, EPA presented two potential approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to the eleven high-benefit agricultural uses in select regions of the country due to "uncertainty" in "the science addressing neurodevelopmental effects," or (ii) application of a 1X FQPA safety factor, which would allow for the retention of all currently registered uses. Regarding the first approach, EPA was unequivocal that "the agency has determined" that limiting use to the eleven "high-benefit agricultural uses" in the select geographic regions "**will not pose potential risks of concerns with an FQPA safety factor of 10X**." PID at 40 (emphasis added). EPA committed to "consider registrant and stakeholder input on the subset of crops and regions from the public comment period" and stated that it may conduct further analysis to determine if any other limited uses may be retained." *Id.* EPA also indicated that it may further refine its assessment based on feedback and recommendations from the September 2020 FIFRA Scientific Advisory Panel. *Id.*

Gharda submitted comments on the PID on February 3, 2021. EPA-HQ-OPP-2008-0850-0999. Gharda urged that the weight of the scientific evidence supported application of a 1X FQPA safety factor, and urged EPA to consider a Corteva drinking water study of chlorpyrifos oxon submitted to the EPA on December 4, 2020, which shows that there are no drinking water risk concerns associated with chlorpyrifos oxon. *See A Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days*, MRID 51392601; *see also* Reiss Decl. ¶¶ 23–30.

B. Gharda's Discussions with EPA Concerning a Potential Voluntary Cancellation of Chlorpyrifos Uses

1. *Initial Discussions Focus on a Potential Voluntary Cancellation of 1X Crop Uses*

In April 2021, EPA regulatory personnel reached out to Gharda to discuss whether Gharda would entertain an agreement to voluntarily cancel some uses of chlorpyrifos.

Seethapathi Decl. ¶ 21. These discussions focused initially on uses identified in the PID as the 1X uses. *Id*. EPA proposed a meeting with Gharda on April 20, 2021, and requested that Gharda confirm in writing in advance of that meeting Gharda's commitment to voluntarily cancel the 1X uses (while retaining the eleven high benefit crop uses identified as the 10X uses). *Id*. In response, even though Gharda was confident that all 1X uses are well supported, Gharda indicated that it would consider phasing out some 1X uses on a reasonable timetable and adopting potential geographic restrictions on crop uses and other risk mitigation measures. *Id.* & Ex A. Gharda expressed concern with the Agency's proposed rushed timetable, however, given the impact of a phase-out on its business and on the grower community, and given that EPA had not yet reviewed comments on the PID. *Id*. EPA cancelled the meeting with Gharda in order to discuss Gharda's letter further internally. *Id*.

On April 29, 2021, the Ninth Circuit issued a decision in *LULAC*, which concerned EPA's handling of an administrative petition to revoke all tolerances filed by several nongovernmental organizations. In a 2-1 decision, a three-judge panel of the Ninth Circuit held that EPA's denial of objections to a 2017 order denying the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition, outside of its normal regulatory processes. *LULAC*, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit ordered EPA "either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "or to revoke all chlorpyrifos tolerances." *Id.* at 678. (emphasis added). In making this ruling the court expressly recognized the importance of the PID. Indeed, the court stated that:

> [D]uring the pendency of this proceeding, in December 2020, the EPA issued a Proposed Interim Registration Review Decision proposing to modify certain chlorpyrifos tolerances. The EPA also convened another SAP [Scientific Advisory Panel] in 2020. **If, based upon the EPA's further research the EPA can now**

> **conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them**.

Id. at 703 (emphasis added). The court also ordered EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." *Id.* at 678.

2. *EPA's Progressively Increasing Demands that Gharda Agree to Cancel Additional Uses and Application Methods*

After the Ninth Circuit issued its decision in *LULAC*, EPA reached back out to Gharda to resume discussions about a potential voluntary cancellation of chlorpyrifos uses. Seethapathi Decl. ¶ 34. EPA career supervisory personnel strongly urged Gharda to agree to voluntarily cancel the 1X uses and emphasized that the Agency had limited time to decide how to implement the court's decision. *Id*. In response, Gharda expressed its disagreement with the Ninth Circuit decision and hope that EPA would seek rehearing of and/or appeal the flawed decision. *Id.* & Ex. B. Nevertheless, in a good-faith effort to work cooperatively with EPA and believing it had little choice but to accept voluntary cancellation terms, Gharda committed to voluntarily cancel yet additional 1X agricultural uses, pursuant to scheduled phase-outs and with appropriate existing stocks orders. *Id*. EPA strongly implied during these discussions that the 10X uses would remain in place as long as Gharda voluntarily cancelled all 1X uses. *Id*.

In further discussions with EPA career supervisory personnel in late May 2021, EPA expressed to Gharda that it was willing to consider retention of only the 10X uses, and reiterated that it was under pressure to act quickly as a result of the Ninth Circuit decision. *Id.* ¶ 24. EPA urged Gharda to confirm in writing its agreement to voluntarily cancel all 1X uses. *Id*. In response, and even though such a reduction in uses would eliminate more than 50% of Gharda's U.S. chlorpyrifos business, Gharda committed to continue working in good faith with EPA

towards an agreement to voluntarily cancel all 1X uses. *Id.* & Ex. C. To that end, **on June 7, 2021, Gharda confirmed in writing to EPA that it would voluntarily cancel all currently approved agricultural uses of chlorpyrifos, other than the uses identified in the PID as 10X uses**. *Id*. In turn, Gharda requested that EPA (i) work with it to address the orderly exhaustion of its existing inventories, particularly given its unique role in the U.S. agrochemical industry; (ii) agree on orderly processes and timing for revising labels; and (iii) agree on existing stocks provisions to mitigate disruption on growers and other users. *Id*.

EPA career supervisory personnel were receptive to Gharda's June 7 commitment, reaching out the next day to ask "if Gharda is prepared to move forward with discussing voluntary use cancellations" and proposing a call with EPA legal counsel. *Id.* ¶ 25. By email dated June 8, 2021, EPA indicated that it was "considering the following dates for existing stocks:

- Technical grade active ingredient: Phase out most [1X] uses by the end of 2021; allow until the end of 2022 (12 to 18 months) for the remaining [1X] uses
- End-use products: 12 to 18 months from the technical registrants for sale/distribution of products
- End users, growers: Until exhausted"

Id. & Ex. D. Gharda responded to EPA's June 8 email proposing a meeting with its attorneys, with the expectation that the parties were close to reaching final agreement on terms and could begin work on modifying labels. *Id.* ¶ 26 & Ex. E.

Then, on June 14, 2021, EPA career supervisory personnel advised Gharda that Gharda's commitment regarding the "voluntary" cancellation of uses were not sufficient for EPA's "leadership," and asked Gharda to consider voluntarily cancelling yet additional uses, this time including the removal of some 10X uses, or face possible revocation of all tolerances. *Id.* ¶ 27.

EPA urged Gharda to agree to voluntarily cancel all but five to six of its most important crop uses. *Id*. This was the first time that EPA asked Gharda to consider voluntarily cancelling 10X crop uses. *Id*. EPA also said that its leadership had raised occupational exposure concerns, and asked that Gharda agree to eliminate the use of aerial application methods, even though these are not issues to be addressed under FQPA but are instead issues to be addressed in Registration Review under FIFRA's risk/benefit standard. *Id*. In subsequent calls, EPA also expressed concerns regarding ecological risks from chlorpyrifos, even though the ecological risk assessment for chlorpyrifos has yet to be completed. *Id*. EPA nevertheless continued to indicate openness to an extended phase-out period for any voluntarily cancelled uses. *Id*.

Gharda was confused, surprised, and disappointed at EPA's request that Gharda agree to voluntarily cancel 10X uses that EPA had confirmed, in a robust scientific assessment in its PID, would not exceed safe levels. *Id.* ¶ 28. Gharda was also concerned that EPA appeared to be relying on occupational and ecological concerns as the basis for its request, neither of which relate to the regulation of tolerances under the FFDCA. *Id*. Despite this dramatic and unexpected shift in the discussions, Gharda remained willing to work with EPA to try to meet its demands. *Id*. Gharda repeatedly urged EPA to ensure an orderly phase-out for manufacturers, distributors, growers, and others in the agricultural supply chain, as EPA's demand would eliminate nearly 80–85% of the U.S. market for chlorpyrifos. *Id.*

Gharda and EPA had a meeting on June 24, 2021 to further discuss terms. *Id.* ¶ 29. In a follow-up email dated June 24, 2021, approximately two months from the deadline for EPA to act in response to the Ninth Circuit order, ***EPA's Chemical Review Manager wrote Gharda*** "to confirm the uses that Gharda has agreed upon for retention following our discussions over the past few weeks and on our call this afternoon" and outlined the following terms:

- Retain alfalfa, apple, asparagus, cherry (tart), citrus, peach, soybean, sugar beet, wheat (summer and winter) in select states as outlined in the December 2020 PID
- Cotton and strawberry will be phased out over two years (until 2023)
- Aerial application will be phased out over 2 years (until 2023)
- Provisions for existing stocks:
    - Technical products [with current labels] may be sold or distributed until 12/31/2021
    - End-use products [with current labels] may be sold or distributed until 12/31/2022

Id. & Ex. F.

In emails dated June 25, 2021, Gharda sought further clarification from EPA on some of the details of its June 25 proposal, including the details of various phase-out periods. *Id.* ¶ 30. In these emails, Gharda thanked EPA "for our good faith negotiations over the last few weeks" and said that it "looks forward to working with the Agency to finalize the above terms." *Id.* & Ex. G. EPA proposed a meeting with its Office of General Counsel. *Id*. It was Gharda's expectation that in involving legal counsel, the parties would be working to finalize a written agreement reflecting the agreed terms. *Id*.

At EPA's request, on July 2, 2021, Gharda had a further call with EPA career supervisory personnel, during which EPA pressed Gharda to agree to voluntarily cancel even more 10X crop uses because of demands from EPA's leadership. *Id.* ¶ 31. EPA also indicated that it would not be able to agree to an extended phase out period but that chlorpyrifos applications would need to cease after six months, instead of the phase-out periods that ***EPA had proposed*** one week earlier in its June 24 email. *Id*. EPA also raised concerns with air blast applications on orchard crops. *Id*. Gharda offered to provide data on mitigation measures that would address EPA's concerns regarding occupational exposure, but EPA said it would not consider mitigation data. *Id*. EPA asked Gharda to put forward its best, final proposal that EPA would take to its leadership. *Id*. Gharda was especially surprised and disappointed with this turn of events, as it in good faith

believed that EPA's June 24 email, *see id.* ¶ 29 & Ex. F, had set forth the final terms of crop use retention and voluntary cancellation. *Id.*

At EPA's request, Gharda had a call with EPA and its counsel on July 6, 2021. *Id.* ¶ 32. During the call EPA pressed Gharda to accept voluntary cancellation of all but three 10X uses and reiterated that it would be unable to allow use beyond six months from the effective date of a final rule. EPA explained that the six-month period was based on the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary measures, not because of a need for the orderly phase-out of chlorpyrifos inventories and existing stocks. *Id.* Gharda explained that six months would not be a meaningful time period, given that it would largely overlap with the off season for chlorpyrifos use and because its customers purchase product at least one to two years in advance of each growing season. *Id.* Following this call, Gharda followed up in writing to offer voluntary cancellation of additional 10X uses and eliminate aerial and air blast methods of application; Gharda urged EPA to extend the phase out periods for formulation, distribution, and use, to allow for an orderly exhaustion of inventories and to minimize potentially catastrophic economic losses to Gharda and others in the supply chain, at a minimum until July 2022 to cover part of the next growing season. *Id* & Ex. H. After this exchange, EPA indicated that it was "very close" to reaching final agreement with Gharda. *Id*.

At EPA's request, Gharda had a further call with EPA and its counsel on July 14, 2021, during which EPA indicated that Gharda's proposal was under review by EPA leadership but that EPA hoped to have a final response within a week. *Id.* ¶ 33. EPA indicated that it would likely need a voluntary cancellation letter from Gharda quickly, in order to be able to reference the voluntary cancellation in the published final rule. *Id.* During the call, EPA, for the first time, indicated that its leadership believed that import tolerances would also need to be voluntarily

cancelled. *Id*. EPA could not explain the basis for this last-minute request, given that import tolerances do not raise drinking water or occupational concerns, and given that the PID did not identify any dietary (non-drinking water) risks associated with chlorpyrifos use in the U.S or import tolerances, even with the retention of the 10X safety factor. *Id*. Nevertheless, believing it was very close to reaching final agreement with EPA and to avoid derailing months of negotiations, Gharda submitted a proposal to EPA for the cancellation of certain import tolerances. *Id.* & Ex. I. Gharda followed up asking EPA to consider its points concerning import tolerances, but stressed that it did not want the import tolerance issue to stand in the way of resolving voluntary cancellation of uses pursuant to the terms discussed, as summarized in Gharda's July 6 email. *Id.* & Ex. J. EPA responded stating that it appreciated Gharda's engagement on this challenging issue. *Id*.

3. *After Leading Gharda to Believe a Final Agreement Regarding Voluntarily Cancellation of Many Uses Was Imminent, EPA Abruptly Ceases Discussions and Announces It Is Revoking All Tolerances*

Following Gharda's July 14 submission and EPA's response, Gharda heard nothing further from EPA for weeks. *Id.* ¶ 34. Growing increasingly concerned as the court deadline for EPA to issue a final rule was approaching, Gharda requested a meeting with EPA leadership. *Id.* ¶ 35. After Gharda's repeated outreach, EPA finally allowed Gharda to have a twenty-five minute meeting with Assistant Administrator Freedhoff and others from EPA on August 16, 2021. *Id.* During the meeting, Gharda reiterated its commitment to voluntarily cancel uses as set forth above, urged EPA to make a decision consistent with science and law, and again stressed the major supply chain disruptions and catastrophic losses that would result from a revocation of tolerances with immediate effect. *Id*. EPA was silent during this meeting, indicating only that it was willing to "work collaboratively" with Gharda going forward. *Id*.

The next day after its meeting with EPA leadership, Gharda discovered a posting on EPA's website announcing the August 2021 revocation of all tolerances for chlorpyrifos, which Gharda also discovered was posted days **before** its meeting with EPA leadership. *Id.* ¶ 36 & Ex. L. When Gharda reached out to EPA about the posting, EPA apologized for the posting and immediately removed it, but confirmed that the final rule would be consistent with the website. *Id*. EPA indicated that there would be "elbow room" on timing of the final rule's implementation. *Id.*

C. EPA's Final Rule Revoking All Tolerances for Chlorpyrifos

EPA announced the Final Rule on August 18, 2021, which was published in the Federal Register on August 30, 2021. 86 Fed. Reg. 48,315. In the Final Rule, EPA stated that it is revoking all food use tolerances for chlorpyrifos. *Id.* at 48,317. EPA stated that, "[b]ased on the currently available data and taking into consideration the currently registered uses for chlorpyrifos," it is unable to make a safety finding under the FFDCA, even including an FQPA safety factor of 10X. *Id.* at 48,315, 48,317. EPA did not rely on any new data or scientific analyses in reaching this conclusion. In fact, the scientific analysis in the Final Rule is largely consistent with the Agency's scientific findings in the PID. Among other things, EPA continued to apply 10% RBC AChE as the regulatory endpoint for risk assessment, which it deemed "well-established." *Id.* at 48,317. Consistent with the PID, EPA stated that it "remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported" in epidemiology studies. *Id.* at 48,324.

As to the aggregate exposure assessment, EPA confirmed in the Final Rule, as it had found in the PID, that "exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern." *Id.* at 48,333. EPA agreed in the Final Rule that it is only drinking water exposures, when combined with food and non-occupational

(residential) exposures, that create risks of concern. *Id.* As to drinking water, the Final Rule acknowledged EPA's findings in the PID that drinking water exposures do not exceed levels of concern when assuming use on only eleven high-benefit crops in select regions. *Id.* Nevertheless, and despite admitting that "there may be limited combinations of uses *that could be safe*," EPA claimed that because it is required to assess aggregate exposure taking into account all "currently registered uses" and based on the 2016 DWA, it could not find that aggregate exposures to chlorpyrifos are safe. *Id*. The Agency stated, with no further explanation, that it lacked "effective mitigation upon which to base a reduced aggregate exposure calculation." *Id.* The Final Rule stated that the tolerances would expire on February 28, 2022, six months from the date of publication, purportedly to comply with international trade obligations. *Id.* at 48,334.

EPA issued a press release in conjunction with the Final Rule. EPA, *EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health*, https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health (Aug. 18, 2021). In the press release, EPA stated that the Final Rule would "help to ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of this pesticide," and "follow[s] the science and put[s] health and safety first." *Id.*

After the Final Rule was announced, EPA held a public briefing session on the Rule. Seethapathi Decl. ¶ 38. EPA invited stakeholders to submit questions to EPA regarding about the Final Rule. *Id*.

Following EPA's public briefing, Gharda and others submitted questions to EPA, concerning the Final Rule's scope, applicability, timing for implementation, and harmonization

with FIFRA. *Id.* ¶ 39. Gharda specifically asked whether EPA would consider mitigation in light of Gharda's commitment to accept label modifications limiting use of chlorpyrifos to the select crop uses in select regions EPA determined were safe in the PID. *Id.* Among other questions, Gharda also asked whether EPA had reviewed or was willing to consider the 2020 Corteva drinking water study. *Id.*

On September 20, 2021, over a month after the Final Rule was announced, EPA posted responses to "Frequent Questions about the Chlorpyrifos 2021 Final Rule" ("FAQs") on its website,[1] and responded directly to Gharda's questions that were not addressed in the FAQs. *Id.* ¶ 40. EPA's responses did not appear to allow any "elbow room" or opportunities to "work collaboratively" on the Rule's timing and implementation, but instead directed interested parties to submit objections. *Id.* EPA also did not respond to Gharda's question concerning label modifications consistent with the Agency's safety finding, and indicated that "due to time constraints" it was unable "to conduct additional scientific analysis beyond what was already available at the time of the court ruling." *Id.*

VI. GHARDA'S OBJECTIONS

A. OBJECTION 1: EPA's Final Rule Revoking All Tolerances Is Arbitrary and Capricious Because it Ignores EPA's Own Safety Finding for Eleven Critical U.S. Crop Uses.

EPA's Final Rule revoked all tolerances because EPA claimed it could not make a safety finding for all currently registered uses. EPA arbitrarily disregarded its own, most conservative assessment in its PID and 2020 DWA, which provided a clear scientific basis for retention of tolerances for eleven critical crop uses. EPA stated unequivocally in the PID that limiting use to eleven high-benefit crop uses in select regions "***will not pose potential risks of concerns with an***

[1] https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-2.

FQPA safety factor of 10X," meaning it had all of the science backing it needed to leave those uses in place. PID at 40 (emphasis added). EPA's Final Rule did not rely on any new scientific data or assessments that deviated from this finding.

EPA said that it was unable to rely on its PID and 2020 DWA because it is required to conduct an assessment that considers all "currently registered uses." *See* 86 Fed. Reg. at 48,333. However, there is nothing in the FFDCA or the Ninth Circuit order that requires EPA to make a safety finding that accounts for all currently approved uses. The FFDCA instructs that EPA consider "all *anticipated* dietary exposures and all other exposures for which there is *reliable information*." FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added) (Determination of safety). This language is forward-looking; it is unreasonable to construe it to require EPA to assess only the uses that it previously approved. *See Kaseman v. District of Columbia*, 444 F.3d 637, 642 (D.C. Cir. 2006) (statutes should be interpreted to avoid untenable distinctions, unreasonable results, or unjust or absurd consequences). There is nothing prohibiting EPA from making a safety finding as to only a subset of uses in certain regions when it has "reliable information" at its disposal to do so. EPA's failure to acknowledge its authority to do so is particularly troubling when, as here, it has engaged in "good faith" negotiations with a registrant that is willing to accept a subset of critical crop uses.

EPA's construction would lead to the absurd result that the Agency could never modify tolerances to limit use of previously registered products based on new or updated scientific data. *See Kaseman*, 444 F.3d at 642. Indeed, EPA's Final Rule is directly at odds with the Ninth Circuit decision, which specifically acknowledged that the PID "propos[ed] to modify certain chlorpyrifos tolerances" and recognized that EPA could find, based on the PID, that "modified tolerances or registrations [are] safe." *LULAC*, 996 F.3d at 703.

Not only does EPA have the authority to modify tolerances and to take other regulatory action to conform to its safety finding, it routinely does so. Reiss Decl. ¶ 17. EPA regularly conducts risk assessments in which it determines that some uses but not others exceed the "risk cup" and requires appropriate relabeling and mitigation measures. *Id.* In fact "[t]his is fundamental to the Agency registration process." *Id.* For example, much like in the 2020 DWA, "EPA conducts an assessment that assumes a set of proposed uses" when it registers a new product. *Id.* This is consistent with the statutory directive that EPA consider "all anticipated exposures." *Id.; see* FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii). "Thus, there is no scientific reason why the 2020 DWA could not form the basis of a decision on the future of those 11 crops and only those 11 crops." *Id.*

Moreover, EPA has a guidance for conducting geographic-specific and regional drinking water assessments that EPA references in the Final Rule. 86 Fed. Reg. at 48,329 (citing https://www.epa.gov/sites/default/files/2020-09/documents/framework-conducting-pesticide-dw-sw.pdf) (Sept. 2020). EPA's guidance "outlines a tiered process for conducting drinking water assessments that relies on increasing refinement of the underlying assumptions in the assessment." Reiss Decl. ¶ 11. "The 2020 DWA applies the highest level of refinement (Tier 4) that is laid out in the EPA guidance" and reflects "the best available science for assessing drinking water risks." *Id.*

EPA states in the Final Rule that "without effective mitigation upon which to base a reduced aggregate exposure calculation, the products as currently registered present risks above the Agency's level of concern." *Id.* at 48,333. But the purpose of the 2020 DWA was to mitigate risks, and the PID provided recommended mitigation based on the 2020 DWA that EPA could have implemented to retain tolerances for a limited subset of uses in select regions. EPA

acknowledged this in the Final Rule. *See id.* at 48,322 (the PID proposal for the retention of 10X uses "was intended to offer stakeholders a way to mitigate the aggregate risk from chlorpyrifos"). It is unclear, and unexplained in the Final Rule, what additional mitigation the Agency believed it needed to determine that this limited combination of uses is safe. Gharda attempted to clarify this with the Agency in questions submitted to EPA after the Final Rule was announced at EPA's invitation, but EPA did not address this issue in its FAQs or responses to Gharda's questions. Seethapathi Decl. ¶ 39.

It is a foundational principle of administrative law that agencies must provide a reasoned explanation for departing from prior conclusions. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *accord Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (the agency must examine the relevant data and articulate a satisfactory explanation for its action). "Reasoned decision-making requires that when departing from precedents or practices, an agency must 'offer a reason to distinguish them or explain its apparent rejection of their approach.'" *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020) (quoting Sw. *Airlines Co. v. FERC*, 926 F.3d 851, 856 (D.C. Cir. 2019); *see also Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D. C. Cir. 1978) (greater scrutiny applies to agency actions departing from prior norms and "it is at least incumbent upon the agency carefully to spell out the bases of its decision when departing from prior norms"). An agency may not "gloss[] over or swerve[] from prior precedents without discussion." *Sw. Ailines Co.*, 926 F.3d at 856 (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970). Equally clear is the requirement that federal agencies act in a consistent, evenhanded manner. *See Sharron Motor Lines, Inc. v. United States*, 633 F.2d 1115, 1116 (5th Cir. 1981);

see also Powell v. United States, 945 F.2d 374, 377 (11th Cir. 1991) (recognizing "a claim for administrative inconsistency").

Here, EPA has arbitrarily and summarily cast aside its thorough and well-reasoned scientific assessments supporting a safety finding for a subset of critical crop uses without any logical explanation. This is precisely the type of agency action held arbitrary and capricious by reviewing courts. *See, e.g., Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000) (vacating EPA rule that "openly overrode" its own science). EPA's abandonment of its scientific findings is especially troubling given that Gharda and other members of the regulated community rely on the Agency's assessments and trust and expect that EPA will make decisions that are rooted in science. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016) (agency reversal of prior policy without a reasoned explanation was arbitrary and capricious, particularly where longstanding policy engenders reliance interests that must be taken into account) (citing *Fox Television Stations, Inc.*, 566 U.S. 502). The law is clear that EPA cannot regulate in this manner.

B. OBJECTION 2: EPA's Final Rule Is Arbitrary and Capricious Because it Disregarded a Commitment from Gharda to Modify its Registration In Accordance with the Agency's Safety Finding.

In addition to ignoring its own safety finding, EPA's Final Rule disregarded a written commitment from Gharda to voluntarily cancel the uses identified in the PID as the 1X uses, consistent with the Agency's safety finding in the PID. Gharda submitted this proposal to EPA nearly two months ahead of the Agency's deadline to act in response to the Court order, and was standing by to discuss the substance of Gharda's voluntary cancellation letter and necessary label modifications with EPA when the Agency abruptly and inexplicably withdrew from discussions. Seethapathi Decl. ¶¶ 24–34. EPA plainly had at its disposal the "effective mitigation" necessary

to modify tolerances based on its safety finding for the 10X uses. Its decision to instead revoke all tolerances, without any explanation, was arbitrary and capricious.

C. OBJECTION 3: EPA Acted Arbitrarily and Capriciously and in Bad Faith in Negotiating a Voluntary Cancellation with Gharda—During which Gharda Met Each of EPA's Continually Increasing and Unjustified Demands—Only to Then Abruptly and Inexplicably Revoke All Tolerances.

All currently approved uses of chlorpyrifos are safe, based on the weight of the scientific evidence, and Gharda disagrees with EPA's application of an FQPA 10X safety factor to address "uncertainties" in the scientific literature concerning neurodevelopmental effects. *See* Gharda Comments on PID, EPA-HQ-OPP-2008-0850-0999. Nevertheless, at EPA's request that Gharda entertain an agreement to voluntarily cancel certain currently approved uses of chlorpyrifos, and in an effort to cooperate with the Agency, Gharda spent months working with EPA to reach mutually agreeable terms. Seethapathi Decl. ¶¶ 21–34. Gharda poured enormous time and resources into these discussions. *See id*.

EPA initially focused these discussions on cancellation of the uses identified in the PID as 1X crop uses. *Id.* ¶¶ 21–26. In an effort to cooperate and given the Agency's timing concerns, Gharda ultimately agreed, even though such a reduction in uses would eliminate a substantial portion of its U.S. chlorpyrifos business. *Id*. Over a period of just a few weeks, EPA continually expanded its requests of Gharda to include cancellation of some 10X crop uses, then application methods, and later import tolerances—all without any scientific or legal basis. *Id.* ¶¶ 27–33. At the same time, EPA refused to consider Gharda's science-based mitigation proposals. *See id*. ¶ 31.

At every stage of these discussions, Gharda stressed to EPA the critical importance of reasonable phase-out and existing stocks periods, to avoid massive supply chain disruption and to minimize harm to growers. *Id.* ¶¶ 21, 23–24, 28. Until near the very end of discussions, EPA

was receptive to these concerns, even proposing phase-out periods of 12–18 months for formulators and distributors and until exhaustion for growers. *Id*. ¶¶ 25, 29. EPA then retreated from these terms, too, even for the 10X crop uses it had found safe. *Id*. ¶¶ 31.

While Gharda was disappointed that EPA repeatedly sought to eliminate additional uses, impose additional label restrictions, and shorten the period for implementation, Gharda met each of EPA's requests cooperatively and fairly. *Id*. ¶¶ 21–33. Believing that it was close to reaching agreement with EPA and given the court-imposed time constraints, Gharda eventually agreed to accept, *in writing*, the voluntary cancellation of most uses, with additional label restrictions. *Id*. As requested by EPA, Gharda stood by, waiting for EPA's request that Gharda submit a formal letter seeking voluntary cancellation of uses. EPA then abruptly and inexplicably ceased discussions with Gharda, until the Final Rule was announced. *Id*.

The Agency's conduct and processes leading up to the Final Rule were fundamentally unfair. Gharda went above and beyond to meet EPA's continually increasing demands, and believed it was dealing with the Agency in good faith. Then, the Agency changed course and announced the Final Rule, with no notice to Gharda or explanation. Beyond lacking a scientific basis, the last-minute turn of events was a surprise to Gharda and other members of the regulated community, and departed from months of discussions in which EPA led Gharda to believe that several key crop uses would survive and Gharda, in turn, acted in reliance on those representations. Even EPA's final pre-final rule meeting with Gharda was stained by the discovery that EPA had already posted on its website *before the meeting* its intentions with respect to the final rule. Despite EPA's claimed interest in working with Gharda "collaboratively," EPA has shown no willingness to do so since the Final Rule was announced, nor any flexibility in the Rule's implementation, notwithstanding the chaos it has caused in the

agricultural supply chain. This is not how a U.S. federal agency should deal with regulated parties.

It appears clear that EPA's Final Rule was not driven by science or fair dealing with the regulated community. This is evident not only from the constantly moving goalposts in Gharda's discussions with EPA leading up to the Rule's announcement, which were not rooted in science, but also from EPA's prejudicial and misleading public messaging around the Rule, which cited reasons for revocation that are unsupported by science and inconsistent with the Rule itself. *See* Seethapathi Decl. ¶ 45.

In short, EPA's conduct and regulatory process demonstrate bad faith, A showing of bad faith by an agency undermines the reasonableness of the agency's decisionmaking and supports a finding that its actions are arbitrary and capricious. *See Dallas Safari Club v. Bernhardt*, 518 F. Supp. 3d 535, 542–43 (D.D.C. 2021) (when a party challenges agency action as arbitrary and capricious, the reasonableness of agency action is judged "in accordance with its stated reasons . . . *unless there is a showing of bad faith or improper behavior*") (emphasis added) (citation omitted); *Ctr. for Biological Diversity v. Trump*, 453 F. Supp. 3d 11, 34 (D.D.C. 2020) ("a strong showing of bad faith or improper behavior . . . suggests arbitrary and capricious decisionmaking") (citations omitted).

D. OBJECTION 4: EPA's Final Rule is Arbitrary and Capricious Because the Agency Failed to Give Adequate Consideration to Relevant Scientific Data and Information.

EPA issued the Final Rule without considering important scientific data. This includes comments and other submissions Gharda supported through an industry task force that highlighted numerous flaws in the Agency's 2016 DWA. *See* DAS Comments on 2016 Notice of Data Availability, Revised Human Health Risk Assessment and Refined Drinking Water Assessment for Chlorpyrifos, at 5EPA-HQ-OPP-2015-0653-0651 (Jan. 17, 2017) (commenting

on 2016 DWA as an overly conservative, screening-level estimate that far over-estimates real world exposures and ignores science-based refinements submitted by the registrant); *see also* DAS Response to Objections to EPA's Denial of Petition to Revoke Tolerances and Cancel Registrations for Chlorpyrifos (and supporting Declarations), EPA-HQ-OPP-2007-1005-0526) (Aug. 27, 2018) (challenging objections asserting drinking water risk concerns as based on the incomplete and unrefined 2016 DWA); *see also* Reiss Decl. ¶ 13 (addressing "significant limitations" in 2016 DWA). EPA's reliance on the 2016 DWA to justify revoking tolerances—without considering these comments on the 2016 DWA and in disregard of EPA's far more robust and highly refined 2020 DWA—is arbitrary and capricious. *See Conner v. Burford*, 848 F.2d 1441, 1453–54 (9th Cir. 1988) (Fish and Wildlife Service acted arbitrarily and capriciously in failing to prepare biological opinion based on best scientific data available).

EPA also failed to review a Corteva drinking water study submitted to EPA in December 2020, around the time the PID was released, which analyzed cholinesterase inhibition in rats following exposure to chlorpyrifos oxon. *See A Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days*, MRID 51392601. EPA was consulted on the design of the study and provided feedback to Corteva, and the interim results were presented to EPA in August 2020, well before the issuance of the PID. Reiss Decl. ¶ 23. The study found "(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure." *Id.* ¶ 27. This study nullified EPA's assumption in the 2020 DWA "that chlorpyrifos oxon is more toxic than the parent chlorpyrifos for drinking water exposure purposes." *Id.* ¶ 29. The study demonstrates that "drinking water risks associated with the oxon are not a risk concern for any agricultural

uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos." *Id.* ¶ 30.

Gharda urged EPA to consider this critical study, both in its comments on the PID and during discussions with EPA concerning a potential voluntary cancellation of uses. *See* Gharda Comments on PID, EPA-HQ-OPP-2008-0850-0999; Seethapathi Decl. Ex. A. Gharda also specifically asked EPA in questions submitted in response to the Final Rule whether EPA had considered the study or was willing to do so in the near term. *Id.* ¶ 39. In response, EPA stated that it "has the Corteva drinking water study in house for review" but that "[d]ue to time constraints, EPA was not able to conduct additional scientific analysis beyond what was already available at the time of the court ruling." Seethapathi Decl. Ex. K.

EPA's position is untenable. To be sure, the Ninth Circuit ordered EPA to revoke or modify tolerances within sixty days and found that it would not "be reasonable to remand for further factfinding after thirteen years of interminable delay." *LULAC*, 996 F.3d at 702. But the Ninth Circuit decision did not give EPA license to ignore highly relevant scientific data invested in by the registrants that EPA has *had at its disposal* for months leading up to the court decision and that EPA will have had for over a year by the time the Final Rule takes effect. Indeed, the Ninth Circuit decision specifically contemplated that EPA's "further research" could provide the basis for "modif[ying] chlorpyrifos registrations rather than cancelling them." *LULAC*, 996 F.3d at 703. Nor does the decision justify EPA's refusal to even entertain science-based mitigation proposals Gharda offered to put forward in response to EPA's occupational risk concerns, concerns which although irrelevant to food tolerances plainly appear to have driven EPA's revocation decision. *See* https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health (EPA press release stating that Final Rule would

protect farmworkers from "potentially dangerous consequences of this pesticide"). The drinking water study and other data Gharda was prepared to submit should not have required significant time or effort for EPA to review. *See* Reiss Decl. ¶ 23 (explaining that the 2020 Corteva study "is not onerous to review or interpret and EPA could have done so before the issuance of the PID and certainly well before the issuance of the Final Rule").[2]

EPA has a statutory duty to make decisions based on valid, complete, and reliable data. FFDCA § 408a(b)(2)(D), 21 U.S.C. § 346a(b)(2)(D)(i). The need for EPA to carefully consider all relevant data at its disposal is all the more important given the significant due process issues at stake, and the disruption its draconian revocation action has caused and will continue to cause on the agricultural marketplace. *See infra* at 35–36; Seethapathi Decl. ¶¶ 41–49. By pressing ahead with its overly broad revocation order while ignoring relevant data under the guise of court-imposed time pressures, the Agency's decision rests on incomplete data and is arbitrary and capricious. *State Farm Mut.*, 463 U.S. at 43 (agency's failure to examine all relevant data is arbitrary and capricious); *see also Love v. Thomas*, 858 F.2d 1347, 1358–59 (9th Cir. 1988) (reversing EPA suspension order based in part on agency's reliance on insufficient data); *Greenpeace v. Nat'l Marine Fisheries Serv.*, 80 F. Supp. 2d 1137, 1150 (W.D. Wash. 2000) (agency acted arbitrarily and capriciously by relying on incomplete information and ignoring relevant data).

[2] Gharda respectfully submits that EPA has all of the scientific data at its disposal to find that chlorpyrifos oxon is not relevant to EPA's aggregate exposure assessment under the FFDCA. To the extent that EPA believes that a fact issue is presented by this data, Gharda respectfully requests a hearing. *See* FFDCA § 408(g)(2)(B), 21 U.S.C. § 346a(g)(2)(B).

E. OBJECTION 5: EPA Failed to Afford Gharda and Other Stakeholders Adequate Procedural Due Process.

A pesticide registration is a recognized property right under FIFRA. *See Reckitt Benckiser, Inc.*, 762 F. Supp. 2d at 45 ("A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute."); *Mem. & Order, Pesticide Action Network N. Am.*, No. C 08-1814, at 4 (N.D. Cal. July 8, 2008), ECF No. 43 ("The registrations involved here are essentially government licenses to produce, distribute and sell pesticides . . . [and] therefore constitute property[.]"). As such, it cannot be taken away without due process of law. *See Indus. Safety Equip. Ass'n*, 656 F. Supp. at 856 ("It is well settled that an agency license can create a protectible [sic] property interest, such that it cannot be revoked without due process of law.").

EPA's revocation of tolerances based on alleged drinking water concerns, without responding to comments and critical scientific data submitted by the registrants that directly address those concerns, raises significant due process issues. Through an industry task force, Gharda has supported the submission of detailed comments on and proposed science-based refinements to the Agency's 2016 DWA. EPA has had these materials since as early as January 2017 but has never responded to them, despite committing to do so. Indeed, in July 2019 EPA acknowledged that "certain uses, application rates, and practices" described in the chlorpyrifos labels overestimate drinking water exposure, and stated that it had requested additional information from the registrants to confirm the accuracy of these assumptions, which it would then incorporate into its Proposed Interim Decision. *See, e.g., Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order*, 84 Fed Reg. 35,555, 35,566 (July 24, 2019). EPA noted for example that it was pursuing surface water monitoring data that would allow it to "confidently estimate pesticide concentrations in surface water that may be sourced by

community water systems." *Id.* EPA's failure to review scientific data and comments provided by the registrants is troubling given that EPA revoked tolerances in the Final Rule *based on the 2016 DWA*, without any reasoned explanation or scientific basis for abandoning its far more robust, highly refined 2020 DWA.

EPA has also refused to consider the Corteva drinking water study submitted in December 2020 (and in draft form months earlier), which nullifies EPA's assumptions concerning drinking water risks from chlorpyrifos oxon. Reiss Decl. ¶¶ 23–30. EPA has also failed to review and respond to comments on the PID and underlying assessments submitted by Gharda and other stakeholders months before the Ninth Circuit's decision. These comments urged EPA to review and act on the Corteva drinking water study and challenged EPA's application of an FQPA 10X safety factor to address "uncertainties" in unreliable epidemiology data. By not responding to these comments and other submissions, which challenge directly EPA's rationale for revocation of all tolerances, EPA has denied Gharda and other interested parties meaningful notice and comment.

EPA must correct its due process violations and commit to a meaningful, thorough review of objections. It must also commit to reviewing the relevant scientific data and science-based comments bearing on the drinking water issues it has had at its disposal for months, years in some instances, and to modifying its revocation order as appropriate, before the Final Rule and tolerance expiration take effect.

F. OBJECTION 6: The Final Rule Infringes the Substantive Due Process Rights of Gharda and other Affected Parties.

There is a fundamental requirement under the Constitution that substantive standards of justice must be applied to assure that there is no deprivation of life, liberty, or property rights. This "substantive due process" doctrine forbids a regulatory body from taking an action that is

substantively so unfair that fundamental rights are abridged, even if proper procedures are followed.

As the Supreme Court stated in *Nebbia v. New York*, 291 U.S. 502, 525 (1934), "the guaranty of due process … demands … that the law shall not be unreasonable, arbitrary or capricious." The law is clear that "the possibility of arbitrary, undocumented action will not be tolerated when protected [property] rights are at stake." *Roane v. Callisburg Indep. Sch. Dist.*, 511 F.2d 633, 639 (5th Cir. 1975); *see also United States v. Carolene Prods. Co.*, 304 U.S. 144, 152–53 &n.4 (1938); *Anthony v. Franklin Cnty.*, 799 F.2d 681, 684 (11th Cir. 1986). Gharda and other registrants affected by the Final Rule have a fundamental property right in their registrations, which is protected by the substantive due process doctrine. The economic value of a registration for food use crops is dependent on having the appropriate tolerances in place. The Agency's action in revoking all tolerances without a reasoned explanation or valid scientific basis, and in disregard of scientific data that support the retention of tolerances, has improperly deprived Gharda of the economic value of its registration for chlorpyrifos. This action constitutes a clear violation of Gharda's substantive due process rights, and has unfairly and arbitrarily deprived Gharda of fundamental property rights.

G. OBJECTION 7: EPA Has Acted Arbitrarily and Capriciously in Imposing an Unreasonably Short Implementation Timeframe That Will Cause Significant Harm to Gharda and Other Affected Parties.

EPA's Final Rule proposes to take effect six months from the date of its publication on August 30, 2021, or on February 28, 2022. 86 Fed. Reg. 48,334. The 2021 growing season has essentially ended, and chlorpyrifos would not be used until the next growing season beginning approximately in April 2022. Seethapathi Decl. ¶ 40. Thus, even if the Final Rule had a valid scientific justification, the six-month period imposed for the Rule's implementation is effectively

meaningless and allows no time for Gharda, distributors, and growers to phase out inventories and exhaust existing stores of chlorpyrifos. *Id.*

EPA has claimed in discussions with Gharda and in the Final Rule that the six-month period is necessary because the WTO Agreement on the Application of Sanitary and Phytosanitary Measures requires members to allow a "reasonable interval" between publication of a sanitary or phytosanitary regulation and its effective date, to allow time for exporting members, particularly developing countries, to adapt their products and production methods to the regulation. *Id.* ¶ 32; 86 Fed. Reg. 48,334. But the WTO has interpreted "reasonable interval" to mean a period of *not less than* six months." 86 Fed. Reg. 48,334 (emphasis added). The six-month requirement under the WTO agreement is thus a floor, not a ceiling as EPA has implied.

EPA's imposition of a six-month, off-season period for the Final Rule to take effect will result in extraordinary economic and other harms to Gharda, its distributors, and the end users of its products. Seethapathi Decl. ¶¶ 41–49. With Corteva's exit from the U.S. market for chlorpyrifos, Gharda increased production in order to meet customer demand and is now the primary supplier of chlorpyrifos for agricultural use in the U.S. *Id.* ¶¶ 10, 42. As a result, Gharda has a significant volume of raw materials and U.S. labeled product in inventory. *Id.* ¶ 42. If Gharda is unable to formulate, sell, and distribute these products for use in the 2022 growing season and beyond, Gharda will suffer CBI economic losses, to say nothing of the nearly CBI loss in its investment in chlorpyrifos and lost future sales of chlorpyrifos products in the U.S. of approximately CBI annually. *Id.*

The short period for implementation has also strained Gharda's relationships with its customers, who distribute its products to suppliers and end users. *Id.* ¶ 44. In the months

leading up to the Final Rule, Gharda assured its customers that it was working cooperatively with EPA to reach an agreement that would allow for key agricultural uses to continue, consistent with EPA's safety finding in the PID. *Id.* EPA's abrupt departure from the negotiations and its own scientific findings has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill. *Id.* ¶¶ 43–44.

Losses from an effectively immediate removal of chlorpyrifos from the U.S. market would not be borne by Gharda alone. *Id.* ¶ 47. It will also cause significant financial hardship to distributors and growers who invested substantial sums in reliance on the registration in products they are no longer able to sell or use. *Id.* Distributors face particularly dire economic consequences. Most distributors purchase products from Gharda at least a year in advance, and as a result have significant product on hand in order to meet market needs and often fluctuating demand by U.S. growers. *Id*. Gharda has been informed by some of its major customers that they currently have inventories of chlorpyrifos product on hand valued at approximately CBI CBI, for which there will no longer be a viable market if the Final Rule takes effect. *Id*. Growers, for their part, not only face a lost investment in unusable product but also must find alternative, sometimes more expensive alternative products or risk significant crop losses. *Id.* In total, the volume of U.S. labeled chlorpyrifos products in the hands of distributors, retailers, and growers is estimated to be valued at CBI. *Id.* Finally, commodity traders and other holders of food and feed with detectable chlorpyrifos residues face significant uncertainty, as it may be practically impossible to demonstrate that the residues result from a lawful application, particularly in the case of finished food and feed product with extended shelf lives. *Id.* ¶ 48. This confusion could result in the unnecessary waste of otherwise safe and nutritious food and

feed. *Id.* In short, EPA's Final Rule will impose damage and harm throughout the agricultural value chain and an already fragile economy.

EPA was well aware of these impacts leading up to the Final Rule, and even signaled in discussions following the Final Rule's announcement that there was "elbow room" on timing for the Rule's implementation. *Id.* ¶ 36. EPA has since refused to engage with Gharda and other affected parties on these issues, outside of a formal objections process. *Id.* ¶ 40. EPA's unwillingness to allow any meaningful period for an orderly phase-out of chlorpyrifos products is unfounded and arbitrary and capricious, particularly in the case of the 10X crop uses that EPA found safe under the PID. At a minimum, EPA should revise the Final Rule to allow for a gradual, multi-year phase-out of crop uses, to mitigate significant economic harm to Gharda and others in the agricultural supply chain and to allow growers time to transition to other products.

H. OBJECTION 8: EPA's Failure to Harmonize its Revocation Decision with FIFRA Is Arbitrary and Capricious.

EPA has also failed to harmonize its Final Rule revoking tolerances with FIFRA, including by following appropriate cancellation procedures and implementing provisions for existing stocks, as it is required to do by statute. The FFDCA contemplates that EPA will coordinate any necessary tolerances revocations with the associated registration cancellations under FIFRA. *See* FFDCA § 408(l)(1), 21 U.S.C. §346a(l)(1) ("in issuing a final rule under this subsection that . . . revokes a tolerance . . . for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA]"). Even the Ninth Circuit order in *LULAC* expressly directed EPA, in issuing a final rule modifying or revoking tolerances, "to correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with [its safety finding]." *LULAC*, 996 F.3d at 678.

The Final Rule is silent on any corresponding action under FIFRA. While EPA has said in its FAQs on the Final Rule that it "intends to cancel registered food uses of chlorpyrifos associated with the revoked tolerances under FIFRA, as appropriate,"[3] EPA has provided no explanation for how or when it will coordinate its revocation action with cancellation procedures under FIFRA. These include issuing a notice informing the registrant and the public of the cancellation, and sixty days prior to that notice, providing a copy of the intended notice to the Secretary of Agriculture, along with an analysis of the impact of the proposed cancellation on the agricultural economy. *See* 7 U.S.C. § 136d(b). EPA must also convene an SAP to provide comments to the Agency on "the impact on health and the environment" of proposed cancellation actions, *id*. § 136w(d), and publish in the Federal Register its analysis of any impacts on the agricultural economy, including impacts on production, prices of agricultural commodities, and retail food prices. *Id.* § 136d(b).

Given the exceedingly short time period for the Final Rule to take effect, it appears clear that any coordinated cancellation action under FIFRA will be *pro forma* at best, and will not provide appropriate due process to regulated parties or fully take into account or adequately notify the public of the significant impacts of cancellation on the agricultural economy. This includes economic harms to growers who rely on chlorpyrifos to meet their pest management needs and who will be forced as a result of the Final Rule to resort to less effective and/or more costly alternative products.

In addition to abridging cancellation procedures under FIFRA, the Final Rule is silent on provisions for existing stocks. In the FAQs accompanying the Final Rule, EPA stated that

[3] https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-2.

because it "has not cancelled any chlorpyrifos products as a result of the final tolerance rule," "there are no existing stocks at this time."[4] In reality, however, there significant volumes of chlorpyrifos technical and end-use products currently log-jammed in the U.S. agricultural supply chain, and no guidance from EPA on how to responsibly handle them once the Final Rule takes effect. Without an existing stocks order, stores of chlorpyrifos products that remain in the supply chain could be used without regard to the product label, with potentially negative impacts on health and the environment, and EPA would be without authority to stop it. This is not what Congress intended. EPA has a statutory mandate under FIFRA to ensure the safe, lawful, and orderly phase-out of these products that it has not fulfilled in issuing the Final Rule.

Indeed, in enacting and amending FIFRA, Congress made clear its intent that EPA oversee a comprehensive regime for the regulation of pesticides in order to prevent unreasonable adverse effects on human health and the environment. *See Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 991–92 (1984). Thus, Congress vested EPA with authority over the sale, distribution, and use of pesticide products at all stages of the product life cycle, including the authority to provide—and enforce—an orderly process for their disposal. 7 U.S.C. § 136d. Specifically, FIFRA Section 6 empowers EPA to cancel the registration of an existing pesticide in certain circumstances, or to suspend the registration of a pesticide to prevent an imminent hazard. FIFRA § 6(a), (b); 7.U.S.C. § 136d(a), (b). Importantly, Section 6 also authorizes EPA to concomitantly enter an "existing stocks" order, in which EPA may "permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled under [FIFRA Sections 6, 3, or 4], to such extent, under such conditions, and for such uses as the

[4] https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule.

Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter." FIFRA § 6(a)(1); 7 U.S.C. § 136d(a)(1).

In the 1980s, Congress became increasingly concerned with EPA's ability to satisfactorily deal with potential adverse effects resulting from the storage, disposal, and transportation of pesticides whose registrations had been cancelled or suspended. *See, e.g.*, Hearing of the Environment, Energy and Natural Resources Subcommittee, Committee on Government Operations, 100th Cong. 1st Sess. (July 9, 1987) (citing cancellations of registrations for ethylene dibromide (EDB), 2,4,5-T, silvex, and dinoseb). As initially conceived, EPA had the authority and financial responsibility to accept suspended or canceled pesticides and dispose of them at government expense. Congress added several key provisions to FIFRA in 1988 to expand EPA's authority to oversee the sale, distribution, and use of pesticides whose registrations have been terminated by some means, including by authorizing EPA to take enforcement action against violations of storage, disposal, and transportation requirements. FIFRA Amendments of 1988, Pub. L. No. 100-532, 102 Stat. 2654; *see also* H.R. Rep. No. 100-939 (1988) (to accompany S. 659). Specifically, Congress added (i) FIFRA Section 19, which makes clear that existing stocks orders issued "under [Section 6]" may include "requirements and procedures" governing disposal, 7 U.S.C. § 136q(a)(2), and (ii) FIFRA Section 12(a)(2)(k), which authorized EPA to take enforcement action against violations of existing stocks orders under FIFRA Section 12, 7 U.S.C. § 136j(a)(2)(K). These provisions fill critical gaps in areas where EPA's authority over newly unregistered pesticides had been lacking or unclear.

EPA's authority to address existing stocks of pesticides for which registrations have been cancelled is critical because FIFRA prohibits the *distribution or sale* of an unregistered pesticide

but does not prohibit its *use*. FIFRA § 3(a); 7 U.S.C. § 136a(a). In fact, Congress omitted reference to "use" in the first sentence of Section 3(a) (making it unlawful to "distribute or sell" an unregistered pesticide) while including "use" in the second sentence (granting EPA authority to regulate "use" of unregistered pesticides in order to prevent unreasonable adverse effects):

> Except as provided by this subchapter, no person in any State may *distribute or sell* to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the *distribution, sale, or use* in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

Id. (emphasis added); *cf. S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 894 (D.C. Cir. 2006) (Congress's inclusion of particular language in one section of a statute but omission of it in another is presumed to be intentional). FIFRA's enforcement provisions reinforce that use of unregistered pesticides is not unlawful: Section 12(a)(1) prohibits only the distribution and sale of unregistered products (not their use), and Section 12(a)(2)(g) prohibits only the "use" of a "registered pesticide" in a manner inconsistent with its labeling. 7 U.S.C. § 136j(a)(1), (a)(2)(G).

This framework presents several challenges in cases where previously registered products are rendered unregistered, including as a result of revoked tolerances.[5] Without an existing stocks order, end users of newly unregistered products would be free to use remaining stocks inconsistently with restrictions on the product label (which in the case of an unregistered pesticide is no longer enforceable). And because under FIFRA no party may "distribute or sell"—which includes "ship," "deliver for shipment," or "receive"—unregistered pesticides, *id*. § 136(gg), end users and others wishing to return existing stocks to the manufacturers or pursue other safe disposal options would be in violation of FIFRA. A comprehensive, enforceable order

[5] Although EPA has not yet issued the requisite cancellation notices, the term "unregistered" is applicable here in light of the practical effect of EPA's tolerance revocation actions.

on existing stocks thus ensures that post-termination use, sale, or distribution of newly unregistered products are within the scope of EPA's enforcement authority and that EPA is able to mitigate potential effects on human health and the environment.

Here, EPA issued the Final Rule revoking all tolerances, and acknowledged that it will be a violation of FIFRA to sell and distribute chlorpyrifos products labeled for use on food crops when the Final Rule takes effect, yet EPA disregarded its authority under FIFRA to oversee the orderly phase-out of existing stocks. As a result, there is considerable confusion as to how to handle significant stores of chlorpyrifos products that exist in the supply chain. Seethapathi Decl. ¶ 47 (explaining how distributors purchase at least a year in advance). Absent some action from EPA to address existing stocks, the agency would be powerless to prevent the use of chlorpyrifos products not in accordance with the previously operative label restrictions, which has the potential to adversely impact the environment. 7 U.S.C. § 136j(a)(1), (a)(2)(G).

In short, in taking action to revoke all tolerances without an existing stocks order, EPA has abdicated its duty under FIFRA to oversee the safe, orderly, and lawful disposal of the products that will be rendered essentially unregistered as a result of the Final Rule. A product that has been extensively used in the United States under EPA's oversight for decades cannot simply become, overnight, a harmful product undeserving of existing stocks provisions. If EPA persists in implementing the flawed Final Rule, it must *at a minimum* extend the expiration of tolerances coextensive with an appropriate existing stocks order, to provide guidance and clarity to affected parties and to mitigate risks to health and the environment.

I. OBJECTION 9: EPA's Revocation of Import Tolerances Lacks a Scientific Basis and Is Therefore Arbitrary and Capricious.

There is no scientific basis for EPA's revocation of import tolerances. Import tolerances regulate pesticide residues in or on foods that are imported into the United States; the pesticide

uses associated with these tolerances occur in other countries. Thus, dietary (food) exposures from imported foods are the only relevant exposures for purposes of EPA's FFDCA risk determination; drinking water is not a component of the FFDCA risk determination. EPA's PID and 2020 RHHRA did not identify any dietary risks associated with chlorpyrifos use in the United States or with import tolerances, even with the retention of the FQPA 10X safety factor. 2020 RHHRA at 12; PID at 14, 18; Reiss Decl. ¶ 31. EPA's dietary risk assessment includes domestic and imported food; if only imported food were considered, any potential risks would be even lower. Gharda raised all of these issues with EPA in discussions leading up to the Final Rule, and yet EPA's Final Rule revoked all tolerances. Seethapathi Decl. ¶ 33. EPA's blanket revocation of import tolerances it has acknowledged are safe is arbitrary and capricious. Reiss Decl. ¶ 31; *see also Nat'l Corn Growers Ass'n v. EPA.*, 613 F.3d 266, 275 (D.C. Cir. 2010) (vacating as arbitrary and capricious EPA decision to revoke import tolerances for carbofuran "because the EPA itself considered them safe").

EPA's guidance on pesticide import tolerances makes clear that where tolerances are revoked for reasons other than due to dietary risk concerns, "use in other countries may continue" and "EPA will consider requests (normally by petition) to modify or maintain a tolerance as an import tolerance." *Pesticides; Guidance on Import Tolerances & Residue Data for Imported Food*, 65 Fed. Reg. 35,069, 35,072 (June 1, 2000). Import tolerances "may be maintained provided that there is a need for the tolerance because the pesticide is used outside of the U.S. on commodities intended for the U.S. market" and provided the tolerance "meets the food safety requirements of FFDCA." *Id.* Gharda accordingly requests that EPA allow for the retention of all import tolerances for chlorpyrifos, consistent with the Agency's safety finding. Any refusal by EPA to allow for the retention of import tolerances it has conceded are safe

would be arbitrary and capricious and an improper attempt to influence the regulatory policy of foreign countries. *Id.* ("The Agency has no authority to regulate pesticide use in other countries."); *see also EPA Order Denying ABC's Petition to Revoke Import Tolerances for Various Pesticides*, 76 Fed. Reg. 49,318 (Aug. 10, 2011) (denying petition to revoke import tolerances based on alleged environmental risks in other countries as outside EPA's authority under the FFDCA).

J. OBJECTION 10: EPA's Final Rule Failed to Comply with Interagency Review Processes.

Under Executive Order 12866, federal agencies must submit "significant regulatory actions" for review to the Office of Management and Budget's Office of Information and Regulatory Affairs ("OIRA"). "Significant regulatory actions" include "any regulatory action that is likely to result in a rule that may … [h]ave an annual effect on the economy of $100 million or more" or "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." *Id.*

Gharda objects to EPA's determination that the Final Rule is exempt from OIRA review. OMB has clarified in guidance that actions that make existing tolerances more stringent are not exempt from OIRA review.[6] This unquestionably includes tolerance revocations.

Moreover, the Final Rule's impact on the economy will easily exceed $100 million and/or materially affect the agricultural economy, given the devastating harms the Final Rule will inflict across the entire agricultural value chain. These harms include lost investment in tens

[6] *See* October 12, 1993 Memorandum for Heads of Executive Departments and Agencies and Independent Regulatory Agencies, App'x C, Regulatory Actions Exempted from Centralized Regulatory Review for the Office of Pesticides and Toxic Substances at EPA, at 15 ("Actions regarding pesticide tolerances, temporary tolerances, tolerance exemptions, and food additives regulations, except those that make an existing tolerance more stringent.").

of millions of dollars of chlorpyrifos products that can no longer be sold, distributed, or used, tens of millions of dollars annually in future lost sales, millions of dollars in needlessly discarded food and feed, and harms to the registrant, including damaged customer goodwill, reputational harm, and potential loss in market share. Seethapathi Decl. ¶¶ 41–49. Not to mention severe financial hardship to U.S. growers facing the possibility of significant crop losses as a result of the Final Rule. Indeed, by EPA's own estimates the economic value of chlorpyrifos to the U.S. economy is as high as $130 million annually, based only on the cost of alternative products; EPA's benefits assessment expresses no uncertainty as to these figures. *See* Revised Benefits at 5. This value is likely much higher in actuality for those growers without viable alternatives to control destructive insect pests who face yield losses if the Final Rule takes effect.

In sum, EPA had an obligation to seek OIRA review for a rule of this magnitude. EPA must immediately withdraw or stay the effective date of the Final Rule, pending the completion of appropriate interagency review processes.

K. OBJECTION 11: EPA's Application of a 10X FQPA Safety Factor to Account for "Uncertainties" in Unreliable Epidemiology Data is Arbitrary and Capricious.

EPA correctly confirmed in the Final Rule that there are no causal linkages between chlorpyrifos exposure and the neurodevelopmental effects alleged in certain epidemiology studies. 86 Fed. Reg. at 48,324. However, Gharda objects to EPA's application of a 10X FQPA safety factor to address "uncertainties" in epidemiology studies claiming neurodevelopmental impacts associated with chlorpyrifos exposure. As detailed in Gharda's comments on the PID, incorporated here by reference, the FFDCA does not support the application of a precautionary 10X safety factor to address "uncertainties" in scientific studies that do not meet basic standards of reliability, particularly where a 10X safety factor results in the elimination of many important crop uses.

The FFDCA, as amended by the FQPA, instructs EPA to make safety factor determinations based on "reliable data." This is made explicit in the statutory text—both the provision defining the "reasonable certainty [of] no harm" standard, FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii), and the provision addressing an additional 10-fold margin of safety. *Id*. § 408(b)(2)(C)(ii), § 346a(b)(2)(C)(ii). Thus, EPA actions to revoke tolerances and/or to increase a safety factor in such a way that effectively results in revocation must, by statute, be based on valid, reliable data.

The FFDCA does not define "reliability" or "reliable data." In guidance, EPA has counseled that "the data and information" relied upon to inform a safety factor determination "must be *sufficiently sound* such that OPP could routinely rely on such information in taking regulatory action." EPA, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment* (Feb. 28, 2002) ("FQPA Safety Factor Policy") at A-6 (emphasis added); *see also id.* at 29, 31 ("As part of the toxicological considerations, OPP evaluates potential pre- and postnatal toxicity on a case-by-case basis taking into account all pertinent information. . . . As in any weight-of-evidence approach, it is important to consider the *quality and adequacy of the data*, and the consistency of responses induced by the chemical across different studies.") (emphasis added). Data that are not replicable, and in some cases not available, are not reliable. EPA, *Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment for Pesticides,* at 30 (Dec. 28, 2016) ("[R]eliability general[ly] refers to the ability to reproduce results . . . ."). And, data that do not accurately reflect exposure are not valid. *Id.* ("[V]alidity generally refers to the extent that exposure estimates reflect true exposure levels.").

The epidemiology studies claiming neurodevelopmental effects from chlorpyrifos exposure suffer from significant limitations and deficiencies that render them unsuitable to guide

major regulatory action. The studies have been consistently criticized in public comments and by EPA's Scientific Advisory Panel as nontransparent, biologically implausible, lacking in validity, and unsupported by the weight of the evidence (including newer lines of epidemiology studies), among other issues. EPA itself has deemed the epidemiology data not sufficiently "valid, complete, and reliable . . . under the FFDCA," 84 Fed. Reg. at 35,557, and again acknowledged the limitations in the data in the Final Rule. 86 Fed. Reg. at 48,322. These studies simply do not meet basic standards of reliability sufficient to justify application of a 10X FQPA safety factor, particularly where this results in the elimination of many critical crop uses.[7] In sum, FQPA safety factors must be based on valid, reliable data, not "uncertainties."

VII. CONCLUSION

For these reasons, and because of the significant, immediate, and irreparable injuries Gharda has and will continue to suffer as a result of the revocation of all tolerances, the Final Rule should be summarily reversed or, at a minimum, stayed pending administrative review by EPA and any potential judicial review of the objections submitted by Gharda, growers, grower groups, and other adversely affected stakeholders.

[7] Indeed, the former EPA official who co-authored the FQPA Safety Factor Policy has observed in comments that "the FQPA safety factor has been primarily used to account for incompleteness or uncertainties in the animal toxicology data base," and applying a 10X FQPA safety factor based on questionable epidemiology data would be contrary to EPA policy. Decls. In Support of Dow AgroSciences LLC's Responses to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos, Decl. of Jennifer Seed ¶¶ 16, 21–23, EPA-HQ-OPP-2007-1005-0526 (Aug. 27, 2018).

Respectfully submitted,

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Chlorpyrifos Registrant

Declaration of Ram Seethapathi

I, Ram Seethapathi, declare as follows:

1. I am the President of Gharda Chemicals International, Inc. ("Gharda"). I am authorized to make this affidavit on behalf of Gharda and have personal knowledge of all facts set forth herein.

2. I have a degree in Agricultural Sciences with a specialization in Entomology from Tamil Nadu Agricultural University; I was a Gold Medalist there, with a 4.0 GPA. I also have a diploma in General Management from the Indian Institute of Management Ahmedabad. I have been working for over four decades in the agricultural chemical industry at various levels, first in field development with Bayer, then as Regional Sales manager for Shell, and finally for eighteen years with Dow AgroSciences LLC (now Corteva Agriscience) in the Agricultural Chemicals Division, with progressively increasing responsibilities as Commercial Manager, Business Leader, and Human Resources Leader. While at Dow AgroSciences, I was involved very closely in chlorpyrifos market expansion from the early phase of the product lifecycle, including assisting in establishing a new manufacturing site in India and providing extensive training to employees working there. I was also the Safety Coordinator for Dow AgroSciences for the Asia Pacific region. I joined Gharda fourteen years ago, providing leadership for their business in North America.

3. I also serve as Administrative Committee Chair for two important Industry taskforces, the Outdoor Residential Exposure Taskforce (ORETF) and the Agricultural Re-entry Taskforce (ARTF). In addition, I serve on the Executive Committee for the Agriculture Handler Exposure Taskforce (AHETF). These taskforces are consortia of agrochemical companies that coordinate to jointly develop scientific studies in support of pesticide registrations.

4. I submit this affidavit in support of Gharda's Petition to Stay the Effective Date of the U.S. Environmental Protection Agency's ("EPA's" or the "Agency's") Final Rule for Chlorpyrifos Tolerance Revocations, 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the "Final Rule") and Gharda's Objections to the Final Rule.

Background on Gharda and Its Role in the Chlorpyrifos Market

5. Established in 1967, Gharda is a research-based company leading in the field of agrochemical manufacturing. Gharda was founded by Dr. Keki Hormusji Gharda, a prominent chemical engineer and chemist. After obtaining a Masters degree and Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor, Dr. Gharda established Gharda Chemicals in a small rented shed. More than four decades of innovation and investment in R&D has transformed Gharda into a successful pioneer agrochemical company. Gharda's product portfolio includes a wide range of insecticides and herbicides, including chlorpyrifos, for which it holds an EPA registration. Gharda sells end-use chlorpyrifos products under the brand name Pilot™ as well as technical grade chlorpyrifos for manufacturing use.

6. Chlorpyrifos is a vitally important agricultural tool, protecting over fifty valuable U.S. food crops from destruction due to insect pests, including alfalfa, cotton, soybeans, sugarbeets, and wheat. Crops protected by chlorpyrifos are worth over a hundred million dollars annually to the U.S. economy. *See* EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos at 5, 7, EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits"). Chlorpyrifos has value to growers in protecting their crops and income, as well as value to consumers who enjoy affordable, healthy, and high quality produce throughout the year.

7. Chlorpyrifos's critical importance as an insect pest management tool is due to its broad-spectrum efficacy, favorable environmental characteristics, and affordability for growers.

It is the leading active ingredient to control a broad spectrum of difficult-to-control insect pests, and for some destructive pests it is the only effective pest management tool available. *Id.* at 2.

8. Because of its broad-spectrum effectiveness, chlorpyrifos is often the first tool growers employ to control new or unknown insect pests, a long-standing problem but one that will be exacerbated by climate change. *See id.* at 12–13 (removal of "broad spectrum materials such as chlorpyrifos . . . from pest management programs can result in unexpected outbreaks of previously minor pests or even the emergence of new pests"). Chlorpyrifos is also less harmful to beneficial insect populations than other insecticides. It requires fewer applications and avoids the use of multiple chemistries to control certain pests, reducing overall insecticide use.

9. Gharda has long supported the registration of chlorpyrifos in the United States, including through an industry task force that provided financial and other support for comments, scientific data, and other materials submitted to EPA by Dow AgroSciences, LLC, now Corteva Agriscience.[1] Gharda has invested over CBI million in the development of data and other information to support the registration of chlorpyrifos in the United States.

10. In February 2020, Corteva announced that it would end production of chlorpyrifos by 2021. At that time, chlorpyrifos continued to be a critically important agricultural tool for many growers. As a result, many distributors and farm input suppliers began looking to Gharda to meet the market demand for chlorpyrifos. In response to this increase in demand, Gharda significantly increased its production of chlorpyrifos. Immediately prior to the Final Rule, Gharda was the primary supplier of chlorpyrifos for agricultural use in the United States.

[1] A list of many of the prior comments and submissions Gharda has supported through the task force is attached as Appendix A and incorporated herein by reference and in Gharda's Objections to the Final Rule.

11. Chlorpyrifos is one of Gharda's most important products. Revenues from sales of chlorpyrifos comprise a significant portion of Gharda's overall U.S. business, which prior to the Final Rule was only expected to increase. In 2020, Gharda's annual U.S. revenues from chlorpyrifos were approximately CBI. 2021 U.S. revenues from chlorpyrifos total CBI CBI to date and prior to the Final Rule were expected to increase to CBI by year end. In 2022 and beyond, Gharda's annual U.S. revenues from chlorpyrifos were projected (before the Final Rule) to be approximately CBI annually.

12. Gharda's position in the U.S. agrochemical industry is unique. Unlike many other registrants and leading suppliers of crop protection tools in the United States, Gharda does not have U.S.-based manufacturing facilities, which adds an additional level of complexity to the supply chain not encountered by U.S.-based manufacturers. Gharda ships materials to the United States and then uses tolling companies to package and label the technical and end use chlorpyrifos products for sale to U.S. distributors, creating significant employment opportunities. The pandemic has exponentially increased the costs and time required to ship Gharda's materials to the U.S. for formulating, packaging, and labeling.

13. Currently, Gharda has a significant volume of raw materials on hand at its manufacturing facility in India. Gharda also has inventory of U.S. labeled chlorpyrifos product on hand at its India facility valued at CBI. In addition, Gharda has inventories of chlorpyrifos product ready for distribution in the U.S. valued at CBI. If Gharda is unable to formulate, sell, and distribute these products for use in the 2022 growing season and beyond, Gharda will suffer CBI economic losses. These losses are in addition to the CBI lost investment described above in Paragraph 9 and future annual lost sales similar to those set forth above in Paragraph 11.

14. There are also significant stores of U.S. labeled chlorpyrifos products in the hands of distributors, retailers, and growers, estimated to be valued at approximately CBI. (Gharda has been specifically informed by some of its major customers that they currently have inventories of chlorpyrifos product on hand valued at approximately CBI.)

EPA's Regulatory Processes Concerning Chlorpyrifos

15. Gharda has a vital interest in pesticide regulatory procedures and food safety standards, and in actions taken by the EPA with respect to agricultural crop protection tools, including actions that relate to pesticide residues found in or on food and the regulation of those residues under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and Food Quality Protection Act ("FQPA"), and associated pesticide registration actions under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

16. On December 7, 2020, as part of its Registration Review of chlorpyrifos pursuant to FIFRA, EPA published its Proposed Interim Registration Review Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0971 (the "PID"). *See* 85 Fed. Reg. 78,849 (Dec. 7, 2020). The PID is supported by analyses included in EPA's September 21, 2020 Third Revised Human Health Risk Assessment, EPA-HQ-OPP-2008-0850-0951 (the "2020 RHHRA"), which in turn relies on, among other documents, a September 15, 2020 Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-0850-0941 (the "2020 DWA"). EPA's PID and 2020 DWA reflected a fulsome, measured, scientific assessment of the human health and drinking water risks of chlorpyrifos by EPA's expert scientists.

17. In its 2020 RHHRA and PID, EPA continued to use 10% red blood cell acetyl cholinesterase inhibition ("RBC AChE") as a regulatory endpoint or point of departure for human health risk assessments for chlorpyrifos. *See* 2020 RHHRA at 2. This long-standing

conservative and health-protective endpoint is supported by decades of scientific study. EPA stated that it "remains unable to verify the reported findings" of epidemiology studies claiming links between prenatal exposure to chlorpyrifos and neurodevelopmental effects. 2020 RHHRA at 89–90.

18. EPA's PID relied on the 2020 DWA, which updated and refined the Agency's 2016 DWA. In the 2020 DWA, EPA focused on eleven uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat) that EPA determined to be high-benefit, critical crop uses. PID at 15–17. The 2020 DWA focused on select regions of the country where estimated drinking water concentrations of chlorpyrifos are below the drinking water level of concern. *Id*. In the 2020 RHHRA and PID, EPA conducted an assessment of potential risk to human health from aggregate exposure to chlorpyrifos residues, taking into account all anticipated dietary exposures from food, drinking water, and residential sources, pursuant to FFDCA Section 408(b). EPA determined that there were *no* potential risks of concern from exposure to chlorpyrifos in food or residential uses alone. 2020 RHHRA at 12; PID at 14, 18. EPA determined that risks from drinking water exposure exceeded safe levels taking into account *all* registered uses but, relying on its 2020 DWA, EPA found that risks were *below* the drinking water level of concern benchmark anticipating use only on the eleven high-benefit crops set forth above in certain identified regions of the country. PID at 18.

19. In its 2020 RHHRA and PID, EPA presented two potential approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to the eleven high-benefit agricultural uses in select regions of the country due to "uncertainty" in "the science addressing neurodevelopmental effects," or (ii) application of a 1X FQPA safety factor, which would allow for the retention of all currently registered uses.

Regarding the first approach, EPA was unequivocal that "the agency has determined" that limiting use to the eleven "high-benefit agricultural uses" in the select geographic regions "**will not pose potential risks of concerns with an FQPA safety factor of 10X**." PID at 40 (emphasis added). EPA committed to "consider registrant and stakeholder input on the subset of crops and regions from the public comment period" and stated that it "may conduct further analysis to determine if any other limited uses may be retained." *Id.* EPA also indicated that it may further refine its assessment based on feedback and recommendations from the September 2020 FIFRA Scientific Advisory Panel. *Id.*

20. Gharda submitted comments on the PID on February 3, 2021. EPA-HQ-OPP-2008-0850-0999. Gharda urged that the weight of the scientific evidence supported application of a 1X FQPA safety factor, including a recent Corteva drinking water study of chlorpyrifos oxon submitted to the EPA on December 4, 2020, which shows that there are no drinking water risk concerns associated with chlorpyrifos oxon (the chlorpyrifos metabolite that exists in drinking water following chlorination). *See A Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days*, MRID 51392601.

Gharda's Discussions With EPA Concerning a Potential Voluntary Cancellation of Chlorpyrifos Uses

21. In April 2021, EPA regulatory personnel reached out to me to discuss whether Gharda would entertain an agreement to voluntarily cancel some uses of chlorpyrifos. These discussions focused initially on uses identified in the PID as the 1X uses. EPA proposed a meeting with Gharda on April 20, 2021, and requested that Gharda confirm in writing in advance of that meeting Gharda's commitment to voluntarily cancel the 1X uses (while retaining the eleven high benefit crop uses identified as the 10X uses). In response, even though Gharda was

confident that all 1X uses are well supported, Gharda indicated that it would consider phasing out some 1X uses on a reasonable timetable and adopting potential geographic restrictions on crop uses and other risk mitigation measures. *See* Exhibit A. Gharda expressed concern with the Agency's proposed rushed timetable, however, given the impact of a phase-out on its business and on the grower community, and given that EPA had not yet reviewed stakeholder comments on the PID. *Id.* EPA cancelled the meeting with Gharda in order to discuss Gharda's letter further internally.

22. On April 29, 2021, the Ninth Circuit issued a decision in the lawsuit *League of United Latin American Citizens v. Regan,* consolidated Case Nos. 19-71979, 19-71982 ("*LULAC*"), which concerned EPA's handling of an administrative petition to revoke all tolerances filed by several nongovernmental organizations. In a 2-1 decision, a three-judge panel of the Ninth Circuit found that EPA's denial of objections to a 2017 order denying the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition, outside of its normal regulatory processes. *LULAC*, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit ordered EPA "either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "or to revoke all chlorpyrifos tolerances." *Id.* at 678 (emphasis added). In making this ruling the court expressly recognized the importance of the PID. Indeed, the court stated that:

> [D]uring the pendency of this proceeding, in December 2020, the EPA issued a Proposed Interim Registration Review Decision proposing to modify certain chlorpyrifos tolerances. The EPA also convened another SAP in 2020. **If, based upon the EPA's further research the EPA can now conclude to a reasonable certainty that modified tolerances or registrations would be safe, then it may modify chlorpyrifos registrations rather than cancelling them.**

Id. at 703. (emphasis added). The court ordered EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." *Id.* at 678.

23. After the Ninth Circuit issued its decision in *LULAC*, EPA reached back out to me to resume discussions about a potential voluntary cancellation of certain chlorpyrifos uses. EPA career supervisory personnel strongly urged Gharda to agree to voluntarily cancel the 1X uses and emphasized that the Agency had limited time to decide how to implement the court's decision. In response, Gharda expressed its disagreement with the Ninth Circuit decision and hope that EPA would seek rehearing of and/or appeal the flawed decision. *See* Exhibit B. Nevertheless, in an effort to work cooperatively with EPA and believing it had little choice but to accept voluntary cancellation terms, Gharda committed to voluntarily cancel yet additional 1X crop uses, pursuant to scheduled phase-outs and with appropriate existing stocks orders. *Id.* EPA strongly implied during these discussions the 10X uses would remain in place as long as Gharda voluntarily cancelled all 1X uses. *Id.*

24. In further discussions with EPA career supervisory personnel in late May 2021, EPA expressed to Gharda that EPA was willing to consider retention of only the 10X uses, and reiterated that it was under pressure to act quickly as a result of the Ninth Circuit decision. EPA urged Gharda to confirm in writing its agreement to voluntarily cancel all 1X uses. In response, and even though such a reduction in uses would eliminate more than 50% of Gharda's U.S. chlorpyrifos business, Gharda committed to continue working in good faith with EPA towards an agreement to voluntarily cancel all 1X uses. *See* Exhibit C. To that end, **on June 7, 2021, Gharda confirmed in writing to EPA that it would voluntarily cancel all currently approved agricultural uses of chlorpyrifos, other than the uses identified in the PID as 10X**

uses. *Id.* In turn, Gharda requested that EPA (i) work with it to address the orderly exhaustion of its inventories for the uses to be voluntarily cancelled, particularly given its unique role in the U.S. agrochemical industry; (ii) agree on orderly processes and timing for revising labels; and (iii) agree on existing stocks provisions for the uses to be voluntarily cancelled, to mitigate disruption on growers and other users. *Id.*

25. EPA career supervisory personnel were receptive to Gharda's June 7 commitment, responding the next day to ask "if Gharda is prepared to move forward with discussing voluntary use cancellations" and proposing a call with EPA legal counsel. By email dated June 8, 2021, EPA indicated that it was "considering the following dates for existing stocks:

- Technical grade active ingredient: Phase out most [1X] uses by the end of 2021; allow until the end of 2022 (12 to 18 months) for the remaining [1X] uses
- End-use products: 12 to 18 months from the technical registrants for sale/distribution of products
- End users, growers: Until exhausted"

Exhibit D.

26. Gharda responded to EPA's June 8 email proposing a meeting with its attorneys, with the expectation that the parties were close to reaching final agreement on terms and could begin work on modifying labels. Exhibit E.

27. Then, on June 14, 2021, EPA career supervisory personnel advised Gharda that Gharda's commitment regarding the "voluntary" cancellation of uses were not sufficient for EPA's "leadership," and asked Gharda to consider voluntarily cancelling yet additional uses, this time including some 10X uses, or face possible revocation of all tolerances. EPA urged Gharda to agree to voluntarily cancel all but five to six of its most important crop uses. This was the first

time that EPA asked Gharda to consider voluntarily cancelling 10X crop uses. EPA also said that its leadership had raised occupational exposure concerns, and asked that Gharda agree to eliminate the use of aerial application methods, even though these are not issues to be addressed under FFDCA but are instead issues to be addressed in Registration Review under FIFRA's risk/benefit standard. In subsequent calls, EPA also expressed concerns regarding ecological risks from chlorpyrifos, even though the ecological risk assessment for chlorpyrifos has yet to be completed. EPA nevertheless continued to indicate openness to an extended phase-out period for any voluntarily cancelled uses.

28. Gharda was confused, surprised, and disappointed at EPA's request that Gharda agree to voluntarily cancel 10X uses that EPA had confirmed, in a robust scientific assessment in its PID, would not exceed safe levels. Gharda was also concerned that EPA appeared to be relying on occupational and ecological concerns as the basis for its request, neither of which relate to the regulation of tolerances under the FFDCA. Despite this dramatic and unexpected shift in the discussions, Gharda remained willing to work with EPA to try to meet its demands. Gharda repeatedly urged EPA to ensure an orderly phase-out for manufacturers, distributors, growers, and others in the agricultural supply chain for the uses to be voluntarily cancelled, as EPA's demand would eliminate nearly 80–85% of the U.S. market for chlorpyrifos.

29. Gharda and EPA had a meeting on June 24, 2021 to further discuss terms of Gharda's voluntary cancellation of registered crop uses. In a follow-up email dated June 24, 2021, approximately two months from the deadline for EPA to act in response to the Ninth Circuit order, ***EPA's Chemical Review Manager wrote Gharda*** "to confirm the uses that Gharda has agreed upon for retention following our discussions over the past few weeks and on our call this afternoon" and outlined the following terms:

- Retain alfalfa, apple, asparagus, cherry (tart), citrus, peach, soybean, sugar beet, wheat (summer and winter) in select states as outlined in the December 2020 PID
- Cotton and strawberry will be phased out over two years (until 2023)
- Aerial application will be phased out over 2 years (until 2023)
- Provisions for existing stocks:
    - Technical products [with current labels] may be sold or distributed until 12/31/2021
    - End-use products [with current labels] may be sold or distributed until 12/31/2022

See Exhibit F.

30. In emails dated June 25, 2021, Gharda sought clarification from EPA on some aspects of its June 25 proposal, including the details of various phase-out periods. In these emails, Gharda thanked EPA "for our good faith negotiations over the last few weeks" and said that it "looks forward to working with the Agency to finalize the above terms." *See* Exhibit G. EPA proposed a meeting with its Office of General Counsel. It was Gharda's expectation that in involving legal counsel, the parties would be working to finalize a written agreement reflecting the agreed terms.

31. At EPA's request, on July 2, 2021, Gharda had a further call with EPA career supervisory personnel, during which EPA pressed Gharda to agree to voluntarily cancel even more 10X crop uses because of demands from EPA's leadership. EPA also indicated that it would not be able to agree to an extended phase out period and that chlorpyrifos applications would need to cease after six months, instead of the phase-out periods that ***EPA had proposed*** one week earlier in its June 24 email. *See* ¶ 29 & Ex. F. EPA also raised concerns with air blast applications on orchard crops. Gharda offered to provide data on mitigation measures that would address EPA's concerns regarding occupational exposure, but EPA said it would not consider mitigation data. EPA asked Gharda to put forward its best, final proposal that EPA would take back to its leadership. Gharda was especially surprised and disappointed with this turn of events,

as it in good faith believed that EPA's June 24 email, *see* ¶ 29 & Ex. F, had set forth the final terms of crop use retention and voluntary cancellation.

32. At EPA's request, Gharda had a call with EPA and its counsel on July 6, 2021. During the call EPA pressed Gharda to accept voluntary cancellation of all but three 10X uses and reiterated that it would be unable to allow use beyond six months from the effective date of a final rule. EPA explained that the six-month period was based on the WTO Agreement on the Application of Sanitary and Phytosanitary measures, not because of a need for the orderly phase-out of chlorpyrifos inventories and existing stocks. Gharda explained that six months would not be a meaningful time period, given that it would largely overlap with the off season for chlorpyrifos use and because its customers purchase product at least one to two years in advance of each growing season. Following this call, Gharda followed up in writing to offer voluntary cancellation of additional 10X uses and eliminate aerial and air blast methods of application; Gharda urged EPA to extend the phase out periods for formulation, distribution, and use, to allow for an orderly exhaustion of inventories and to minimize potentially catastrophic economic losses to Gharda and others in the supply chain, at a minimum until July 2022 to cover part of the next growing season. *See* Exhibit H. After this exchange, EPA indicated that it was "very close" to reaching final agreement with Gharda.

33. At EPA's request, Gharda had a further call with EPA and its counsel on July 14, 2021, during which EPA indicated that Gharda's proposal was under review by EPA leadership but that EPA hoped to have a final response within a week. EPA indicated that it would likely need a voluntary cancellation letter from Gharda quickly, to reference the voluntary cancellation in the published final rule. During the call, EPA, for the first time, indicated that its leadership believed that import tolerances would also need to be voluntarily cancelled. EPA could not

explain the basis for this last-minute request, given that import tolerances do not raise drinking water or occupational concerns, and given that the PID did not identify any dietary (non-drinking water) risks associated with chlorpyrifos or import tolerances, even with the retention of the 10X safety factor. Nevertheless, believing it was very close to reaching final agreement with EPA and to avoid derailing months of negotiations, Gharda submitted a proposal to EPA for the cancellation of certain import tolerances. *See* Exhibit I. Gharda followed up asking EPA to consider its points concerning import tolerances, but stressed that it did not want the import tolerance issue to stand in the way of resolving voluntary cancellation of uses pursuant to the terms discussed, as summarized in Gharda's July 6 email. *See* Exhibit J. EPA responded stating that it appreciated Gharda's engagement on this challenging issue. *See id.*

34. Following this submission and response, Gharda heard nothing further from EPA for weeks.

35. Growing increasingly concerned as the court deadline for EPA to issue a final rule was approaching, Gharda requested a meeting with EPA leadership. After Gharda's repeated outreach, EPA finally allowed Gharda to have a twenty-five-minute meeting with Assistant Administrator Michal Freedhoff and others from EPA on August 16, 2021. During the meeting, Gharda reiterated its commitment to voluntarily cancel uses as set forth above, urged EPA to make a decision consistent with science and law, and again stressed the major supply chain disruptions and catastrophic losses that would result from a revocation of tolerances with immediate effect. EPA was silent during this meeting, indicating only that it was willing to "work collaboratively" with Gharda going forward.

36. The next day after its meeting with EPA leadership, Gharda discovered a posting on EPA's website announcing the August 2021 revocation of all tolerances for chlorpyrifos,

which Gharda also discovered was posted days **before** its August 16 meeting with EPA leadership. When Gharda reached out to senior career leadership at EPA about the posting, EPA apologized for the posting and immediately removed it, but confirmed that the final rule would be consistent with the website posting. EPA indicated that there would be "elbow room" on timing of the final rule's implementation.

37. The next day, the EPA Final Rule was announced. In the Final Rule, EPA stated that it was revoking all food use tolerances for chlorpyrifos, as "[b]ased on the currently available data and taking into consideration the currently registered uses for chlorpyrifos," it was unable to make a safety finding under the FFDCA. 86 Fed. Red. 48,315. The Final Rule stated that revocations of the tolerances would take effect on February 28, 2022, six months from the date of publication, to comply with international trade obligations. *Id*. at 48,334.

38. On August 18, 2021, the day the Final Rule was announced, EPA held a public briefing session regarding the Final Rule. EPA invited stakeholders to submit questions to EPA regarding about the Final Rule.

39. Following EPA's public briefing, Gharda and others submitted questions to EPA, concerning the Final Rule's scope, applicability, timing for implementation, and harmonization with FIFRA. Gharda specifically asked whether EPA would consider mitigation in light of Gharda's commitment to accept label modifications limiting use of chlorpyrifos to the select crop uses in select regions EPA determined in the PID were safe and what additional mitigation EPA believed it needed to act on its safety finding. Among other questions, Gharda also asked whether EPA had reviewed or was willing to consider the 2020 Corteva drinking water study.

40. On September 20, 2021, over a month after the Final Rule was announced, EPA posted responses to "Frequent Questions about the Chlorpyrifos 2021 Final Rule" ("FAQs") on

its website,[2] and responded directly to Gharda's questions that were not addressed in the FAQs. *See* Exhibit K. EPA's responses did not appear to allow any "elbow room" or opportunities to "work collaboratively" on the Rule's timing and implementation, but instead directed interested parties to submit objections. EPA also did not respond to Gharda's question concerning label modifications consistent with the Agency's safety finding, and indicated that "due to time constraints" it was unable "to conduct additional scientific analysis beyond what was already available at the time of the court ruling." *Id.*

EPA's Final Rule Has Caused and Will Continue to Cause Significant Harm

41. The Final Rule has caused and will continue to cause significant and irreparable harm to Gharda and others in the agricultural value chain. This is particularly so as to the six-month period for the Final Rule's implementation. The current 2021 growing season has essentially ended, and chlorpyrifos would not be used until the next growing season beginning approximately in April 2022. Thus, the six month period provided in the Final Rule beginning in August 2021 and running through February 2022 is effectively meaningless and allows no time for Gharda, distributors, and growers to phase out and exhaust existing inventories and that will result in the needless waste of safe and wholesome food. The realities of the current supply chain were pointed out to EPA in discussions leading up to the Final Rule.

42. As a result of Gharda's increased production to meet market demand after Corteva's exit from the market, Gharda has a significant volume of raw materials and U.S. labeled product in inventory. Without the ability to formulate, distribute, and sell these products, Gharda will suffer CBI economic losses, to say nothing of the nearly CBI

[2] https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-2.

loss in its investment in chlorpyrifos and lost future sales of chlorpyrifos products in the U.S. of approximately CBI annually. In total, the economic losses Gharda will face if the Final Rule is not reversed or rescinded will be catastrophic.

43. Beyond these economic losses, Gharda has suffered and will continue to suffer significant reputational harm as a result of EPA's arbitrary action against chlorpyrifos. By revoking all tolerances, EPA has directly attacked the safety of chlorpyrifos in the eyes of growers, processors, and consumers, and the credibility of Gharda in selling and distributing chlorpyrifos products. EPA has done this despite a finding by its own expert scientists that a subset of eleven high-benefit chlorpyrifos uses in certain geographic areas are safe, and in disregard of written commitments provided to EPA by Gharda ***prior to the Final Rule*** to modify Gharda's label consistent with EPA's safety finding in its PID.

44. EPA's revocation action has and will continue to strain Gharda's relationships with its customers, who distribute its products to suppliers and end users. Indeed, during its months of negotiations with EPA, Gharda assured its customers that it was working cooperatively with EPA to reach agreement that would allow for many continued agricultural uses. Given EPA's scientific assessment in the PID which provided a clear scientific record on which to retain at least the 10X chlorpyrifos uses, neither Gharda nor its customers expected that EPA would take draconian action to eliminate all uses. EPA's abrupt departure from its own scientific findings has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill.

45. In addition to the immediate and irreparable harm caused to Gharda by EPA's action, EPA's revocation action could create long-term irreparable harm to Gharda because of the stigma attached to the unfounded public statements by EPA that its action was taken "to

ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of this pesticide," and "follow[s] the science and put[s] health and safety first." https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health. There is no scientific basis for these statements, which are in fact directly at odds with EPA's Final Rule and the scientific findings set forth in the PID. *See, e.g.*, 86 Fed. Reg. at 48,324 (EPA "remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by [epidemiology studies reporting neurodevelopmental impacts in children]"); *id.* at 48,335 ("EPA has not conducted a formal EJ analysis for this rule"); PID at 10 ("the science addressing neurodevelopmental effects remains unresolved").

46. The stigma attached to EPA's public statements not only has the potential to cause ill-will against Gharda by customers, consumers, and the public, but will also adversely affect Gharda's ability to meet the needs of growers for effective pesticide products, compounding the ill-will against Gharda. Customers who abandon Gharda products now because of the Agency's action may not return to using products produced by Gharda even in the event of a final adjudication in Gharda's favor. Gharda may thus permanently lose a significant portion of its market share. Moreover, EPA's actions may trigger other federal or state regulatory requirements or bans, as well as restrictions by foreign governments, who look to EPA as the gold standard for making regulatory decisions based on science.

47. Losses from an immediate removal of chlorpyrifos from the U.S. market would not be borne by Gharda alone. It will also cause significant financial hardship to distributors and growers who invested substantial sums in reliance on the registration in products they are no longer able to sell or use. Most distributors purchase products from Gharda at least a year in advance, and as a result have significant product on hand in order to meet market needs and often

fluctuating demand by U.S. growers. Gharda has been specifically informed by some of its major customers that they currently have inventories of chlorpyrifos product on hand valued at approximately CBI. Growers, for their part, not only face a lost investment in unusable product but also must find alternative, sometimes more expensive alternative products or risk significant crop losses. In total the volume of U.S. labeled chlorpyrifos products in the hands of distributors, retailers, and growers is estimated to be valued at CBI.

48. Commodity traders and other holders of food and feed with detectable chlorpyrifos residues face significant uncertainty, as it may be practically impossible to demonstrate that the residues result from a lawful application, particularly in the case of finished food and feed product with extended shelf lives. This confusion could result in the unnecessary waste of otherwise safe and nutritious food and feed.

49. Moreover, by insisting on giving immediate effect to the revocation actions, EPA has caused confusion on the part of the public with respect to the safety of dozens of commodities on which chlorpyrifos may legally be used.

50. For these reasons, and those set forth in its Objections, Gharda believes that the Final Rule should be summarily reversed or, at a minimum, stayed pending administrative and, potentially, judicial review of the objections of Gharda, growers, grower groups, and other adversely affected stakeholders.

I declare that the foregoing is true and correct to the best of my knowledge.

Dated: October 22, 2021

Ram Seethapathi
President

Appendix A
List of Comments and Other Submissions to EPA Gharda has Supported Through the Chlorpyrifos Industry Task Force

1. DAS Response to 2014 Revised Human Health Risk Assessment for Chlorpyrifos, (Apr. 29, 2015), EPA-HQ-OPP-2015-0653-0214;
2. Decl. of C. Burns in support of DAS Comments on EPA's Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for Organophosphate Pesticides, (Dec. 22, 2015), EPA-HQ-OPP-2015-0653-0230 (submitted to docket EPA-HQ-OPP-2010-0119);
3. DAS Response to EPA's Proposed Rule to Revoke Chlorpyrifos Tolerances (including all references and appendices), (Jan. 4, 2016), EPA-HQ-OPP-2015-0653-0386;
4. DAS Legal and Policy Comments in Response to EPA's Proposed Rule to Revoke Tolerances for Chlorpyrifos, (Jan. 5, 2016), EPA-HQ-OPP-2015-0653-0266;
5. DAS Response to Chlorpyrifos-Methyl Human Health Draft Risk Assessment, (Sept. 15, 2015), EPA-HQ-OPP-2010-0119-0044;
6. DAS Legal and Policy Comments in Response to (i) EPA's Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for Organophosphate Pesticides and (ii) EPA's Chlorpyrifos-Methyl Human Health Draft Risk Assessment, (Feb. 19, 2016), EPA-HQ-OPP-2010-0119-0033;
7. DAS Comments on 2016 Revised Human Health Risk Assessment and Refined Drinking Water Assessment for Chlorpyrifos, (Jan. 17, 2017), EPA-HQ-OPP-2015-0653-0651;
8. Decl. of C. Burns in support of DAS Comments on EPA's Response to Comments Related to Applying the FQPA 10X Safety Factor for the Organophosphate Pesticides (Dec. 29, 2016), EPA-HQ-OPP-2008-0316-0071, (submitted to docket EPA-HQ-OPP-2010-0119);

9. DAS Legal and Policy Comments on (i) EPA's Response to Comments Related to Applying the FQPA 10X Safety Factor for the Organophosphate Pesticides; (ii) Response to Occupational and Residential Exposure-Related Comments on the Preliminary Organophosphate Human Health Risk Assessments; and (iii) Response to Dietary-Related Comments on the Preliminary Organophosphate Human Health Risk Assessments, (July 24, 2017) (submitted to docket EPA-HQ-OPP-2010-0119);
10. DAS Response to Objections to EPA's Denial of Petition to Revoke Tolerances and Cancel Registrations for Chlorpyrifos (and supporting Declarations), (Aug. 27, 2018) (submitted to docket EPA-HQ-OPP-2007-1005-0526);
11. Br. of Amicus Curiae Dow AgroSciences in Supp. of EPA, LULAC v. Wheeler, Nos. 19-71979, 19-71982 (9th Cir. Mar. 6, 2020), ECF No. 53-2;
12. D. Juberg and J. Driver, A Review of Recent Studies - Red Blood Cell Cholinesterase Inhibition as a Point of Departure for Regulation of Chlorpyrifos is Protective Against Neurodevelopmental Toxicity, (June 17, 2020) ("DAS Review of Recent Studies");
13. D. Juberg and J. Driver, Scientific Bases and Perspectives on Uncertainty and Safety Factors for Assessing Risks Associated with Human Chlorpyrifos Exposures, (June 17, 2020) ("DAS Submission on Uncertainty and Safety Factors");
14. A Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days, MRID 51392601, submitted by Corteva Agriscience, and
15. Corteva Agriscience's Comments on Chlorpyrifos Proposed Interim Registration Review Decision (Feb. 2, 2021).

EXHIBIT A

Gharda Chemicals International, Inc.

April 19, 2021

Dana Friedman
Branch Chief
Risk Management and Implementation Branch I
Pesticide Re-Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
friedman.dana@epa.gov

Via Email

Re: Gharda Chemicals International, Inc.'s Registration of Chlorpyrifos

Dear Ms. Friedman,

On behalf of Gharda Chemicals, Inc. ("Gharda"), I look forward to our April 20, 2021 meeting with the U.S. Environmental Protection Agency ("EPA" or the "Agency") to discuss Gharda's registration of chlorpyrifos, a critically important U.S. agricultural tool. Gharda submits this letter in response to the Agency's request that Gharda confirm in writing in advance of the meeting Gharda's agreement to voluntarily cancel numerous currently approved uses of chlorpyrifos.

As set forth below, Gharda believes that such a curtailment of currently approved uses on such a rushed timetable is not reasonable. Gharda is, however, willing to have discussions with the Agency on a reasonable timetable regarding the phase-out of several uses of chlorpyrifos, under appropriate terms and conditions.

Gharda understands that the new Administration is prioritizing its review of certain products, including chlorpyrifos. Respectfully, however, the timetable EPA is asking Gharda to meet is not reasonable and represents a rush to judgment, particularly when the Agency has not completed its review of comments on its Proposed Interim Decision (PID) for chlorpyrifos submitted by Gharda and other stakeholders, or an important recent drinking water study submitted to the Agency by Corteva Agriscience (MRID 51392601). Gharda is especially concerned that EPA would entertain the elimination of certain highly beneficial uses like corn, before examining public comments and recent additional scientific evidence supporting both EPA's current regulatory standard for assessing human health risks of chlorpyrifos and a Food Quality Protection Act safety factor of 1X. *See* Gharda's Comments on PID, EPA-HQ-OPP-2008-0850-0999. EPA's new Administrator has said publicly that the Agency's decisions

concerning chlorpyrifos will be driven by science and the rule of law. Gharda thus trusts and expects that EPA will afford stakeholders appropriate due process and consider the full weight of the scientific evidence before taking action that would eliminate important uses, with significant disruptive consequences.

Gharda is nevertheless willing to discuss with EPA some possible modifications to its registration label for chlorpyrifos that would allow for a continuation of crucial agricultural uses, while being responsive to the Agency's request. For example, Gharda may be willing to agree to elimination of the following crop uses: caneberry, kiwifruit, cherimoya, banana, fig, feijoa, date, calamondin, chironja, citron, pummelo, tangor, barley, pepper, filberts, tobacco, spearmint, and peppermint. Gharda may also be willing to agree to elimination of the following non-crop uses: crack and crevice/void/general outdoor, golf course turf, lawncare (commercial), wood treatment, wide area use, foundation/walls, perimeter, and cattle ear-tag. Gharda is also willing to discuss potential geographic restrictions on crop uses and other risk mitigation measures. Gharda believes that, where possible, a phased implementation of any label modifications should be employed, to avoid negatively impacting growers and others in the agricultural value chain.

While Gharda is committed to engaging in a dialogue with EPA on these issues, Gharda is not currently able to meet the rushed timetable the Agency has presented. Chlorpyrifos comprises a significant portion of our U.S. agrochemical business, on which many jobs depend. Chlorpyrifos is also a vitally important pest management tool; it is often the first tool growers employ to control new or unknown insect pests and, as the Agency knows, for some destructive insect pests it is growers' last line of defense. Indeed, at a time when our growers need as many tools in their tool box as possible to adapt to the adverse effects of climate change, reducing their ability to use such a highly efficacious pesticide as chlorpyrifos would be an unfortunate action for the federal government to take. Gharda thus needs additional time to evaluate different options for label modifications and their potential impacts on Gharda's business, its customers, and the agricultural economy.

We thank you in advance for your consideration of the concerns we have outlined and look forward to a productive meeting.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

EXHIBIT B

Gharda Chemicals International, Inc.

May 12, 2021

Dana Friedman
Branch Chief
Risk Management and Implementation Branch I
Pesticide Re-Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
friedman.dana@epa.gov

Via Email

Re: Gharda Chemicals International, Inc.'s Registration of Chlorpyrifos

Dear Ms. Friedman,

On behalf of Gharda Chemicals, Inc. ("Gharda"), I write in follow up to our discussions concerning the request by the U.S. Environmental Protection Agency ("EPA" or the "Agency") that Gharda agree to a voluntary cancellation of certain currently approved uses of chlorpyrifos.

It continues to be Gharda's position that all currently approved uses of chlorpyrifos are strongly supported by scientific data, including the application of a 1X safety factor pursuant to the Food Quality Protection Act ("FQPA"). However, Gharda understands that the Agency is under time constraints to act with respect to chlorpyrifos tolerances in light of the recent decision by the U.S. Court of Appeals for the Ninth Circuit in *League of United Latin American Citizens, et al. v. Michael Regan, et al*, consolidated Case Nos. 19-71979, 19-71982 ("*LULAC II*"). Gharda believes the decision is flawed and remains hopeful that EPA will seek rehearing of and/or appeal the decision. Gharda is nevertheless willing to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users.

In particular, Gharda is willing to negotiate and execute an agreement with EPA containing at least the following key terms:

- Uses remain in place for the 11 high-benefit agricultural crops in certain regions that the Agency listed in its 2020 Proposed Interim Decision (PID) for chlorpyrifos as uses, together with their associated tolerances, that will not pose potential risks of concerns with an FQPA safety factor of 10X; some of the geographic restrictions set forth in the PID as to the 11 crops to be further discussed;

- Existing uses for some additional key crops, specifically corn, mint, and grapes, would remain in place in certain regions together with their associated tolerances; Gharda is willing to negotiate geographic restrictions and other label modifications and risk mitigation measures that would allow for a continuation of these critical agricultural uses;
- Gharda would agree to a voluntary cancellation of all other agricultural uses of chlorpyrifos pursuant to scheduled phase-outs;
- Gharda's production, sale, and distribution of chlorpyrifos products permitting use on the voluntarily cancelled uses would be allowed as follows;
    - through December 31, 2022 for Caneberry, Kiwifruit, Carrot (Grown for seed), Ginseng, Rutabagas, Cherimoya, Banana, Fig, Feijoa, Date, Calamondin, Chironja, Citron, Kumquat, Mandarin (tangerine), Pummelo, Satsuma mandarin, Tangelo, Tangor, Barley, Triticale, Cucumber, Pumpkin, Leek, Tomatoes, Pepper, Nectarines, Plum, Plums/Prunes, Filberts, Tobacco, Sugarcane, Spearmint, Peppermint, Crack and Crevice/Void/General Outdoor, Golf Courses Turf, Lawncare (Commercial), Trash Storage Areas, Wood Treatment, Wide Area Use, Foundation/Walls, Perimeter, Nursery (Conifer Plantations, Forest Plantings, Forest Trees, Cottonwood/Poplar Plantations, Nursery Stock, Ornamental/Shade Trees, Ornamental Nonflowering Plants, Ornamental Woody Shrubs), Perennial Grass Seed Crops, Cattle Ear-Tag;
    - through December 31, 2024 for Blueberry, Cranberries, Potatoes, Sweet Potato, Clover (Grown for Seed), Oats, Grass Forage, Fodder, Hay, Legume Vegetables (Succulent (All), Dried (All)), Peas (Seed Treatment), Cherry (sweet), Pears, Broccoli, Broccoli (cavalo, Chinese and raab), Brussels sprouts, Cabbage, Cabbage (Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Turnips, Radishes, Rape greens, Nursery (Christmas Tree Plantations);
    - through December 31, 2026 for Canola, Sorghum (Milo), Sunflower, Onions, Almonds, Pecans, Walnuts, Tree/Nut (pecan orchard floors), Tree/Nut (walnut orchard floors), Peanuts.
- Appropriate existing stocks orders and applicable label changes would take effect after each of the scheduled phase-outs for the voluntarily cancelled uses;
- All import tolerances for chlorpyrifos would be retained;
- Gharda reserves the right to withdraw from the written agreement in the event that the Ninth Circuit grants panel rehearing or rehearing *en banc* in *LULAC II* or the U.S. Supreme Court grants *certiorari* in that case;
- Gharda would reserve all rights to seek approval of new or previously approved uses of chlorpyrifos in the future, in accordance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act; and,
- Nothing in the written agreement between EPA and Gharda would constitute a finding or admission that the voluntarily cancelled uses present any neurodevelopmental or other human health risks.

Gharda is prepared to cooperate with the Agency and looks forward to a productive discussion with EPA concerning these issues.

Respectfully submitted,

Ram Seethapathi
President, Gharda Chemicals International, Inc.

EXHIBIT C

Gharda Chemicals International, Inc.

June 7, 2021

Dana Friedman
Branch Chief
Risk Management and Implementation Branch I
Pesticide Re-Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
friedman.dana@epa.gov

Via Email

Re: Gharda Chemicals International, Inc.'s Registration of Chlorpyrifos

Dear Ms. Friedman,

On behalf of Gharda Chemicals, Inc. ("Gharda"), I write in follow up to our discussions concerning the request by the U.S. Environmental Protection Agency ("EPA" or the "Agency") that Gharda agree to a voluntary cancellation of certain currently approved uses of chlorpyrifos.

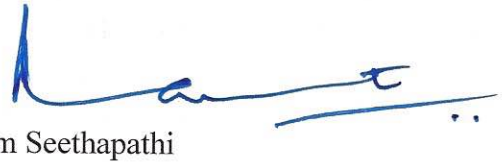
Gharda understands that the Agency believes it has insufficient time to complete further analyses at this time and must act immediately with respect to chlorpyrifos tolerances under the recent decision by the U.S. Court of Appeals for the Ninth Circuit in *League of United Latin American Citizens, et al. v. Michael Regan, et al*, consolidated Case Nos. 19-71979, 19-71982 ("*LULAC II*"). Gharda believes that the *LULAC II* decision is flawed and that a Food Quality Protection Act ("FQPA") safety factor of 1X and point of departure based on 10% red blood cell cholinesterase inhibition are strongly supported by the scientific record. Gharda is nevertheless willing to continue to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users.

Accordingly, Gharda commits to voluntarily cancel all currently approved agricultural uses of chlorpyrifos other than uses for the 11 high-benefit agricultural crops in select regions that the Agency has identified on pages 40–41 of its 2020 Proposed Interim Decision (PID) for chlorpyrifos (EPA-HQ-OPP-2008-0850) (those 11 high-benefit agricultural crops are alfalfa, apple, asparagus, cherry (tart), citrus, cotton, peach, soybean, strawberry, sugar beet, wheat (spring and winter)). Gharda's agreement to voluntarily cancel uses is subject to the following conditions:

- Uses, together with their associated tolerances, for the 11-high benefit agricultural crops will remain in place in the select regions, as outlined on pages 40–41 of the PID, as well as in Texas for cotton;
- EPA and Gharda reach mutually agreeable provisions that will (i) allow finished technical product in Gharda's warehouse at its manufacturing facility outside of the United States and in transit from the manufacturing facility that have not yet cleared the U.S. Customs and Border Protection and EPA import approval process at the time of the order for voluntarily cancelled uses to be processed and sold in the United States for all currently registered uses, and (ii) allow product in Gharda's possession in the United States at the time of the order for voluntarily cancelled uses to be processed and sold for all currently registered uses;
- EPA and Gharda reach mutually agreeable label revisions and approval process and timing that mitigate disruption on growers and other users and are consistent with the agreement in the previous bullet;
- EPA and Gharda reach mutually agreeable existing stocks provisions that mitigate disruption on growers and other users;
- All current import tolerances for chlorpyrifos are retained;
- Gharda reserves all rights to seek approval of new or previously approved uses of chlorpyrifos in the future, in accordance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act;
- Gharda and EPA agree that products (including commodity products like corn and soybean) lawfully treated with chlorpyrifos prior to a final cancellation order taking effect will be permitted to clear the channels of trade, pursuant to 21 U.S.C. Section 346a(l)(5);
- Gharda and EPA agree that Gharda's voluntary cancellation of uses would not constitute a finding or admission that the voluntarily cancelled uses present any neurodevelopmental or other human health risks; and,
- Gharda reserves the right to withdraw from the voluntary cancellation of uses in the event that the Ninth Circuit grants panel rehearing or rehearing *en banc* in *LULAC II* or the U.S. Supreme Court grants *certiorari* in that case.

Gharda looks forward to working with the Agency on next steps.

Respectfully submitted,



Ram Seethapathi
President, Gharda Chemicals International, Inc.

EXHIBIT D

[redacted]

\f0From: Biggio, Patricia <biggio.patricia@epa.gov>
Sent: Tuesday, June 8, 2021 2:42 PM
To: Friedman, Dana; Ram Seethapathi
Cc: Pyne, Jaclyn; Feitel, Alexandra
Subject: RE: Chlorpyrifos: Gharda letter

\f0

\f0

Hi Ram,

Thank you for your letter. We see that Gharda has requested to maintain use of chlorpyrifos on cotton in Texas. The PID indicated that if cotton were maintained, it could be used in AL, FL, GA, NC, SC, and VA. Unfortunately, Texas would not be an option for this use based on the revised drinking water assessment which took into account the US watershed regions as part of the refined assessment.

We would like to see if Gharda is prepared to move forward with discussing voluntary use cancellations. If so, we can look to schedule a call that will include EPA counsel. We are considering the following dates for existing stocks:

- Technical grade active ingredient: Phase out most uses by the end of 2021; allow until the end of 2022 (12 to 18 months) for the remaining uses
- End-use products: 12 to 18 months from the technical registrants for sale/distribution of products
- End users, growers: Until exhausted

Please let us know if you are available for a call in the next week or so.

Thank you,

Trish

From: Friedman, Dana <Friedman.Dana@epa.gov>
Sent: Tuesday, June 8, 2021 6:40 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: RE: Chlorpyrifos: Gharda letter

Thanks Ram. We'll take a look today and be back in touch with you as soon as possible.

From: Ram Seethapathi <sramanathan@gharda.com>
Sent: Monday, June 7, 2021 5:49 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: Chlorpyrifos: Gharda letter

Dear Ms. Friedman,

Please see attached letter from Gharda based on our continued discussions on chlorpyrifos.

Thanks very much for giving time extension until today to send this letter. Appreciate your help.

Look forward to hearing from you further in this regard.

Thanks and best regards,

Ram Seethapathi.

President

Gharda Chemicals International Inc.,

760, Newtown Yardley Road, Suite 110,

Newtown, PA 18940

Ph: 215-968-9474

Mob: 215-791-0956

EXHIBIT E

[redacted]

From: Ram Seethapathi <sramanathan@gharda.com>
Date: Friday, June 11, 2021 at 3:27 PM
To: Biggio, Patricia <biggio.patricia@epa.gov>, Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: Re: Chlorpyrifos: Gharda letter

Hi Trish,

Thanks for your email below.

I have sent an email to Dana just now seeking 10 minutes of her time to get answers for some follow up questions.

As soon as we connect, meeting with your attorneys can be scheduled, as desired by you.

Have a great weekend.

Best Regards,

Ram

From: Biggio, Patricia <biggio.patricia@epa.gov>
Date: Tuesday, June 8, 2021 at 2:42 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>, Ram Seethapathi <sramanathan@gharda.com>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: RE: Chlorpyrifos: Gharda letter

Hi Ram,

Thank you for your letter. We see that Gharda has requested to maintain use of chlorpyrifos on cotton in Texas. The PID indicated that if cotton were maintained, it could be used in AL, FL, GA, NC, SC, and VA. Unfortunately, Texas would not be an option for this use based on the revised drinking water assessment which took into account the US watershed regions as part of the refined assessment.

We would like to see if Gharda is prepared to move forward with discussing voluntary use cancellations. If so, we can look to schedule a call that will include EPA counsel. We are considering the following dates for existing stocks:

- Technical grade active ingredient: Phase out most uses by the end of 2021; allow until the end of 2022 (12 to 18 months) for the remaining uses
- End-use products: 12 to 18 months from the technical registrants for sale/distribution of products
- End users, growers: Until exhausted

Please let us know if you are available for a call in the next week or so.

Thank you,

Trish

From: Friedman, Dana <Friedman.Dana@epa.gov>
Sent: Tuesday, June 8, 2021 6:40 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: RE: Chlorpyrifos: Gharda letter

Thanks Ram. We'll take a look today and be back in touch with you as soon as possible.

From: Ram Seethapathi <sramanathan@gharda.com>

Sent: Monday, June 7, 2021 5:49 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: Chlorpyrifos: Gharda letter

Dear Ms. Friedman,

Please see attached letter from Gharda based on our continued discussions on chlorpyrifos.

Thanks very much for giving time extension until today to send this letter. Appreciate your help.

Look forward to hearing from you further in this regard.

Thanks and best regards,

Ram Seethapathi,

President

Gharda Chemicals International Inc.,

760, Newtown Yardley Road, Suite 110,

Newtown, PA 18940

Ph: 215-968-9474

Mob: 215-791-0956

EXHIBIT F

[redacted]

From: Biggio, Patricia <biggio.patricia@epa.gov>
Sent: Thursday, June 24, 2021 6:18 PM
To: Ram Seethapathi
Cc: Friedman, Dana; Pyne, Jaclyn; Feitel, Alexandra
Subject: Chlorpyrifos discussion notes

Dear Ram,

Thank you for your time this afternoon. We are writing to confirm the uses that Gharda has agreed upon for retention following our discussions over the past few weeks and our call this afternoon:

- Retain alfalfa, apple, asparagus, cherry (tart), citrus, peach, soybean, sugar beet, wheat (summer and winter) in select states as outlined in the December 2020 PID
- Cotton and strawberry will be phased out over two years (until 2023)
- Aerial application will be phased out over 2 years (until 2023)
- Provisions for existing stocks:
    - Technical products may be sold or distributed until 12/31/2021
    - End-use products may be sold or distributed until 12/31/2022

Please let me know if there are any questions.

Thank you,

Trish

Patricia Biggio

Chemical Review Manager

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

Phone: 703-347-0547

biggio.patricia@epa.gov

EXHIBIT G

[redacted]

From: Ram Seethapathi <sramanathan@gharda.com>
Date: Friday, June 25, 2021 at 5:25 PM
To: Biggio, Patricia <biggio.patricia@epa.gov>
Cc: Friedman, Dana <Friedman.Dana@epa.gov>, Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: Re: Chlorpyrifos discussion notes

Dear Trish,

Thank you for your email and telephone conversation this morning. In order to bring more clarity to your email and my response, the following terms are consistent with the group discussions yesterday (6/24/21):

- Retain alfalfa, apple, asparagus, cherry (tart), citrus, peach, soybean, sugar beet, wheat (summer and winter) in select states as outlined in the December 2020 PID
- Provisions for the exhaustion of remaining inventories:
    - Technical products for current label uses brought into the United States by 12/31/2021 can be sold or distributed by Gharda through that date
    - End-use products for the current label uses may be formulated, packaged, sold or distributed by Gharda and others until 12/31/2022
- Provisions for existing stocks:
    - Existing stocks for the current label uses exhausted by distributors, growers and other users by 12/31/2023
- Aerial application will be voluntarily removed from the label by 12/31/2023
    - Gharda can manufacture, sell, and distribute for the 11 high-benefit crops set forth in Table 10 of the December 2020 PID with aerial application as to technical and end use products through 12/31/23
    - Entities other than Gharda in the channels of trade can sell or distribute chlorpyrifos products for the 11 high-benefit crops with aerial application to be further discussed with Gharda's preference through exhaustion
    - Growers/end users can use chlorpyrifos products for the 11 high-benefit crops with aerial application to be further discussed with Gharda's preference through exhaustion
- Cotton and strawberry will be voluntarily removed from label by 12/31/2023
    - Time periods for existing stocks orders and label changes to be addressed for the phased-out uses on cotton and strawberry

With respect to import tolerances, Gharda has considered and believes that all import tolerances should be retained, as previously agreed. In addition, as set forth in our previous correspondence

- Terms will be set forth in a separate, written agreement between Gharda and EPA
- Gharda reserves the right to withdraw from the written agreement in the event that the U.S. Supreme Court grants certiorari in the *LULAC II* case
- Gharda would reserve all rights to seek approval of new or previously approved uses of chlorpyrifos in the future, in accordance with FIFRA
- Nothing in the written agreement between EPA and Gharda would constitute a finding or admission that the voluntarily cancelled uses or method of application present any neurodevelopmental or other human health risks or ecological risks.

Gharda looks forward to working with the Agency to finalize the above terms.

Let me know if you have any questions.

Have a great weekend.

Best regards,

Ram

From: Ram Seethapathi <sramanathan@gharda.com>
Date: Friday, June 25, 2021 at 9:19 AM
To: Biggio, Patricia <biggio.patricia@epa.gov>
Cc: Friedman, Dana <Friedman.Dana@epa.gov>, Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: FW: Chlorpyrifos discussion notes

Hi Trish, good morning again. Thanks for being available when I called just now.

As desired, I am showing some of my immediate observations from your email, marked in RED in the body of your email. For want of time I have done this!

Thanks & regards,

Ram

From: Biggio, Patricia <biggio.patricia@epa.gov>
Date: Friday, June 25, 2021 at 8:01 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Friedman, Dana <Friedman.Dana@epa.gov>, Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: RE: Chlorpyrifos discussion notes

Hi Ram,

We will be meeting internally this morning and would like to know if we can present where Gharda stands using the list below. Please let us know by 9:00 this morning or let me know if you would like a quick call to discuss.

Thank you,

Trish

From: Biggio, Patricia
Sent: Thursday, June 24, 2021 6:18 PM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Friedman, Dana <Friedman.Dana@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>
Subject: Chlorpyrifos discussion notes

Dear Ram,

Thank you for your time this afternoon. We are writing to confirm the uses that Gharda has agreed upon for retention following our discussions over the past few weeks and our call this afternoon:

- Retain alfalfa, apple, asparagus, cherry (tart), citrus, peach, soybean, sugar beet, wheat (summer and winter) in select states as outlined in the December 2020 PID
- Cotton and strawberry will be phased out/eleminated ~~over~~ in two years (~~until~~ by end 2023): Time frame to be defined for Inventory to be cleared in channel and farmer
- Aerial application will be eliminated ~~phased out~~ on the label in ~~over~~ 2 years (~~until~~ by end 2023): Time frame to be defined for Inventory to be cleared in channel and farmers
- Provisions for existing stocks:
    - Technical products should be in the country by 12/31/2021 and may be packaged for end use with current labels or sold or distributed until 12/31/2021
    - Such End-use products may be sold or distributed by Gharda until 12/31/2022
    - We discussed about a period for channel to clear the inventory and farmers to use product: Ask was 18 months but you have not yet decided on this.
- Prior letters

Import tolerances and some others in our prior letter: We have not discussed your email internally yet and I think I covered most and revert soon if there are any omissions:

Thanks for our good faith negotiations over the last few weeks and looking forward to get confirmation from you.

Please let me know if there are any questions.

Thank you,

Trish

Patricia Biggio

Chemical Review Manager

Pesticide Re-evaluation Division

Office of Pesticide Programs, EPA

Phone: 703-347-0547

biggio.patricia@epa.gov

EXHIBIT H

[redacted]

From: Friedman, Dana <Friedman.Dana@epa.gov>
Date: Tuesday, July 6, 2021 at 3:50 PM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: RE: Chlorpyrifos

Thanks Ram, I appreciate your quick turnaround on this after our conversation at noon today. We'll take this to our senior leadership and will let you know what we hear.

Many thanks,

Dana

Dana L. Friedman

Chief, Risk Management and Implementation Branch 1

Pesticide Re-Evaluation Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

703-347-8827

From: Ram Seethapathi <sramanathan@gharda.com>
Sent: Tuesday, July 6, 2021 6:06 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: Chlorpyrifos

Dana—

I am following up our discussion today with this summary of Gharda's position:

· Gharda is willing to accept voluntary cancellation of all 1X crop uses as set forth in EPA's December 2020 PID

· Gharda is willing to accept voluntary cancellation of strawberry, asparagus, cherry (tart) and cotton (from EPA's 10X list in the PID), but asks that the Agency reconsider allowing retention of cotton.

· Gharda is willing to accept voluntary cancellation of the aerial method of application for the 11 high-benefit crops set forth in Table 10 of the PID

· Gharda is willing to accept voluntary cancellation of the air blast method of application for tree fruit crops (apple, citrus, peach)

· EPA will allow for continued use on alfalfa, soybean, sugar beet, wheat (summer and winter), apple, citrus and peach in select states as outlined in the December 2020 PID.

· In return for Gharda agreeing for all of the foregoing voluntary cancellations, Gharda asks the Agency to (i) allow formulation and distribution of end use products for all current uses through the end of June 2022 instead of February 2022, and (ii) allow use of these products by growers through the end of June 2023 instead of August 2022. June 2022 instead of February 2022 is critical for Gharda because this is a very important sale and use period for this product. Additional time for growers to complete use is critical to minimize disruption and allow for an orderly phase-out of the product for the voluntarily cancelled uses consistent with long-standing EPA policy.

· Gharda continues to believe that a written agreement between the parties should be completed in the near future.

· Gharda reserves all of its rights as previously communicated.

Thanks very much and I hope Gharda has tried our best to resolve all the concerns expressed by EPA

under given circumstances.

Warm regards,

Ram Seethapathi,

President

Gharda Chemicals International Inc.,

760, Newtown Yardley Road, Suite 110,

Newtown, PA 18940

Ph: 215-968-9474

Mob: 215-791-0956

EXHIBIT I

[redacted]

From: Ram Seethapathi <sramanathan@gharda.com>
Date: Thursday, July 15, 2021 at 6:12 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: Chlorpyrifos

Hi Dana,

As agreed, I am responding to our discussion yesterday about import tolerances for chlorpyrifos. Gharda continues to ask EPA to consider the points raised during our discussion and in my email message to you subsequent to our discussion, but does not want the import tolerance issue to stand in the way of resolving this matter pursuant to the other terms that we discussed, as summarized in my email message dated July 6, 2021.

Thanks and best regards,

Ram Seethapathi,

President

Gharda Chemicals International Inc.,

760, Newtown Yardley Road, Suite 110,

Newtown, PA 18940

Ph: 215-968-9474

Mob: 215-791-0956

EXHIBIT J

[redacted]

From: Friedman, Dana <Friedman.Dana@epa.gov>
Date: Friday, July 16, 2021 at 7:24 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: RE: Chlorpyrifos

Hi Ram,

I just wanted to confirm our receipt of the below and provide an update that we have forwarded both the import tolerance list and notification of the below for consideration and additional discussion. We do not have an update on when those next internal discussions are set to occur, but should we get any additional updates we can provide, be assured that we will forward that information along as soon as possible.

Again, I really appreciate your continued patience and engagement on this challenging issue.

Regards,

Dana

Dana L. Friedman

Chief, Risk Management and Implementation Branch 1

Pesticide Re-Evaluation Division

Office of Pesticide Programs

U.S. Environmental Protection Agency

703-347-8827

From: Ram Seethapathi <sramanathan@gharda.com>
Sent: Thursday, July 15, 2021 6:13 PM
To: Friedman, Dana <Friedman.Dana@epa.gov>
Cc: Biggio, Patricia <biggio.patricia@epa.gov>
Subject: Chlorpyrifos

Hi Dana,

As agreed, I am responding to our discussion yesterday about import tolerances for chlorpyrifos. Gharda continues to ask EPA to consider the points raised during our discussion and in my email message to you subsequent to our discussion, but does not want the import tolerance issue to stand in the way of resolving this matter pursuant to the other terms that we discussed, as summarized in my email message dated July 6, 2021.

Thanks and best regards,

Ram Seethapathi,

President

Gharda Chemicals International Inc.,

760, Newtown Yardley Road, Suite 110,

Newtown, PA 18940

Ph: 215-968-9474

Mob: 215-791-0956

EXHIBIT K

[redacted]

From: Feitel, Alexandra <feitel.alexandra@epa.gov>
Date: Monday, September 20, 2021 at 10:25 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Friedman, Dana <Friedman.Dana@epa.gov>, Grable, Melissa <Grable.Melissa@epa.gov>
Subject: RE: Update on chlorpyrifos rule

Hi Ram,

Apologies for multiple emails. Gharda's questions on the chlorpyrifos final rule that are not addressed in the FAQs are answered below:

Will EPA consider an extension of the effective date of the Final Rule so that existing inventories can be formulated, sold/distributed and used? For how long?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation including consideration of an extension of the effective date. Any person may also request a hearing on those objections. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before 60 days after the final rule was published in the Federal Register. Please see Section 1C of the final rule for instructions on providing feedback.

What input on the Final Rule does EPA expect to receive from FDA?

EPA has been working closely with FDA on a guidance for treated commodities in the channels of trade. For additional information on channels of trade, please contact the Center for Food Safety and Applied Nutrition at the US FDA (CFSANTradepress@fda.hhs.gov).

Does EPA expect to receive input from the WTO and other sources regarding the effective date of the Final Rule? What is the timing of this anticipated input from the WTO?

The WTO was notified of the Agency's decision on this Final Rule. The Agency will respond to all WTO member comments as they are received.

Has EPA had an opportunity to review the Corteva drinking water study? Is EPA willing to review that study in the near term?

EPA has the Corteva drinking water study in house for review. Due to time constraints, EPA was not able to conduct additional scientific analysis beyond what was already available at the time of the court ruling.

Does this action cover livestock feed as well as food for human consumption?

This action revokes all tolerances, including tolerances for food, feed, and livestock commodities.

-

From: Feitel, Alexandra
Sent: Monday, September 20, 2021 9:54 AM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Subject: RE: Update on chlorpyrifos rule

Good morning Ram,

The chlorpyrifos FAQs were just posted to the EPA website: https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule#question-1

Please let me know if you have any further questions.

Thank you,
Alex

From: Ram Seethapathi <sramanathan@gharda.com>
Sent: Thursday, August 26, 2021 5:53 PM
To: Feitel, Alexandra <feitel.alexandra@epa.gov>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>
Subject: Re: Update on chlorpyrifos rule

Hi Alexandra,
Thanks for your note below.
Will look forward to the FAQs and reach out to you for clarifications.

Thanks and best regards,
Ram

From: Feitel, Alexandra <feitel.alexandra@epa.gov>
Date: Thursday, August 26, 2021 at 2:24 PM
To: Ram Seethapathi <sramanathan@gharda.com>
Cc: Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>, Friedman, Dana <Friedman.Dana@epa.gov>
Subject: Update on chlorpyrifos rule

Hi Ram,

We were just notified that the chlorpyrifos final tolerance rule is scheduled to be published in the Federal Register on Monday, August 30th. Additionally, we are finalizing the FAQs and will notify you as soon as they are posted to the EPA website. Please let me know if you have any further questions in the meantime.

Thank you,
Alex Feitel

Alexandra Feitel
Chemical Review Manager, Risk Management and Implementation Branch I
Pesticide Re-evaluation Division
U.S. EPA Office of Pesticide Programs
703-347-8631

I, Dr. Richard Reiss, declare as follows:

1. I am competent to provide the information in this declaration, and I have personal knowledge of all facts set forth herein.

Introduction

2. I understand that the U.S. Environmental Protection Agency ("EPA") has issued a Final Rule revoking all tolerances for the pesticide chlorpyrifos (the "Final Rule") and that there is a 60-day period for the filing of objections regarding the Final Rule. This declaration is provided in support of objections to the Final Rule submitted by Gharda Chemicals International, Inc.

My Credentials

3. I am a Group Vice President and Principal Scientist with the consulting firm Exponent. I am an Environmental Health Scientist with expertise in risk assessment, exposure assessment, environmental chemistry and fate, mathematical modeling, and applied statistics. I have worked on scientific issues associated with numerous environmental statutes and have expertise in areas of air quality modeling, drinking water assessment, and chemical risk assessment. A complete copy of my *curriculum vitae* is attached to this Declaration.

4. I have been conducting and reviewing drinking water assessments with respect to pesticides since 1998, and I have reviewed several chlorpyrifos drinking water assessments over the last decade. I have conducted such assessments for dozens of pesticides over this time period and provided comments on many of the major refinements to drinking water assessment methodology that EPA has considered over the years. In performing these assessments, I have used all of the major models that EPA uses for surface water and groundwater drinking water risk assessments, and I regularly interact with EPA on issues associated with drinking water exposure.

5. I have also been significantly involved in toxicity issues associated with chlorpyrifos. I have written a journal publication that analyzed chlorpyrifos toxicity data and estimated benchmark doses (BMDs) that represent the level at which chlorpyrifos and chlorpyrifos oxon cause 10% acetylcholinesterase inhibition, which is the basis that EPA regulates chlorpyrifos. I have also recoded the chlorpyrifos physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) model that EPA used to estimate points of departure (PODs) for chlorpyrifos risk assessment.

6. By way of background, I received a Bachelor of Science in Chemical Engineering from the University of California, Santa Barbara in 1989; a Master of Science in Environmental Engineering from Northwestern University in 1991; and a Doctor of Science in Environmental Health from Harvard University in 1994.

7. I am actively involved in several scientific societies, and I am the past-President of the Society for Risk Analysis, the leading scientific society devoted to the field of risk assessment. I was the Managing Editor of *Risk Analysis: An International Journal*, the leading scholarly journal for risk analysis from 2001-2008. I was the winner of the 2001 Chauncey Starr Award from the Society for Risk Analysis. This award recognizes a risk analyst less than forty years of age who has made major contributions to the field of risk analysis. In 2010, I was elected a Fellow of the Society for Risk Analysis. In 2018, I won the Outstanding Practitioner Award from the Society for Risk Analysis.

EPA's Drinking Water Assessment in Proposed Interim Decision (PID)

8. In December of 2020, EPA released a Proposed Interim Decision (PID) for chlorpyrifos that included a Drinking Water Assessment (DWA). Previous DWA assessments considered all registered chlorpyrifos uses, but the DWA in support of the PID considered a

subset of eleven uses that are considered critical/high benefit, including alfalfa, apples, asparagus, cherries, citrus, cotton, peaches, soybeans, strawberries, sugar beet, and wheat. It included an assessment of drinking water risks using a highly refined methodology following EPA's most recent guidance on refining drinking water exposure. Risks were estimated both assuming a 1X and 10X Food Quality Protection Act (FQPA) factor. In the Final Rule, EPA retained the 10X FQPA factor based on what EPA believes to be uncertainties in the literature on potential neurodevelopmental effects. The PID concluded that there are regions in the U.S. where drinking water risks are acceptable for chlorpyrifos uses for all eleven of the critical/high benefit crops as listed in Table 10 of the PID, which is titled "Agricultural Uses Proposed for Retention in Chlorpyrifos Labels with an FQPA Safety Factor of 10X."

9. Drinking water risk assessments combine an assessment of toxicity and estimation of exposure. In both aspects, the chlorpyrifos drinking water risk assessment in the 2020 DWA that supports the PID was highly refined and among the most advanced assessments ever conducted by EPA for a pesticide.

10. The exposure assessment in the 2020 DWA represents one of the most refined (Tier 4 refinement) drinking water analyses that EPA has conducted. EPA used its latest surface water modeling methods, including new scenarios that were developed in 2020. EPA also accounted for the portion of a watershed that used a particular crop and the portion of that cropped area that is potentially treated with chlorpyrifos. EPA uses the terms percent cropped area (PCA) and percent crop treated (PCT) to represent these factors. EPA also accounted for available surface water monitoring data by using the seasonal wave with streamflow adjustment and extended capability (SEAWAVE-QEX) model and sampling bias factors (SBFs).

11. The 2020 DWA utilized new guidance on conducting refined drinking water assessments. EPA used its September 2020 "Framework for Conducting Pesticide Drinking Water Assessments for Surface Water." The framework outlines a tiered process for conducting drinking water assessments that relies on increasing refinement of the underlying assumptions in the assessment. The 2020 DWA applies the highest level of refinement (Tier 4) that is laid out in the EPA guidance. A Tier 4 assessment produces the spatial and temporally resolved estimates and quantitatively uses monitoring data. Thus, the 2020 DWA used the best available science for assessing drinking water risks.

12. EPA took the unusual step of having nine EPA staff peer-review the 2020 DWA. I am familiar with many EPA drinking water assessments and other types of risk assessments. Typical EPA assessments do not include this level of peer review.

13. The chlorpyrifos drinking water exposure assessment was refined several times before 2020. The first assessment was conducted in 2011 using EPA's standard methods. An updated assessment was conducted in 2014 that estimated regionally derived estimates for the Pacific Northwest and the South Atlantic-Gulf, and the 2016 assessment provided a more complete regional assessment, but still had significant limitations. The 2020 update focused on high-benefit crops and refined the 2016 assessment by (a) incorporating new surface water modeling scenarios, (b) presentation of the entire distribution of community water systems PCA adjustment factors and integration of state level crop treated data using PCT factors, and (c) quantitative use of surface water monitoring data.

14. In the 2020 DWA, EPA assumed that, for most drinking water systems, any chlorpyrifos that reaches a drinking water treatment system is converted to chlorpyrifos oxon via chlorination. Chlorpyrifos oxon is the active moiety that inhibits acetylcholinesterase (AChE),

an enzyme involved in neurotransmission. In our bodies, chlorpyrifos is partially metabolized to chlorpyrifos oxon, which results in AChE inhibition. For a smaller set of drinking water facilities that do not use free chlorine as a disinfectant, EPA assumed that chlorpyrifos was unconverted in the drinking water system.

15. In the 2020 DWA, to estimate points of departures (PODs) for risk assessment, EPA conducted one of the most advanced analyses that I am familiar with. PODs are a measure of the toxicity of the chemical and represents, in the case of chlorpyrifos, a level that is not considered toxic to a typical individual. EPA applied uncertainty factors to the POD to account for variability within the human population. To estimate PODs for chlorpyrifos and chlorpyrifos oxon, EPA used a physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model that was developed by Corteva Agriscience over the course of more than a decade and was reviewed by the EPA Scientific Advisory Panel (SAP) several times. The PBPK/PD model simulates a dose of chlorpyrifos or chlorpyrifos oxon in the body and models its metabolism, tissue partitioning and clearance, and quantifies inhibition of AChE to estimate PODs. It represents one of the most advanced methodologies to estimate PODs.

16. After the substantial refinements described above, EPA concluded in the PID that there were regions in the U.S. where the drinking water risks were acceptable even with the application of the FQPA 10X factor. Therefore, the latest risk assessment produced by EPA concludes that there are acceptable drinking water risks for the eleven high-benefit crops.

17. In the Final Rule, EPA stated that it could not rely on the 2020 DWA for the following reason:

> When assessing different combinations of only those 11 uses in specific geographic regions, the modeling assumed that chlorpyrifos would not be labeled for use on any other crops and would not otherwise be used in those geographic regions. At this time, however, the currently registered chlorpyrifos uses go well beyond the 11 uses in the

> specific regions assessed in the 2020 DWA. Because the Agency is required to assess aggregate exposure from *all* anticipated dietary, including food and drinking water, as well as residential exposures, the Agency cannot rely on the 2020 DWA to support currently labeled uses.

86 Fed. Reg. 38315, 48,333 (Aug. 30, 2021). However, the 2020 DWA followed the most recent guidance from EPA on conducting the most highly refined regional drinking water assessments and represents the best available science. Further, EPA's reasoning does not make sense. Based on my decades of experience, the Agency routinely conducts assessments that presume what the use pattern will be upon a registration decision. This is fundamental to the Agency registration process. For example, for a new product, EPA conducts an assessment that assumes a set of proposed uses. The 2020 DWA was much like such an assessment for a new product. It presumed that only eleven crop uses may exist and conducted an assessment as such. The quote above references "*all* anticipated" exposures. The latest discussions between registrants and EPA focused on the eleven high-benefit crops; thus, those crops represent the set of "anticipated" uses. Thus, there is no scientific reason why the 2020 DWA could not form the basis of a decision on the future of those eleven crops and only those eleven crops.

18. Corteva commented on the lack of refinement in the 2016 DWA that EPA is now relying on (Corteva, 2017). For example, in the 2016 DWA, EPA used a PCA of 1, which unrealistically assumes that an entire watershed is planted with the crop that is being considered. This assumption was refined in the 2020 DWA. The 2020 DWA used both maximum regional-specific PCA values and it also used the full distribution of PCAs from the majority of the approximately 6500 drinking water treatment intakes from the EPA Office of Water Drinking Water Information System.

19. For the PID, EPA conducted a highly refined drinking water risk assessment for the 11 high-benefit crops. The assessment was refined over the course of nearly a decade and

utilized some of the most advanced risk assessment methods ever utilized by the Agency for a pesticide. The assessment went through substantial internal EPA peer-review. The result was that there are regions of the U.S. where there are acceptable drinking water risks for all eleven critical/high benefit crops even with the application of an FQPA 10X.

20. It should also be considered that even the 2020 DWA is overly conservative. EPA's standard index reservoir scenario for assessing drinking water risk is based on a small watershed in Shipman, Illinois that has an upper percentile drainage area to normal capacity (DA/NC). A high-end DA/NC means that there is large watershed drainage area relative to the volume of the reservoir. While it may be reasonable to base the index reservoir on a high-end DA/NC, EPA combines this assumption with several other factors to create a scenario that is not realistic even of the highly vulnerable Shipman reservoir.

21. For example, it unrealistically assumes that all applications in a watershed occur at the same time. For a scenario where two applications of chlorpyrifos are allowed per year with a 7-day treatment interval, the EPA standard scenario assumes that all first applications in the watershed occur on the same day and all second applications occur seven days later. It repeats this same assumption over a 30-year simulation.

22. EPA's standard methods for estimating drinking water concentrations produces conservative estimates of real-world chlorpyrifos and chlorpyrifos oxon drinking water concentrations even after the significant refinements that EPA made in the 2020 DWA.

Chlorpyrifos Oxon Drinking Water Study

23. EPA said that its 2020 DWA "assumed 100% conversion of chlorpyrifos to the more toxic chlorpyrifos oxon" EPA's 2020 Third Revised Chlorpyrifos Human Health Risk Assessment at 10. However, Corteva submitted a new chlorpyrifos oxon drinking water study in

December of 2020, around the time the PID was released, and provided EPA with interim study results in August of 2020. The results of the study were not considered in the PID despite EPA being aware of the study. EPA was consulted on the design of the study and provided feedback to Corteva. The interim results were presented to EPA before the issuance of the PID. The study is not onerous to review or interpret, and EPA could have done so before the issuance of the PID and certainly well before the issuance of the Final Rule.

24. The study dosed rats via drinking water with chlorpyrifos oxon for twenty-one days at concentrations as high as the solubility limit of chlorpyrifos. The reason for using the solubility limit of chlorpyrifos to set the chlorpyrifos oxon dose was that the oxon is assumed to potentially occur in drinking water through conversion of chlorpyrifos to chlorpyrifos oxon. Therefore, the chlorpyrifos oxon concentration in drinking water cannot be higher than the chlorpyrifos concentration.

25. The study measured AChE inhibition in red blood cells (RBCs), brain, and in several other tissues. While it is widely used as a marker of exposure, RBC AChE inhibition is not considered to be of direct biological significance. EPA regards RBC AChE inhibition as a "surrogate" for peripheral nervous system AChE inhibition. Brain AChE inhibition is the relevant endpoint for any potential neurotoxicity.

26. A prior study showed that even a very high dose of 10 mg/kg of chlorpyrifos oxon given orally did not cause measurable brain AChE inhibition even though the same dose of chlorpyrifos caused 48% brain AChE inhibition. This result shows that, given by the oral route, the oxon is a less potent inhibitor of brain AChE than parent chlorpyrifos. It is likely that the relative difference in brain AChE for chlorpyrifos and chlorpyrifos oxon is the result of a lack of systemic bioavailability of the oxon. The lack of systemic bioavailability is likely due to

significant hydrolysis in the gastrointestinal tract and portal vein, substantial first-pass metabolism in the liver, and additional loss in circulation due to interactions with plasma and RBC cholinesterases. All of this limits access of chlorpyrifos oxon to peripheral tissues such as the brain, which is where AChE inhibition is relevant.

27. The chlorpyrifos oxon drinking water study found (a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure.

28. Given that the oxon drinking water study was conducted at the limit that the oxon could be present in drinking water is of regulatory significance. It shows that even at the limit that the oxon could be present in drinking water, neither RBC AChE nor brain AChE, the two compartments of regulatory interest to EPA, were inhibited.

29. The demonstration that the oxon has even less potential to inhibit brain AChE, the true target for potential neurotoxicity, than parent chlorpyrifos is further evidence that oxon concentrations in drinking water are not a risk concern. Thus, EPA incorrectly assumed in the 2020 DWA that chlorpyrifos oxon is more toxic than the parent chlorpyrifos for drinking water exposure purposes.

30. The oxon drinking water study shows that drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos.

Import Tolerances

31. In the Final Rule, EPA also canceled all import tolerances for chlorpyrifos. However, the only risk associated with imported food is dietary exposure from food residues. EPA's assessment clearly shows that dietary risk is not of concern even with the 10X FQPA

factor. Drinking water, bystander, or occupational exposure risks are not relevant for import tolerances. Therefore, EPA's assessment provides no scientific basis for canceling import tolerances. In fact, the assessment confirms the opposite – there is no risk associated with imported food.

I, Dr. Richard Reiss, declare that the forgoing statement are true and correct to the best of my knowledge.

Dated: October 21, 2021

Dr. Richard Reiss

APPENDIX A

Exponent®
Engineering & Scientific Consulting

Richard Reiss, Sc.D.

Group Vice President, Office Director, & Principal Scientist | Chemical Regulation & Food Safety
1800 Diagonal Road, Suite 500 | Alexandria, VA 22314
(571) 227-7228 tel | rreiss@exponent.com

Professional Profile

Dr. Reiss is an environmental health scientist with expertise in risk assessment, exposure assessment, environmental chemistry and fate, mathematical modeling, and applied statistics. He provides consulting services related to scientific issues associated with numerous environmental statutes, and has expertise in both air quality and chemical risk assessment. He has conducted risk assessments, data analyses, probabilistic exposure modeling, and environmental exposure modeling for environmental agents, such as pesticides, industrial chemicals, and consumer product chemicals. He has conducted risk assessments for new and existing products.

Dr. Reiss is very active in the application and development of quantitative methods in risk assessment. He is the developer of the Probabilistic Exposure and Risk assessment model for FUMigants (PERFUM), which is an air dispersion model designed to evaluate bystander inhalation exposure following fumigant applications. PERFUM is widely used by Environmental Protection Agency (EPA) and other public agencies for evaluating bystander risks for pesticide volatilization. Generally, he has used a variety of mathematical models in conducting occupational and ecological risk assessments for pesticides and industrial chemicals; and performed statistical analyses, including dose-response modeling to evaluate chemical toxicity. He has published in the areas of human and ecological risk assessment, exposure assessment, dose-response, nutrition, and epidemiology.

Dr. Reiss is actively involved in several scientific societies and he is the Past-President and Fellow of the Society for Risk Analysis (SRA), the leading scientific society devoted to the field of risk assessment. Dr. Reiss was the Managing Editor of Risk Analysis: An International Journal, the leading scholarly journal for risk analysis, from 2001 through mid-2008. He was the winner of the 2001 Chauncey Starr (early career) award from SRA. In 2018, he was awarded the Outstanding Practitioner Award from SRA.

Academic Credentials & Professional Honors

Sc.D., Environmental Health, Harvard University, 1994

M.S., Environmental Engineering, Northwestern University, 1991

B.S., Chemical Engineering, University of California, Santa Barbara, 1989

Outstanding Practitioner Award from the Society for Risk Analysis, 2018, recognizing a scientist with an outstanding risk assessment practice.

Chauncey Starr Award from the Society for Risk Analysis, 2001, recognizing a scientist under 40 years of age who has made significant contributions to risk analysis

Outstanding Service Award, Society for Risk Analysis, 2009

Leslie Silverman Scholarship, Harvard University, 1991

Walter P. Murphy University Fellowship, Northwestern University, 1989-1990

Prior Experience

Vice President, Sciences International, 2000-2006

Senior Scientist, Quantitative Risk Assessment Expert, Jellinek, Schwartz & Connolly, Inc., 1998-2000

Senior Air Quality Analyst, Sonoma Technology, Inc., 1994-1998

Engineer, Environmental Solutions, Inc., 1990-1991

Publications

Gollapudi BB, Su S, Li AA, Johnson GE, Reiss R, Albertini RJ. Genotoxicity as a toxicologically relevant endpoint to inform risk assessment: a case study with ethylene oxide. Environ Mol Mutagen. 2020 Nov; 61(9):852-871.

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Reiss R, Johnston J, Tucker K, DeSesso JM, Keen CL. Estimation of cancer risks and benefits associated with a potential increased consumption of fruits and vegetables. Food Chem Toxicol 2012; 50:4421-4427.

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Beevers C, Badding M, Barraj L, Reiss R, Williams AL. CLARITY-BPA core study: analysis for non-monotonic dose-responses. Poster presentation, 55th Congress of the European Societies of Toxicology, Helsinki, Finland, 2019

Badding MA, Barraj L, Williams AL, Reiss R. CLARITY-BPA core study: analysis for non-monotonic dose-responses. Presented at the Annual Meeting of the Society of Toxicology, Baltimore, MD. March 2019. Toxicologist (Abstract 3144).

Reiss R, Badding M, Barraj L. Assessing potential for non-monotonic dose response for BPA in the CLARITY-BPA study. Presented at Society for Risk Analysis Annual Meeting. Washington, DC.

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Buonagurio R, Cryer S, van Wesenbeeck I, Reiss R. Development of the soil fumigant exposure assessment (SOFEA) model. Presented at he Fall 2019 ACS National Meeting, San Diego, CA. August 2019.

Pai N, Sall E, Stryker J, Popovic J, Reiss R, Cubbage J. Comparison of three flux models across five field studies. Presented at Fall 2019 ACS National Meeting, San Diego, CA. August 2019.

Orr T, Pai N, Sall E, DesAutels C, Popovic J, Reiss R. Evaluating spatial scale effects of dicamba applications on off-target vapor movement. 256th ACS National Meeting. Boston, MA. August 2018.

Reiss R, Driver J, Ross J, Young B. Aggregate and cumulative exposure contribution for pyrethroids: consideration of modeling and biological monitoring. International Society of Exposure Analysis and Epidemiology. Research Triangle Park, North Carolina, September 2017.

Reiss R. Recent history of fumigant and semi-volatile bystander risk assessment and use of PERFUM. American Chemical Society. Washington, DC. August 2017.

Aslund M, Breton R, Padilla L, Reiss R, Whatling P, Winchell M, Wooding K, Moore M, Ecological risk assessment for Pacific salmon exposed to dimethoate in California. American Chemical Society, Boston, MA, August 2016.

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Reiss R. An evaluation of epidemiologic studies of low-level exposures to organophosphorus insecticides and implications for risk assessment. Society for Risk Analysis, Arlington, VA, December 2015.

Reiss R, Tucker K, Weidling R. Validation of pesticide dietary exposure model using biomonitoring data — Case study for chlorpyrifos. Society for Risk Analysis, Denver, CO, December 2014.

Beyer D, Hays S, Hentz K, Lamb J, Reiss R, Hentges S. EFSA's WoE analysis of bisphenol A (BPA) is sound, but improved BMDL and HEDF calculations support reconfirming the 50 µg/kg-bw/day TDI. Eurotox, Edinburgh, Scotland, 2014.

Reiss R, Tucker K, Johnston J. Fruits and vegetables are good for you: Cancer risks and benefits as a case study. American Chemical Society/IUPAC Joint Meeting, San Francisco, CA, 2014.

Poletika N, Mosquin P, Aldworth J, Reiss R, Williams M. Interpretation of peak concentration estimates for a typical NAWQA/NASQAN surface water monitoring dataset using a weight-of-evidence approach. American Chemical Society/IUPAC Joint Meeting, San Francisco, CA, 2014.

Ma Q, Reiss R, Whatling P. Non-equilibrium sorption of flutriafol on predicted environmental concentrations. Presentation to the 245th American Chemical Society (ACS) National Meeting & Exposition, New Orleans, LA, April 7-11, 2013.

Reiss. R. Assessing risks from pesticide post-application volatilization. Presentation to the 246th American Chemical Society (ACS) National Meeting, Indianapolis, IN, September 8-12, 2013.

Ma Q, Reiss R, Whatling P. Influence of time-dependent sorption of flutriafol on predicted environmental concentrations. Presentation to the 246th American Chemical Society (ACS) National Meeting, Indianapolis, IN, September 8-12, 2013.

Reiss R. What can we learn and apply from journal peer review. Society for Risk Analysis, Baltimore, MD,

2013.

Reiss R. Assessing risks of pesticide post-application exposure. American Chemical Society, Indianapolis, IN, 2013.

Reiss R. Estimation of cancer risks and benefits associated with a potential increased consumption of fruits and vegetables. Invited presentation at the U.S. Department of Agriculture, Washington, DC, 2012.

Reiss R. Measuring risk exposure when using global supplier. Society for Risk Analysis World Congress, Sydney, Australia, 2012.

Reiss R, Johnston J, DeSesso J, Tucker K. Pesticide residues on food: A mountain or a molehill. Society for Risk Analysis, Charleston, SC, 2011.

Reiss R, Bogen K. Modeling risk to aquatic species subject to realistic, dynamic exposures using a generalized form of Haber's law. American Chemical Society, Denver, CO, 2011.

Ma Q, Reiss R, Habig C. Applying the joint probability distribution analysis for Pacific Northwest salmonid risk assessment. American Chemical Society, Denver, CO, 2011.

Li A, Reiss R, Lowe K, McIntosh L, Mink P. Framework for integration of human and animal data for risk assessment. Society of Toxicology, Washington, DC, 2011.

Reiss R. Atmospheric modeling of fumigants. Workshop on methyl bromide alternatives, Kansas State University, Manhattan, KS, May, 2010.

Reiss R. Health risk assessment for fumigants. Keynote address to the annual meeting of the Australia-New Zealand Chapter of the Society for Risk Analysis, Sydney, Australia, September 2010.

Reiss R. Evaluation of water contamination from consumer product uses. Invited presentation to the National Capitol Area Chapter of the Society for Toxicology, Washington, DC, April, 2010.

Reiss R. The evolution of health risk assessment in the United States. Keynote address to the first annual Society for Risk Analysis meeting of the Taiwan SRA chapter, Taichung, Taiwan, January, 2010.

Reiss R. Risk analysis: The evolution of a science. Invited presentation to the Joint IRAC-SRA-CBER-JIFSAN Symposium on New Tools, Methods and Approaches for Risk Assessment, Baltimore, MD, December, 2009.

Reiss R. Exposure analysis: Pathways to refining regulatory risk assessments. Midwest States Risk Assessment Symposium, Indianapolis, IN, November 2009.

Williams P, Reiss R. Modeling the variability in consumer product use patterns. International Society for Exposure Analysis annual meeting, Minneapolis, MN, November 2009.

Cramer S, Poletika N, Everich R, Schocken M, Habig C, Reiss R. Framework for estimating exposure to ESA-listed salmon to pesticides. American Chemical Society semiannual meeting, Washington, DC, August 2009.

Reiss R, Edwards M. Analysis of cholinesterase variability in animals and implications for risk assessment. Society for Risk Analysis Annual Meeting, Boston, MA, December 2008.

Reiss R, Lewis G, Griffin J, Inauen J, Navarro L. Terrestrial risk assessment for triclosan. Poster presentation, Pacific Northwest Organic Residuals Symposium, Davis, CA, October 2008.

Reiss R, Chan R. Estimation of emission rates for building fumigations. Methyl Bromide Alternative Outreach conference, San Diego, CA, October 2007.

Reiss R, Chan R. Impact of estimation methods and tarping methods on flux rates. Methyl Bromide Alternative Outreach conference, San Diego, CA, October 2007.

Reiss R, Anderson E, Turnham P. Exposure and risk assessment for residents and contractors associated with vermiculite attic insulation. International Society for Exposure Analysis. Durham, North Carolina, October 2007.

Reiss R. A critical evaluation of the National Ambient Air Toxics Assessment (NATA) program for benzene. Society for Risk Analysis Annual Meeting, Baltimore, MD, December 2006.

Reiss R, Inauen J, Hoffman-Kamensky M, Capdevielle M. Terrestrial risk assessment for triclosan. Society of Environmental Toxicology and Chemistry Meeting, Montreal, Canada, November 2006.

Reiss R. Near-field air quality impacts from fumigant applications. American Chemical Society Meeting, San Francisco, CA, September 2006.

Reiss R. A probabilistic model for estimating bystander inhalation risks following fumigant applications. American Chemical Society Meeting, San Francisco, CA, September 2006.

Reiss R, Gaylor D. Statistical evaluation to determine the most appropriate endpoint for dimethoate risk assessment. Society for Risk Analysis Annual Meeting, Orlando, FL, December 2005.

Reiss R. Bystander risk assessment for fumigant: an evaluation of current regulatory activity. Society for Risk Analysis Annual Meeting, Orlando, FL, December 2005.

Gibb HJ, Kozlov K, Centeno J, Kolker A, Conko K, Reiss R. Potential health risks from long term mercury exposure in Gorlovka, Ukraine. Society for Risk Analysis Annual Meeting, Orlando, FL, December 2005.

Reiss R. Development of risk-based buffer zones for a fumigant application. Society for Risk Analysis Annual Meeting, Palm Springs, CA, December 2004.

Reiss R. Estimating fumigant buffer zones by air dispersion modeling. Methyl Bromide Alternatives Outreach Conference, Orlando, FL, October 2004.

Reiss R. Air exposure following a fumigant application. International Society of Exposure Analysis Meeting, Philadelphia, PA, October 2004.

Reiss R. Analysis of benzene and 1,3-butadiene emissions in the Houston Ship Channel. Presented at API/EPA Conference on Emissions Uncertainties, Houston, TX, 2003.

Reiss R, Anderson EL. A framework and case study for the Voluntary Children's Chemical Evaluation Program. Presented at the Society for Risk Analysis Annual Meeting, New Orleans, December 2002.

Reiss R. Emerging issues in environmental health for children. Invited lecture given at the Air and Waste Management Association meeting in Baltimore, MD, June 2002.

Reiss R, Griffin, J. A critical review of the National Emissions Inventory for Air Toxics. Presented at the Coordinating Research Council conference on Air Toxics Modeling, Houston, TX, February 2002.

Reiss R, MacKay N, Habig C, Griffin J. A probabilistic ecological risk assessment for Triclosan in lotic systems following discharge from wastewater treatment systems. Presented at the Society of Environmental Toxicology and Chemistry meeting, Baltimore, MD, November 2001.

Reiss R. A review of the National Air Toxics Assessment. Presented at the Mid-Atlantic Section Meeting of the Air and Waste Management Association, Baltimore, MD, December 11, 2000.

Reiss R, Wilkinson CW. Exposure to chemicals with same mechanism of action: How to add the risk? Presented at the Annual Meeting of the American College of Toxicology, McLean, VA, November 9, 1999.

Lurmann FW, Reiss R. Analysis of the first three years of PM2.5 data collected in the Southern California Children's Health Study. Presented at PM2.5 A Fine Particle Standard, Long Beach, CA, sponsored by A&WMA, U.S. Environmental Protection Agency, and the U.S. Department of Energy, January 28-30, 1998.

Reiss R, Chinkin L. Ozone exceedance data analysis: representativeness of the 1995 summer ozone season in the Northeast. Paper presented at the 1st NARSTO Northeast Data Analysis Symposium and Workshop, Norfolk, VA, December 10-12, 1996.

Coe D, Chinkin L, Reiss R, DiSogra C, Hammerstrom K. An emission inventory of agricultural internal combustion engines for California's San Joaquin Valley. Paper presented at the Air & Waste Management Association Emission Inventory: Key to Planning, Permits, Compliance & Reporting Conference, New Orleans, LA, September 4-6, 1996.

Main HH, Roberts PT, Korc ME, Coe DS, Dye TS, Lindsey CG, Reiss R. Analysis of PAMS and NARSTO-Northeast data — Supporting evaluation and design of ozone control strategies: A workshop. Presented at U.S. Environmental Protection Agency, Research Triangle Park, NC by Sonoma Technology, Inc., Santa Rosa, CA, December 11-12, 1995.

Chinkin LR, Ryan PA, Reiss R. A critical evaluation of biogenic emission systems for photochemical grid modeling in California. Paper presented at the Air & Waste Management Association and U.S. Environmental Protection Agency Emissions Inventory Conference, Research Triangle Park, NC, October 11-13, 1995.

Main HH, Roberts PT, Lurmann FW, Wright DB, Reiss R, Hering SV. Measurement of acid gases and PM2.5 in 12 Southern California communities for use in an epidemiologic study. Paper presented at the Air & Waste Management Association and U.S. Environmental Protection Agency Conference on Measurement of Toxic and Related Air Pollutants, Research Triangle Park, NC, May 16-18, 1995.

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Allen G, Koutrakis P, Reiss R, Lurmann F, Roberts PT, Burton R, Wilson W. Evaluation of the TEOM method for measurement of ambient particle mass in urban areas. In: Transactions of the Air & Waste Management Association Conference on Particle Matter: Health and Regulatory Issues, Pittsburgh, PA. Air & Waste Management Association, Pittsburgh, PA, April 4-6, 1995.

Reiss R, Ryan PB, Tibbetts S, Koutrakis P. Ozone reactive chemistry in residential environments. Presented at Air & Waste Management Association Conference, Measurement of Toxic and Related Air Pollutants, Durham, NC, May 1994.

Reiss R, Ryan PB, Koutrakis P, Bamford S. Modeling ozone deposition onto indoor surfaces. Presented at an Air & Waste Management Association Conference, Measurement of Toxic and Related Air Pollutants, Durham, NC, May 1993.

Book Chapters

Ma Q, Reiss R, Habig C, Whatling P. Use of the joint probability distribution analysis for assessment of the potential risks of dimethoate to aquatic endangered species. Chapter 12, pp. 171-181. In: Pesticide Regulation and the Endangered Species Act. ACS Symposium Series, Vol. 1111, American Chemical Society, 2012.

Reiss R. Use of simple stream modeling methods to assess the potential risks of malathion to salmonids. Chapter 11, pp. 159-169. In: Pesticide Regulation and the Endangered Species Act. ACS Symposium Series, Vol. 1111, American Chemical Society, 2012.

Cantor R, Lyman M, Reiss R. Asbestos claims and litigation. In: Product Liability, 2011.

Reiss R. Ozone reactive chemistry on interior surfaces of buildings. In: Encyclopedia of Environmental Analysis and Remediation, 1998.