UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re:	)	
Tolerance Revocations: Chlorpyrifos.	)	FFDCA-HQ-2021-0001 (EPA-HQ-OPP-2021-0523)

PETITION OF GHARDA CHEMICALS INTERNATIONAL, INC. TO STAY THE EFFECTIVE DATE OF THE REVOCATION OF ALL TOLERANCES FOR CHLORPYRIFOS

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Chlorpyrifos Registrant

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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"). This action was taken 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 eleven key crop uses in select regions are currently safe, as set forth in the Agency's December 2020 Proposed Interim Decision for Chlorpyrifos, EPA-HQ-OPP-2008-0850-0971 ("PID"), EPA revoked *all* tolerances for chlorpyrifos. EPA did so because it claimed that it is required under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a to assess aggregate exposure risks taking into account all "currently registered uses" and that, when taking into account drinking water exposures, it could not conclude that "the products as currently registered" are safe. The Final Rule states that tolerances will expire six months from the date of publication, on February 28, 2022. 86 Fed. Reg. at 48,336.

Established in 1967, Gharda Chemicals International, Inc. ("Gharda") is a research-based agrochemical manufacturing company with offices in the United States. Declaration of Ram Seethapathi ("Seethapathi Decl.") ¶ 5. One of Gharda's main products is chlorpyrifos, for which Gharda holds a U.S. EPA registration. *Id.* Gharda sells end-use chlorpyrifos products under the brand name Pilot™ as well as technical grade chlorpyrifos for manufacturing use. *Id.* Immediately prior to the Final Rule, Gharda was the primary supplier of chlorpyrifos for agricultural uses in the United States. *Id.* ¶ 10. Accordingly, Gharda is an "adversely affected"

party, and is entitled to file objections on the issues relevant to this action. 40 C.F.R. § 178.20. Gharda's objections to the Final Rule are incorporated by reference here.

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 states are currently safe, and in disregard of a written commitment from Gharda to modify its registration in accordance with the Agency's safety finding. EPA's Final Rule is at odds with its statutory directive under the FFDCA to assess risks from "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.

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 metabolite that exists in drinking water following chlorination) submitted by the registrants that significantly undermines EPA's assumptions concerning 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 revokes 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 Final Rule will have catastrophic consequences for all members of the agricultural value 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 existing stocks of chlorpyrifos products that will soon be rendered unusable as a result of the Final Rule. 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 unjustified demands, in a good-faith effort to cooperate with the Agency. EPA led Gharda to believe that the parties were 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 suddenly withdrew from these discussions, without a scientific basis or explanation to Gharda, and revoked all tolerances. EPA's conduct and processes leading up to the Final Rule ignored its own science and were 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 and others have and will continue to suffer as a result of the revocation of all tolerances, the Final Rule and expiration of chlorpyrifos tolerances 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. 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 11 key crops found safe in the PID.

II. REQUEST FOR STAY

Gharda hereby requests that the Final Rule be summarily reversed or, at a minimum, requests a stay of the effective date of the Final Rule and the expiration date for chlorpyrifos tolerances. Gharda requests that the stay of the effective date of the Final Rule and expiration of tolerances remain in effect until a final Agency resolution of all of the critical issues raised by the objections of Gharda, growers, grower groups, and other adversely affected stakeholders. If these issues are not resolved in Gharda's favor by the Agency's final order addressing these issues, Gharda further requests that the Agency stay the effective date of any revocation action and tolerance expiration until such time as judicial review in the courts is exhausted.

III. GHARDA HAS MET THE CRITERIA FOR A STAY

For the reasons presented herein, and discussed in detail in Gharda's objections and supporting documentation, which are incorporated into this petition by reference, Gharda submits that it has met the criteria for a stay of administrative decision set forth by the Food and Drug Administration ("FDA") at 21 C.F.R. § 10.35.[1] Under this criteria, a stay will be granted

[1] EPA has stated that it relies on the criteria set forth in FDA's regulations regarding stays of administrative proceedings at 21 C.F.R. § 10.35. 74 Fed. Reg. at 23,088.

if: (1) the petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. *Id.* § 10.35(e)(1)–(4) (as amended by 81 Fed. Reg. 78,500 (Nov. 8, 2016)).

A. Gharda Will Suffer Irreparable Injury.

In order to demonstrate irreparable harm, a party must show both "(1) that the harm is 'certain and great, actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm' and (2) that the harm is 'beyond remediation.'" *Catholic Legal Immigration Network, Inc. v. Executive Office for Immigration Review*, 513 F. Supp. 3d 154, 175 (D.D.C. 2021) (citation omitted); *see also Olu-Cole v. E.L. Haynes Pub. Charter Sch.*, 930 F.3d 519, 529 (D.C. Cir. 2019) (to show irreparable harm, "injury must be both certain and great; it must be actual and not theoretical and of such imminence that there is clear and present need for equitable relief") (internal quotation marks and citations omitted). Irreparable injury can be based on substantial and unrecoverable economic losses, such as lost sales and loss of market share, as well as other losses like damaged consumer goodwill or reputational harm. Indeed, courts have found the irreparable harm requirement met where many forms of irreparable injury are alleged, including "reputational harm, loss of goodwill, loss of longstanding clients, loss of ability to compete for and attract new clients and partners, incalculable lost profits, and consequential damages for which [petitioner] has no recourse at law." *Beacon Assocs., Inc. v. Apprio, Inc.*, 308 F. Supp. 3d 277, 287–88 (D.D.C. 2018).

Losses for which an aggrieved party has no recourse, such as those caused by a governmental entity immune from suit for monetary relief, are "irreparable *per se*." *Feinerman*

v. Bernardi, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); *see also Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) (seller of anti-microbial agent would suffer irreparable harm from EPA stop sale order because it had no right of recourse against the federal government). Additionally, a due process violation, such as the deprivation of a legally protectable property right (*i.e.*, pesticide registration), constitutes irreparable harm. *See Blackman v. District of Columbia*, 277 F. Supp. 2d 71, 79 (D.D.C. 2003) (due process violations fulfill the irreparable injury requirement for a preliminary injunction); *see also Padberg v. McGrath-McKenchnie*, 108 F. Supp. 2d 177 (E.D.N.Y. 2000) (deprivation of a government-issued license constituted irreparable harm); *Small Hearts Daycare, II, LLC v. Quick*, No. 09CV2132, 2010 WL 427766, at *1 (E.D. Mo. Feb. 1, 2010) (same); *see also 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.").

The Final Rule has caused and will continue to cause significant and irreparable harm to Gharda that is both imminent and beyond remediation, requiring a clear and present need for equitable relief in the form of an administrative stay. The Final Rule revokes all tolerances for chlorpyrifos effective on February 28, 2022, after which tolerances will be "expired" and chlorpyrifos can no longer be distributed, sold, or used. This six-month time period is effectively meaningless and allows no time for Gharda, distributors, and growers to phase out and exhaust existing inventories. Seethapathi Decl. ¶ 41. This will result in devastating financial losses to Gharda, which earlier this year had increased production to meet market demand for chlorpyrifos after Corteva's exit from the market and, as a result, now has a significant volume of raw materials and U.S.-labeled product in inventory. *Id.*. ¶ 42. Without the ability to formulate, distribute, and sell these products, 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.* In total, the economic losses Gharda will face if the Final Rule is not reversed or rescinded will be catastrophic. *Id.*

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. *Id.* ¶ 43. 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. *Id.* 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 by Gharda ***prior to the Final Rule*** to modify Gharda's label consistent with EPA's safety finding in its PID. *Id.*; *see also Jones v. District of Columbia*, 177 F. Supp. 3d 542, 547 (D.D.C. 2016) (citations omitted) (reputational injury can be used to establish irreparable); *Xiaomi Corp. v. Dep't of Def.*, Civ. A. No. 21-280, 2021 WL 950144, at *1, *10 (D.D.C. Mar. 12, 2021) (reputational damage, in conjunction with serious unrecoverable financial harm, weighs in favor of granting preliminary relief).

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. Seethapathi Decl. ¶ 44. 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. *Id.* Given EPA's scientific assessment in the PID which provided a clear scientific record on which to retain *at least* the 10X uses, neither Gharda nor its customers expected that EPA would take draconian action to eliminate *all* uses. *Id.* EPA's abrupt

departure from its own scientific findings has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill. *Id.*

In addition to the immediate and irreparable harm caused by 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."[2] *Id.* ¶ 45. 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. *Id.* (citing 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").

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. Seethapathi Decl. ¶ 46. 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. *Id.* Gharda may thus permanently lose a significant portion of its market share. *Id.* Moreover, EPA's actions may trigger other federal or state regulatory requirements or bans, as well as restrictions by foreign governments, who look to

[2] 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).

EPA as the gold standard for making regulatory decisions based on science. *Id.*

Losses from an 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.* 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 specifically informed by some of its major customers that they currently have inventories of chlorpyrifos product on hand valued at approximately CBI. *Id.* Growers, for their part, not only face a lost investment in unusable products 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.* 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. *Id.* ¶ 49.

In short, Gharda has readily satisfied the irreparable harm requirement for an administrative stay, given the significant and irreparable harm it has and will continue to suffer as a result of EPA's Final Rule.

B. Gharda's Case Is Not Frivolous And Is Being Pursued In Good Faith.

Gharda's case is not frivolous and is being pursued in good faith. Gharda has submitted nearly fifty pages of objections to the Final Order setting forth in detail the numerous substantive and procedural flaws in the Final Order, and the grounds for its objections, with supporting authorities, documentation, and declarations. The objections and supporting materials Gharda has submitted demonstrate, among other things, that the alleged basis for EPA's revocation of all

tolerances of chlorpyrifos lacks any scientific support, is contrary to EPA's own safety finding and its consistent regulatory practice, and is at odds with text of the FFDCA and the Ninth Circuit order. Gharda's objections also demonstrate that EPA has also abridged the due process rights of Gharda and other affected parties in issuing the Final Rule, including by refusing to engage in meaningful review of highly relevant scientific data and other information that *directly address* the alleged drinking water concerns EPA relied on to revoke all tolerances. Gharda has more than demonstrated that it is pursuing its case with great seriousness and in good faith to rectify the Agency's arbitrary and unlawful action.

C. Gharda Has Demonstrated Sound Public Policy Grounds Supporting The Stay Request.

Gharda's objections demonstrate that sound public policy grounds support its stay request. Substantively, EPA's Final Rule ignores the fulsome and carefully considered assessments of Agency expert scientists demonstrating that there are safe uses for chlorpyrifos that can and should remain approved, without any logical or reasoned explanation. Good public policy does not support regulatory decisions that blatantly override the Agency's best available science, particularly a decision of this magnitude.

Procedurally, the Agency has issued the Final Rule in a manner that is fundamentally unfair and demonstrates bad faith, by abruptly revoking tolerances after months of discussions with Gharda concerning a voluntary cancellation that would have allowed many key agricultural uses to continue, consistent with the Agency's safety finding. 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, and abdicated its responsibility to oversee a lawful and orderly phase-out of products, including existing stocks. Sound public policy dictates that a government agency issue rules and

regulations affecting the rights and interests of regulated parties and the public in a reasonable, even-handed, and transparent manner.

Practically, the Agency's Final Rule ignores the realities of the agricultural economy by imposing an impossibly short timeframe for tolerance expiration that allows no meaningful time for Gharda, its distributors, and growers to exhaust existing inventories of chlorpyrifos and that will result the needless waste of safe and wholesome food. Seethapathi Decl. ¶ 41. The Final Rule will also cause significant hardship to U.S. growers who will be forced to rely on more expensive and/or less effective products to meet their crop protection needs. *Id.* 48. Increased pesticide applications could also impact the environment. In short, Gharda has amply demonstrated that there are strong public policy grounds favoring a stay.

D. The Delay Resulting From The Stay Is Not Outweighed By Public Health Or Other Public Interests

There are no public health or other public interests that will be adversely impacted by granting a stay. The safety of chlorpyrifos is supported by decades of scientific study. Few pest control products have undergone this level of scientific review. EPA itself has conceded that eleven key crop uses in select geographic are safe. Its assessments as to the remaining uses ignore relevant data and information that address the alleged drinking water risk concerns and are otherwise predicated on incorrect application of a precautionary 10X FQPA safety factor, which cannot be used to address "uncertainties" in unreliable data concerning alleged neurodevelopmental effects. In contrast, if not stayed, the Final Rule will wreak havoc on the agricultural economy, significantly and irreparably harm Gharda and other affected parties, and negatively impact the environment.

IV. CONCLUSION

For all the above reasons, granting a stay is in the public interest and in the interest of

justice. Therefore, Gharda requests that the Agency grant this petition for a stay of the effective date of the Final Rule and the expiration date for chlorpyrifos tolerances until a final resolution, including potential judicial review, is reached on all of the critical issues raised in Gharda's objections.

Respectfully submitted,

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