EXHIBIT 1

Letter from U.S. Environmental Protection Agency to Ram Seethapathi, Gharda Chemicals International, Inc., (Mar. 1, 2022)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA E-MAIL, RETURN RECEIPT REQUESTED

March 1, 2022

Subject**:** Tolerance expiration and active chlorpyrifos product labels with uses tied to tolerances that require action

Dear Mr. Seethapathi,

In 2007, the Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC) filed a petition with EPA under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(d), requesting that EPA revoke all chlorpyrifos tolerances. On April 29, 2021, the United States Court of Appeals for the Ninth Circuit ordered EPA to issue a final rule concerning the chlorpyrifos tolerances by August 20, 2021.[1] In August 2021, EPA granted the 2007 Petition and issued a final rule revoking all tolerances for chlorpyrifos.[2] These tolerances were established under 40 C.F.R. § 180.342 (*"Chlorpyrifos; tolerances for residues"*)[3] as required by 21 U.S.C. § 346a (*"Tolerances and exemptions for pesticide chemical residues"*). That provision included tolerances for residues of chlorpyrifos on specific food and feed commodities, on all food commodities treated in food handling and food service establishments in accordance with prescribed conditions, and on specific commodities when used under regional registrations.

You are receiving this letter because your company holds active registrations for chlorpyrifos products with uses tied to tolerances, and the tolerances expired on February 28, 2022. Changes will be needed to your registration, and this letter outlines options for your product. The issuance of the final rule on August 30, 2021, served as public notification that EPA could not make a safety finding to support leaving the tolerances for residues of chlorpyrifos in place as required under the FFDCA section 408(b)(2).

[1] *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673 (9th Cir. 2021)
[2] https://www.federalregister.gov/documents/2021/08/30/2021-18091/chlorpyrifos-tolerance-revocations. *See also*, 86 FR 48315 (August 30, 2021). This document may also be found in the public docket at http://www.regulations.gov/ under docket number EPA-HQ-OPP-2021-0523.[2]
[3] https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.342

The final rule went into effect on October 29, 2021, and the tolerances for all commodities expired on February 28, 2022. Without tolerances established, food commodities treated with chlorpyrifos on or after February 28, 2022 may contain levels of residues and be deemed adulterated under 21 U.S.C § 342(a)(2)(B). Cancellation of chlorpyrifos uses tied to tolerances will need to be made immediately. After February 28, 2022, if these products are not cancelled or appropriately relabeled, they will be considered misbranded pesticides and their distribution or sale will be unlawful under FIFRA. Should you be interested in having product returned to your company, please contact Trish Biggio, contact information listed below, for further information. A list of your currently registered products is attached to this letter.

- For products where all uses are impacted by the tolerance revocation, registrants may submit a voluntary cancellation letter within 30 days after the date the tolerances expired (March 30, 2022).
- For products where only a subset of uses are impacted by the tolerance revocation, you may either amend the registration to remove impacted uses or cancel the registration.
    - Should you choose to amend your labels, please submit a letter formally expressing your intention to submit label amendments to Trish Biggio, contact information listed below, within 30 days after the date the tolerances expired (March 30, 2022). Submission of label amendments, along with voluntary cancellation of uses impacted by the tolerance revocation, are requested within 60 days after the date the tolerances expired (April 29, 2022). Label amendments must include deletion of all uses of chlorpyrifos on food and feed, as well as label changes for livestock, in accordance with the Environmental Protection Agency's (EPA's) final rule published in the docket on August 30, 2021.
    - Should you pursue voluntary cancellation of your registration, please submit a voluntary cancellation letter within 30 days after the date the tolerances expired (March 30, 2022).
    - Please refer to Attachment 1 for a list of uses applicable to tolerance revocation.

For relevant label amendments, please submit a cover letter, a completed Application for Registration (EPA form 8570-1) and copies of your amended product labels. For each label, submit two copies, a clean copy and an annotated copy with changes. In order for the application to be processed, include the following statement on the Application for Registration (EPA form 8570-1): "I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this product is found in violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), it may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP). The PSP can be accessed through EPA's Central Data Exchange (CDX) using the following link: https://cdx.epa.gov/. Please be aware that the Agency is currently not accepting paper submissions because of COVID-19.

In the absence of this revised labeling, chlorpyrifos products will be considered misbranded under FIFRA since they will not have sufficient directions for use and/or

precautionary statements to adequately protect human health and the environment. Therefore, failure to submit amended labels may result in regulatory action.

This letter serves as EPA's formal request for voluntary cancellation of registrations and/or uses impacted by the chlorpyrifos tolerance revocation. If voluntary cancellation requests are not forthcoming, EPA intends to initiate cancellation procedures to cancel registered uses of chlorpyrifos associated with the tolerances that have been revoked by issuing a Notice of Intent to Cancel (NOIC) under the FIFRA. That NOIC will be published in the Federal Register. For more information on the NOIC process, visit EPA's website: https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative.

Please contact Patricia Biggio if you have any questions about this letter. She may be reached at (202) 566-1938 or at biggio.patricia@epa.gov.

Sincerely,

Dana Friedman, Branch Chief
Pesticide Re-evaluation Division
Office of Pesticide Programs

Attachments:

(1) *List of uses applicable to tolerance revocation and list of uses where no action is required.*
(2) *List of Currently Registered Pesticide Products Containing Chlorpyrifos*

cc: Mike Walsh, PM #11, Registration Division (RD)

Attachment 1:

Products where action is required:
Action is required for all products registered for food uses for which there are currently tolerances. This includes products registered for use on fruits, vegetables, seed treatment, and uses which may result in exposure to livestock by consumption such as feed (e.g., alfalfa) or direct application to livestock. These uses include:

- Agricultural crops, terrestrial food crops, greenhouse food crops including alfalfa, apple, asparagus, banana, bean (snap, lima), beet (sugar, table, including crops grown for seed), blueberry, brassica (cole) leafy vegetables (bok choy, broccoli raab, broccoli, Brussels sprout, cabbage, Chinese cabbage, cauliflower, collard, kale, kohlrabi), caneberry, cherimoya, cherry (sour, sweet), citrus (lemon, orange, grapefruit and citrus, other) citrus orchard floor, corn (field, sweet, including crops grown for seed), cotton, cranberry, cucumber, date, feijoa, fig, grape, kiwifruit, leek, legume vegetables, mint, nectarine, onion (dry bulb), pea, peach, peanut, pear, pepper, plum, prune, pumpkin, radish (including crops grown for seed), rutabaga, sapote, seed and pod vegetables, sorghum (grain, milo), soybean, strawberry, sugarcane, sunflower, sweet potato, tree nuts (almond, filbert, pecan, walnut, other), turnip, wheat, and seed treatment of any food use.
- Commercial livestock uses: Cattle ear tags, poultry houses, turkey barns, swine barns, and dairy barns only
- All commodities listed under 40 C.F.R. § 180.342.

Products that will not require action:
Though additional action may be required at a later date under registration review, no action is currently required for registered products for non-food uses for which there are currently no tolerances, or for uses that will not result in residues in livestock. These uses include:

- Ornamentals - Commercial production, commercial terrestrial non-food crop, commercial greenhouse non-food crop, greenhouse, outdoor, field grown and nursery grown ornamentals (including flowers, shrubs, evergreens, vines, shade and flowering trees, and non-bearing fruit, nut, and citrus trees) (wholesale nursery operations only); Christmas tree plantations, nurseries (wholesale nursery operations only), forest tree nurseries (wholesale nursery operations only), sod farms, perennial grass seed crops, soil treatment of potted, containerized or balled and burlapped nursery stock plants in nurseries and greenhouses only (USDA quarantine purposes only); annual and perennial plants; flowers, shrubs, evergreens, vines, shade, and flowering trees in nurseries or greenhouses; Christmas trees, forest tree nurseries, non-bearing fruit, nut, and citrus trees, commercial sod farms; grass grown for seed.
- Tobacco
- Forest trees (forestry): Plantations, forests seed orchards, felled trees, cut stumps
- Commercial indoor non-residential: Warehouses, ship holds, railroad boxcars, industrial plants, manufacturing plants, food processing plants or containerized baits.
- Outdoor residential: Public health uses: fire ant mount (individual), mosquito control.
- Outdoor non-residential: Golf courses, road medians, and industrial plants, fence posts, utility poles, railroad ties, landscape timbers, logs, poles, and posts.
- Indoor residential: Ant and roach bait (containerized)

- Commercial outdoor: Underground utility cables and conduits; Turf and ornamental in road medians and industrial plant sites; Interior treatment of warehouses, railroad boxcars, industrial plants, manufacturing plants, and food processing plants only.
- Turf: Golf course turf, turf in road medians, and turf in industrial plant sites.
- Public Health: USDA quarantine (soil treatment of containerized plants) in nurseries and greenhouses; fire ant mounds (individual mounds), and mosquito control.

Attachment 2: Gharda Chemicals International, Inc. Registrations and Supplement Distribution Products

Table 1: Gharda Chemicals International, Inc. Registrations

Product name	Registration No.	Current uses listed on label	Active ingredients	Actions
Chlorpyrifos Technical	93182-3	Agricultural Uses - Alfalfa, Asparagus, Christmas Tree Plantations, Banana, Blueberry, Caneberry, Cherimoya, Citrus Fruits, Corn, Cotton, Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, Soybeans, Sunflowers, Sugar Beets, Sugarcane, Strawberries, Sweet Potatoes, Tobacco, Tree Fruit, [apples (Only one application of any chlorpyrifos containing product can be made per year. pears, cherries, plums/prunes, peaches and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and wheat. Non-Agricultural Uses - Non-Residential Outdoor Pest Control (golf courses, road medians, and industrial plant sites); and, Non-Residential Ornamentals (flowers, shrubs, vines, shade & flowering trees, non-bearing fruit, nut, and citrus trees, and evergreens), Sod Farms, Perennial Grass Seed Crops, Annual and Perennial Plants, Road Medians, and Industrial Plant Sites.	Chlorpyrifos	Registrant must submit an amendment to remove food uses (food crops and livestock) or submit a voluntary cancellation request.
Pilot 4E Chlorpyrifos Agricultural Insecticide	93182-7	For control of listed insects infesting certain field, fruit, nut, and vegetable crops and wheat. Alfalfa, apple, tree trunk, asparagus, brassica (cole), leafy vegetables, radish, rutabaga, turnip, citrus fruits, citrus orchard floors), corn (field corn and sweet corn, including corn grown for seed) cotton, cranberries figs, grape, legume vegetables (succulent or dried) except soybean, onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), soybean, strawberry, sugar beet, sunflower, sweet potato, tobacco tree fruit, almond, and walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip,) tree nuts (foliar sprays) tree nut orchard floors, turfgrass, and wheat. Christmas trees (nursery and plantations)	Chlorpyrifos	
Pilot 15G Chlorpyrifos	93182-8	Citrus, citrus orchards broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions,	Chlorpyrifos	

Agricultural Insecticide		radishes, rutabagas, sweet potatoes, corn, asparagus, alfalfa, sorghum, soybeans peanuts, sugar beets, turnips, sunflowers, and tobacco.		

Table 2: Supplemental Distribution Products

Distributor Product Number	Distributor Company Name	Distributor Product Name	Actions
93182-7-55467	Tenkoz, Inc.	Govern Insecticide	Registrant must submit an amendment to remove food uses (food crops and livestock) or submit a voluntary cancellation request.

EXHIBIT 2

Petitioners' Renewed Motion for a Partial Stay Pending Review, *RRVSGA*, No. 22-1422 (8th Cir. Mar. 3, 2022), Entry ID 5132688

In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 22-1422

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITIONERS' RENEWED MOTION FOR A PARTIAL STAY PENDING REVIEW

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INTRODUCTION

Petitioners seek to preserve critical uses of the insecticide chlorpyrifos that the Environmental Protection Agency ("EPA" or "the Agency") agrees are safe and provide great benefit to American agriculture. These uses pertain to eleven crops (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in states where EPA concluded such use is safe ("EPA's Designated Safe Uses"). Att. 1, Ex. B (Proposed Interim Registration Review Decision, hereinafter "PID") at 40–41. The value of these crops to the U.S. economy surpasses $59 billion annually. Moreover, these eleven crops are critical to the livelihoods of the family farmers represented here.

Despite finding that EPA's Designated Safe Uses are safe for everyone, EPA issued a rule that prohibited *all* uses of chlorpyrifos for agricultural commodities. *See Final Rule for Chlorpyrifos Tolerance Revocations*, 86 Fed. Reg. 48,315 (Aug. 30, 2021) (the "Final Rule"), Declaration of Nash E. Long ("Long Decl.") Ex. A. EPA has denied Petitioners' objections to and requests to administratively stay the Final Rule ("EPA's Denial"). *Chlorpyrifos; Final Order Denying*

Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11,222 (Feb. 28, 2022), Long Decl. Ex. FF. EPA made clear in EPA's Denial that it "does not dispute its own scientific conclusions and findings" concerning EPA's Designated Safe Uses. 87 Fed. Reg. at 11,241. Rather, EPA attempted to justify prohibiting all uses, rather than limiting permissible uses to EPA's Designated Safe Uses, by claiming that it had an obligation under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to make a decision considering all currently registered uses. *Id.*

That is not the law. EPA did not have to make one safety determination on the basis of all currently registered uses. The plain language of the FFDCA requires a tolerance-by-tolerance analysis for revocation—not a wholesale approach that ignores individual tolerances that EPA knows to be safe. 21 U.S.C. § 346a(b)(2)(A)(i) (EPA "shall modify or revoke *a* tolerance if the Administrator determines *it* is not safe") (emphasis added). EPA must base those safety determinations upon "anticipated" uses—not current uses. *Id.* § 346a(b)(2)(A)(ii). EPA regulates these pesticide uses under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), and has a statutory obligation to

harmonize its registrations under FIFRA with its tolerance decisions under FFDCA. *Id.* § 346a(l)(1).

At its core, the Petition seeks review of a legal question, as EPA's Denial concedes: whether EPA's new interpretation of the FFDCA and FIFRA—requiring all registered uses of a pesticide to rise or fall together when considering the safety of tolerances—allows EPA to ignore its findings that certain uses and tolerances are safe. EPA had already done the work necessary to identify the tolerances that should be retained: EPA's Designated Safe Uses. The Agency should have followed its statutory duty and taken the steps necessary to preserve EPA's Designated Safe Uses and to oversee an orderly phase-out of all other food uses. Indeed, EPA held extensive talks with Petitioner Gharda to do just that. EPA then reversed course at the eleventh hour and made a wholesale revocation of all agricultural uses, contrary to its own science.

EPA's sweeping rule will cause significant and irreparable harm to the thousands of farmers represented here, who need chlorpyrifos to

fight insect infestation and preserve their crops.[1] In many cases, growers have no adequate substitute for controlling insects that attack their crops. Where alternatives exist, those insecticides are more expensive and less effective than chlorpyrifos. Without the ability to apply chlorpyrifos for EPA's Designated Safe Uses, crop yields will decrease and costs of production will increase. The resulting economic losses will be substantial. For example, over half of the domestic supply of sugar comes from sugarbeets grown by farmers represented by Petitioners Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, and Minn-Dak Farmers Cooperative. Att. 1, Ex. F at 9. Petitioners

[1] Petitioners Red River Valley Sugarbeet Growers Association, U.S. Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, South Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Association, and National Cotton Council of America (hereinafter, the "Grower Petitioners") represent individual farmers and growers who collectively cover each of the eleven agricultural commodities for which EPA found the use of chlorpyrifos safe and of high benefit.

Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, and Minn-Dak Farmers Cooperative estimate that their members will suffer losses approaching $82 million per year under the Final Rule. Att. 2, Ex. F (Geselius Decl.) at ¶22; Att. 2, Ex. G (Hastings Decl.) at ¶20; Att. 2, Ex. I (Metzger Decl.) at ¶18. The crop losses EPA estimates will occur threaten the viability of the sugarbeet cooperatives here. Att. 2, Ex. G (Hastings Decl.) at ¶27. Losses suffered by individual sugarbeet farmers will be equally significant. For example, a sugarbeet grower (one of the 10,000 family farmers represented by the sugarbeet petitioners) estimates his farm will lose up to $400,000 annually under EPA's Final Rule. Att. 2, Ex. B (Baldwin Decl.) at ¶14. These harms are imminent, as farmers will need to apply chlorpyrifos beginning in April 2022 to control destructive pests. Att. 2, Ex. H (Haugrud Decl.) at ¶8. And these harms are certain, as EPA's own calculations show. PID at 42.

The Final Rule will also irreparably harm Gharda, the primary supplier of chlorpyrifos for agricultural use in the United States. The Final Rule will effectively deprive Gharda of its legally protectable property interest in its chlorpyrifos registration. It will also cause

Gharda significant unrecoverable economic losses and reputational harm from lost sales, lost investment in inventory, and customer and public ill-will.

Petitioners made these facts known to EPA, in written objections to the Final Rule and in requests for an administrative stay of its effective date.[2] EPA ignored these entreaties for over four months, then issued EPA's Denial rejecting them. EPA's Denial acknowledged the "cases for a stay" made by certain Petitioners "are not frivolous and are being pursued in good faith." 87 Fed. Reg. at 11,268.

Pursuant to Federal Rule of Appellate Procedure 18, to avoid irreparable harm, this Court should stay implementation of the rule with respect to EPA's Designated Safe Uses. This Court should also stay the tolerance expiration date for all other crop uses of chlorpyrifos until the Agency coordinates its action with FIFRA and provides an appropriate existing stocks order for those uses.

[2] All Petitioners except the National Cotton Council of America filed objections.

BACKGROUND

Chlorpyrifos, a broad-spectrum, organophosphate insecticide, has been registered for use in the United States since 1965 and is currently registered for use on food crops and in non-food use settings. 86 Fed. Reg. 48,315, 48,320 (Aug. 30, 2021). Grower Petitioners represent individual farmers, particularly in the upper Midwest, who rely on chlorpyrifos to fight destructive insects, to meet demand for their products, and to avoid significant crop losses. Chlorpyrifos is a critical tool—sometimes the only tool—for addressing several pest problems for the crops at issue. *See, e.g.*, Att. 2, Ex. G (Hastings Decl.) at ¶11; Att. 2, Ex. F (Geselius Decl.) at ¶12; Att. 2, Ex. J (Crittenden Decl.) at ¶¶10–15; Att. 2, Ex. Q (Schmitz Decl.) at ¶¶11–15.

EPA regulates the use of insecticides under the FFDCA and FIFRA. The FFDCA requires EPA to set food safety "tolerances" that represent the maximum levels of pesticide residues allowed in or on agricultural commodities. 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." *Id.* § 346a(b)(2)(A)(i). When establishing, modifying, or revoking 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." *Id.* § 346a(b)(2)(D)(i).

The Food Quality Protection Act ("FQPA") amended the FFDCA to establish a safety standard for pesticide tolerances for residues in or on raw agricultural commodities. Such a tolerance is deemed "safe" 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." *Id.* § 346a(b)(2)(A)(ii). This provision contemplates exposures from food, drinking water, and non-occupational exposure. When assessing "reasonable certainty [of] no harm," EPA applies an additional tenfold ("10X") 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. *Id.* § 346a(b)(2)(C)(ii)(II). The Agency may apply a different margin of safety (e.g., a 1X safety factor) if there is "reliable data" to support doing so. *Id.*

FIFRA establishes a licensing or "registration" regime for regulating pesticide uses. 7 U.S.C. § 136a(a). In approving a pesticide registration, EPA must review and approve pesticide labeling, which governs its use. *Id.* § 136j(a)(2)(G). When revoking a tolerance for a pesticide chemical residue in or on food, the FFDCA requires EPA to "coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(l)(1). That "related action" may include canceling the pesticide's registration and entry of an "existing stocks" order for "the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled." 7 U.S.C. § 136d(a), (b).

As described in the Final Rule, EPA's action came after years of administrative process and litigation surrounding EPA's established chlorpyrifos tolerances. In 2007, several nongovernmental organizations ("NGOs") petitioned EPA to revoke all existing chlorpyrifos tolerances. EPA issued an order denying the petition in 2017 and subsequently denied the NGOs' objections. *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 680–90 (9th Cir. 2021) ("*LULAC*"). On April 29, 2021, the U.S. Court of Appeals for the Ninth Circuit vacated those denials and ordered EPA to "issue a final

regulation within 60 days following issuance of the mandate that either (a) revokes all chlorpyrifos tolerances or (b) modifies chlorpyrifos tolerances and simultaneously certifies that, with the tolerances so modified, the EPA has determined that there is a reasonable certainty that no harm will result." *Id.* at 703–04. The court further instructed that EPA "modify or cancel related FIFRA registrations for food use in a timely fashion." *Id.*

The court's order made clear that EPA could "choose to modify chlorpyrifos tolerances, rather than to revoke them," based on a safety determination. *Id.* at 702. In making this statement, the court was aware of the Agency's PID. *Id.* at 703. The court explained that "[i]f, 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.* In discussions in May and June 2021, EPA expressed to Gharda its willingness to consider retaining EPA's Designated Safe Uses, and Gharda committed to accept a narrowing of its registration consistent with the Agency's safety finding. Seethapathi Decl. ¶¶ 21–33. EPA then abruptly ceased discussion. *Id.* at ¶ 34.

On August 30, 2021, EPA issued the Final Rule, revoking all tolerances for chlorpyrifos. 86 Fed. Reg. at 48,315. The Final Rule stated that "given the currently registered uses of chlorpyrifos, EPA cannot determine there is a reasonable certainty that no harm will result from aggregate exposure to residues, including all dietary (food and drinking water) exposures and all other exposures for which there is reliable information," notwithstanding the FQPA 10X safety factor. *Id.* at 48,317.

Applying the conservative 10X safety factor, EPA confirmed key findings from its PID—namely that there are no risk concerns based on exposures to chlorpyrifos from food alone. Factoring in drinking water exposures, EPA found that risks exceeded safe levels when taking into account all registered uses, but are within safe limits assuming only EPA's Designated Safe Uses. *Id.*

EPA conducted a drinking water assessment (DWA) in 2016 based on modeling all registered uses. *Id.* at 48,330. EPA conducted a refined 2020 DWA to better account for variability and estimate regional and watershed concentrations. 86 Fed. Reg. at 48,332. The 2020 DWA

underwent peer review,[3] and focused on a "subset of uses [(EPA's Designated Safe Uses)] . . . to determine, if these were the only uses permitted on the label, whether or not the resulting estimated drinking water concentrations" would be safe. 86 Fed. Reg. at 48,331. The results indicated that exposures for EPA's Designated Safe Uses were below the level of concern. *Id.*

EPA's Final Rule nevertheless put aside the 2020 DWA's results because, in EPA's view, "the Agency is required to assess aggregate exposure from all anticipated dietary, including food and drinking water, as well as residential exposure," and the 2020 drinking water assessment cannot be used to support "currently labeled uses." 86 Fed. Reg. at 48,333. EPA thus decided that, rather than maintain the tolerances for uses of chlorpyrifos it found safe, it should revoke all of them.

Petitioners filed objections to EPA's decision and requested a stay of the Final Rule, which EPA denied on February 22, 2022. Long Decl.,

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[3] *See generally* U.S. EPA, Memorandum, Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review, EPA-HQ-OPP-2008-0850-0941 (Sept. 15, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941.

Att. 1, Ex. FF. Petitioners exhausted all administrative means of staying the Final Rule, which took effect on February 28, 2022. The 2022 growing season, and the need for farmers to use chlorpyrifos in planting and protecting their crops, beginning in mid-April, is quickly approaching. Att. 2, Ex. H (Haugrud Decl.) at ¶8. Without a stay of the Final Rule as requested herein, Petitioners will suffer immediate and ongoing irreparable harm from the inability to sell and use chlorpyrifos.

ARGUMENT

Courts consider four factors in determining whether to stay agency action pending judicial review: (1) the applicant's likelihood of success on the merits; (2) irreparable injury absent a stay; (3) the balance of equities among interested parties; and (4) the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009); *accord Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013) (quoting *Dataphase Sys., Inc. v. C L Sys., Inc.,* 640 F.2d 109, 113 (8th Cir. 1981) (en banc)). Although "no single factor is determinative," *Dataphase Sys.*, 640 F.2d at 113, "the 'likelihood of success on the merits is most significant,'" *Barrett v. Claycomb*, 705 F.3d 315, 320 (8th Cir. 2013) (quoting *S.J.W. ex rel. Wilson v. Lee's Summit R-7 School Dist.*, 696 F.3d 771, 776 (8th

Cir. 2012)). Petitioners satisfy these factors for a stay of the revocation of the tolerances for EPA's Designated Safe Uses and, for all other crop uses, a stay of the revocation until EPA issues an appropriate existing stocks order.

I. Petitioners Are Likely to Succeed in Challenging EPA's Unlawful Decision to Revoke the Tolerances For the Crop Uses EPA Found Safe.

This Court must set aside agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. Agency action is arbitrary and capricious if

> [1] the agency has relied on factors which Congress has not intended it to consider, [2] entirely failed to consider an important aspect of the problem, [3] offered an explanation for its decision that runs counter to the evidence before the agency, or [4] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *accord Nebraska v. EPA*, 812 F.3d 662, 666 (8th Cir. 2016).

EPA's decision to revoke tolerances for EPA's Designated Safe Uses is arbitrary and capricious and contrary to law for at least three reasons. First, EPA ignored the plain text of the FFDCA and FIFRA, rendering its decision contrary to law. Second, EPA's explanation for

its decision runs counter to its own finding that the tolerances for EPA's Designated Safe Uses are safe. Finally, EPA ignored important aspects of the problem in issuing the Final Rule, including Petitioners' reliance interests and the need for harmonization with FIFRA.

A. EPA ignored the plain text of the FFDCA and FIFRA in reaching its decision.

The FFDCA specifies how EPA must approach decisions concerning tolerances. For insecticides such as chlorpyrifos, EPA has established multiple tolerances: a separate one for each agricultural commodity on which it may be used. The plain language of the FFDCA specifies a tolerance-by-tolerance examination by EPA of these separate safety standards in determining whether to leave it in place, to modify it, or to revoke it. EPA "may establish or leave in effect *a tolerance* . . . if the Administrator determines that *the tolerance* is safe . . . [and] shall modify or revoke *a tolerance* if the Administrator determines *it* is not safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). This plain language requires that a determination on the safety of a tolerance occur on an individual basis.

Once EPA has made its safety decisions for the existing tolerances, then FFDCA and FIFRA require EPA to modify or cancel

the FIFRA registrations accordingly. *See* 21 U.S.C. § 346a(l)(1) ("[T]he Administrator shall coordinate such action with any related necessary action under [FIFRA]."). In short, FFDCA and FIFRA required EPA to address chlorpyrifos tolerances on a tolerance-by-tolerance basis—revoking any chlorpyrifos tolerances where it could not make a safety finding, leaving in place the tolerances for the eleven uses EPA found safe, or modifying individual tolerances as the science would require—and then cancel or modify chlorpyrifos registrations under FIFRA in accordance with that science. This is precisely how EPA has applied the law previously, Seethapathi Decl. Ex. 4, Reiss Decl. at ¶17, consistent with FFDCA's forward-looking mandate to consider "anticipated" uses in making a safety decision. 21 U.S.C. § 346a(b)(2)(A)(i).

EPA had already done the work in the PID to identify the tolerances to be maintained: EPA's Designated Safe Uses. Instead of following the science and adjusting the registrations to conform to its safety findings, EPA concluded—contrary to the plain language of FIFRA—that it could not do so. EPA asserted, for the first time, that all "currently registered" uses had to rise or fall together. EPA had no

basis for fashioning this new rule, and the Final Rule and EPA's Denial claim none.

At most, EPA suggests that the Ninth Circuit's order mandated this approach. 86 Fed. Reg. at 48,316. That argument fails. EPA had already drawn the necessary lines in the 2020 PID, identifying for retention EPA's Designated Safe Uses. Citing the PID, the Ninth Circuit gave EPA 60 days to make its decision to modify or revoke chlorpyrifos tolerances on the basis of the available evidence. With the science already in hand, EPA had more than enough time to "act based upon the evidence" as required by the Ninth Circuit's order. *Id.* at 703. EPA's Denial confirms that EPA does not dispute its conclusions that EPA's Designated Safe Uses are in fact safe.

Because EPA's decision-making departed from the plain language of FFDCA and FIFRA, as well as the agency's own settled practice, EPA's Final Rule is contrary to law and must be set aside.

B. EPA's explanation for its decision runs counter to its own safety findings.

The Final Rule and EPA's Denial are arbitrary and capricious because they runs counter to the evidence in the record, including EPA's own safety findings. EPA acknowledged as much in the Final

Rule, 86 Fed. Reg. at 48,333, and again in EPA's Denial, 87 Fed. Reg. at 11,241. EPA's Final Rule explained that the "PID recognized that there might be limited combinations of uses in certain geographic areas that could be considered safe." 86 Fed. Reg. at 48,333 (citing PID at 40 (discussing EPA's Designated Safe Uses)). Indeed, the PID explained that EPA's Designated Safe Uses "will not pose potential risks of concern" and at least these uses could be retained. PID at 40. EPA's Denial confirmed that EPA "does not dispute" these conclusions. 87 Fed. Reg. at 11,241.

EPA nevertheless refused to apply its own scientific findings and instead decided to revoke all of the tolerances, including those for EPA's Designated Safe Uses. EPA's Denial upheld the Final Rule's claim that EPA could not modify chlorpyrifos labels under FIFRA to narrow permissible uses. 86 Fed. Reg. at 48,333; 87 Fed. Reg. at 11,237–38. EPA also claimed that it could not make a safety finding for a narrowed subset of uses unless "EPA has a reasonable basis to believe" that other uses will cease. 87 Fed. Reg. at 11,246.

EPA fails to explain why it could not make label changes consistent with its safety finding. 86 Fed. Reg. at 48,320–33; 87 Fed.

Reg. at 11,238. EPA had the time and ability to do just that, as its negotiations with Gharda prior to the Final Rule demonstrate. No data review would have been required: EPA had already made the safety finding months earlier.[4] EPA and Gharda had already discussed, for several weeks, registration and label modifications. Gharda had already agreed to cancellation of the registrations for everything but EPA's Designated Safe Uses. Seethapathi Decl. ¶ 24. EPA has offered no genuine basis for ignoring its safety findings supporting retention of EPA's Designated Safe Uses. Its decision is therefore arbitrary and capricious. *See Siddiqui v. Holder*, 670 F.3d 736, 744 (7th Cir. 2012) (agency use of "only generalized language to reject the evidence" is improper).

Courts have rejected similarly overbroad agency actions where the agency ignored its own science. For example, the D.C. Circuit rejected EPA's revocation of import tolerances for carbofuran where EPA had acknowledged that the imported foods were safe. *Nat'l Corn Growers*

[4] Label changes with data review generally take four months, but that would not be necessary here. *See* EPA, PRIA Fee Category Table – Registration Division – Amendments, last visited January 19, 2022, https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments.

Ass'n v. EPA, 613 F.3d 266 (D.C. Cir. 2010). Likewise, this Court rejected agency action where the weight of the evidence went against the agency's decision. *Sugule v. Frazier*, 639 F.3d 406, 412 (8th Cir. 2011). Here, EPA's action was similarly arbitrary and capricious because EPA ignored its own science and provided an unsupported justification for its decision.

C. EPA failed to consider important aspects of the problem.

EPA's decision is also arbitrary and capricious because EPA failed to consider important aspects of the problem. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. First, EPA failed to consider Petitioners' significant reliance interests. "When an agency changes course, . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'" *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)). The agency is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Id.* at 1915.

Grower Petitioners have a significant reliance interest in the EPA-approved use of chlorpyrifos as a safe and effective insecticide for protecting their crops. EPA failed to consider the interests of the farmers who have relied on chlorpyrifos for decades to grow a number of agricultural commodities safely. Similarly, Gharda has a reliance interest in EPA following the science in making decisions that impact Gharda's investment in its registration. EPA failed to consider this interest as well. EPA's overbroad decision upended decades of approved chlorpyrifos use, when EPA could lawfully, and based on its own science, leave in effect the tolerances for EPA's Designated Safe Uses.

EPA also failed to consider the need for an existing stocks order for crop uses other than EPA's Designated Safe Uses. EPA has a statutory mandate under FIFRA to ensure the safe, lawful, and orderly phase-out of these products. Yet EPA failed to do this in coordination with the Final Rule. *See* 86 Fed. Reg. 48,315. EPA's failure to deal with the issue of existing stocks of chlorpyrifos causes substantial harm, and further demonstrates that its Final Rule was arbitrary and capricious.

II. Petitioners Will Suffer Irreparable Harm Absent a Partial Stay As Requested Herein.

To demonstrate irreparable harm, "a party must show that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 425 (8th Cir. 1996). The threat of unrecoverable economic loss qualifies as irreparable harm. *Id.* at 426. Economic losses are unrecoverable where the injured party would not be able to bring a lawsuit to recover their economic losses if agency rules are eventually overturned. *Id.* Further, the "potential loss of consumer goodwill qualifies as irreparable harm." *Id.*; *see also Med. Shoppe Int'l, Inc. v. S.B.S. Pill Dr., Inc.*, 336 F.3d 801, 805 (8th Cir. 2003) (loss of reputation and goodwill constitute irreparable injury).

Chlorpyrifos is a critical tool for which "there is no equal replacement," and in some cases, no replacement at all. *See, e.g.*, Att. 2, Ex. T (Harris Decl.) at ¶8. For example, chlorpyrifos is "the only tool that is consistently effective in controlling destructive pests" for sugarbeets. Att. 2, Ex. F (Geselius Decl.) at ¶12; *see also* Att. 2, Ex. A (Weber Decl.) at ¶8; Att. 2, Ex. B (Baldwin Decl.) at ¶10. As a result, loss of chlorpyrifos will have "a devastating impact," including up to

$400,000 in annual losses to just one family farm. Att. 2, Ex. B (Baldwin Decl.) at ¶¶11, 14. As another grower explained, due to the lack of alternatives, "our only plan is to hope that there is not a significant pest problem." Att. 2, Ex. H (Haugrud Decl.) at ¶9. These impacts are industry-wide, impacting over 10,000 family farmers. For example, without the ability to use chlorpyrifos, the three farming cooperative Petitioners estimate unrecoverable losses for their sugarbeet grower members approaching $82 million per year. *See* Att. 2, Ex. G (Hastings Decl.) at ¶¶20-21; Att. 2, Ex. F (Geselius Decl.) at ¶22; Att. 2, Ex. I (Metzger Decl.) at ¶18. The Final Rule threatens the viability of these businesses. Att. 2, Ex. G (Hastings Decl.) at ¶27.

Similar issues exist with other crops at issue here. For example, a peach grower represented by Petitioners has been unable, after six years, to find an effective alternative to fight the lessor peach tree borer. Att. 2, Ex. J (Crittenden Decl.) at ¶14. Chlorpyrifos is also the only effective insecticide to protect against trunk borers in cherry trees. Att. 2, Ex. T (Harris Decl.) at ¶10; *see also* Att. 2, Ex. J (Crittenden Decl.) at ¶15. When a tree is lost to trunk borers, it can take up to ten

years to get a replacement tree into production. Att. 2, Ex. T (Harris Decl.) at ¶12.

Even where alternatives exist, losing chlorpyrifos causes significant problems because of pesticide resistance. *See, e.g.*, Att. 2, Ex. K (Scott Decl.) at ¶¶9–11; Att. 2, Ex. Q (Schmitz Decl.) at ¶¶11–16; Att. 2, Ex. R (Johnson Decl.) at ¶¶9–16. "If growers have fewer tools to rotate and mix as a result of losing chlorpyrifos, the effectiveness of the remaining tools will erode more quickly as pest populations develop resistance." Att. 2, Ex. Q (Schmitz Decl.) at ¶14; Att. 2, Ex. J (Crittenden Decl.) at ¶12 (pesticide resistance is "a serious problem"). For example, alternatives for controlling soybean pests are limited. Loss of chlorpyrifos "would result in a rapid buildup of insecticide resistance to the other remaining options." Att. 2, Ex. Q (Schmitz Decl.) at ¶¶11–16. This will have "devastating economic impacts" for soybean farms, Att. 2, Ex. L (Goblish Decl.) at ¶13, including an estimated $1.26 million in annual cost increases, Att. 2, Ex. K (Scott Decl.) at ¶13, due to the loss of chlorpyrifos.

A partial stay is needed now because these losses will occur before litigation concludes. As one grower explained, "pest infestation will be

worse on my farm in 2023 if chlorpyrifos cannot be used during the spring of 2022." Att. 2, Ex. B (Baldwin Decl.) at ¶12. These losses are unrecoverable should the Final Rule be overturned. *See Iowa Utils. Bd.*, 109 F.3d at 426. Also, these growers are likely to suffer loss of customer trust because "EPA also attacked the safety of prior uses of chlorpyrifos in the eyes of the public." Att. 2, Ex. A (Weber Decl.) at ¶19; *see also* Att. 2, Ex. C (Bladow Decl.) at ¶22; Att. 2, Ex. I (Metzger Decl.) at ¶20. Such reputational harm is irreparable. *See Iowa Utils. Bd.*, 109 F.3d at 426.

Gharda will also suffer irreparable harm from revocation of tolerances, effectively causing the loss of its EPA registration for chlorpyrifos, in which it has a legally protectable property interest. *See Reckitt Benckiser Inc. v. EPA,* 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used."); *see also Blackman v. District of Columbia*, 277 F. Supp. 2d 71, 79 (D.D.C. 2003) (due process violations constitute irreparable injury). Revocation of all tolerances will also cause Gharda devastating economic and reputational harm from lost sales, lost investment in

significant quantities of existing inventory it is unable to exhaust, and customer and public ill-will. Seethapathi Decl. ¶¶46–51.

III. The Public Interest and Balance of the Equities Support a Partial Stay.

The public interest and the balance of the equities support Petitioners' request for a stay. The partial stay requested will provide critical relief to the family farms that will be significantly harmed by the Final Rule. *Supra* at 21-25. Further, the agricultural commodities grown by the farmers represented here contribute significantly to the U.S. economy as a whole and to local communities in particular. *See, e.g.*, Att. 2, Ex. F (Geselius Decl.) at ¶7 (sugarbeet farming has a $4.9 billion impact in Minnesota and North Dakota). Thus, the losses suffered by Petitioners and the farmers represented will be magnified and spread to connected parts of the farming economy and beyond. *Id*.

Public health and public interest considerations do not outweigh the need for a partial stay. As EPA's Denial confirms, EPA's Designated Safe Uses present no concerns for food safety or public health. *Supra* at 18. The weighing of the public interest supports a stay based on the substantial, irreparable economic harm to growers, to Gharda, and to the public absent the stay requested herein.

CONCLUSION

This Court should stay EPA's decision revoking the tolerances for EPA's Designated Safe Uses, pending judicial review of that decision. This Court should also stay the tolerance expiration date for all other crop uses, until the Agency provides an appropriate existing stocks order for those uses.

March 3, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Petitioners' Renewed Motion for Partial Stay Pending Review complies with the type-volume limitation of Federal Rule of Appellate Procedure because it contains 5,199 words. This Motion complies with the typeface and the type style requirements of Federal Rule of Appellate Procedure 27 because this brief has been prepared in a proportionally spaced typeface using Word 14-point Century Schoolbook typeface.

Dated: March 3, 2022

s/ Nash E. Long
Nash E. Long

CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2022, I electronically filed the foregoing Petitioners' Renewed Motion for Partial Stay Pending Review with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system, which will send a notice of electronic filing to all parties on the electronic filing receipt.

I also hereby certify that I have, on this day, served by overnight mail a copy of the foregoing document upon the parties below.

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Dated: March 3, 2022

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EXHIBIT 3

Order Exercising Jurisdiction and Denying Motion for a Partial Stay Pending Review, *RRVSGA*, Nos. 22-1422 (8th Cir. Mar. 15, 2022), Entry ID 5136844

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No: 22-1422

Red River Valley Sugarbeet Growers Association, et al.

Petitioners

v.

Michael S. Regan, Administrator, U.S. Environmental Protection Agency and U.S. Environmental Protection Agency

Respondents

League of United Latin American Citizens, et al.

Amici Curiae

Petition for Review of an Order of the Environmental Protection Administration
(EPA-HQ-OPP-2021-0523)

ORDER

The court exercises jurisdiction in this matter, *see* 21 U.S.C. § 346a(h)(1); 40 C.F.R. § 178.65, and the motion for a partial stay pending review is denied.

March 15, 2022

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

EXHIBIT 4

Respondents' Opposition to Petitioners' Motion for Stay Pending Review, *RRVSGA*, No. 22-1422 (8th Cir. Mar. 11, 2022), Entry ID 5135786

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, ET AL. Petitioners, v. MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, ET AL., Respondents.	No. 22-1422

Respondents' Opposition to Petitioners' Motion for Stay Pending Review

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INTRODUCTION

Petitioners' motion to stay EPA's decision under the Federal Food, Drug, and Cosmetic Act ("FFDCA") revoking unsafe chlorpyrifos tolerances should be denied.

First, there is no likelihood of success on the merits. Petitioners' argument that EPA erred in revoking all chlorpyrifos tolerances when it purportedly found 11 uses safe (in certain geographic areas and under certain conditions) mischaracterizes the statute and the record. As required under the FFDCA, EPA considered "*all* anticipated dietary exposures and other exposures" based on existing registered (*i.e.,* legally permitted) uses when determining that existing chlorpyrifos tolerances were unsafe. Even if it were lawful to consider only a subset of current uses, EPA never concluded that the 11 uses *are* safe. Petitioners rely on a *proposed* determination prepared for a separate regulatory proceeding under a different statute, in which EPA considered whether a proposed scenario of reduced uses of chlorpyrifos—a scenario that did not presently exist—would lead to exposures that EPA could find safe. In any event, despite captioning their motion as one for a "partial stay," Petitioners ask this Court to stay EPA's revocation of tolerances for *all* chlorpyrifos uses, not just the 11 so-called "designated safe uses."

Second, Petitioners' harm allegations do not satisfy the high bar of irreparable harm required for a stay. While Petitioners allege economic losses from the inability to sell and use chlorpyrifos, such losses alone are insufficient to warrant a stay.

Third, the balance of equities weighs against staying EPA's revocation of chlorpyrifos tolerances. Congress directed EPA to consider only safety in assessing tolerances. Based on an extensive assessment of the risks from chlorpyrifos exposures, EPA found the existing tolerances were not safe. Accordingly, the FFDCA's strict safety standard required that EPA revoke them. EPA's decision conforms to the Ninth Circuit's mandate that EPA act within 60 days to grant a revocation petition pending since 2007. Petitioners now ask this Court to put chlorpyrifos tolerances back into place without a safety finding, in direct contravention of Congress's command. Petitioners' motion to stay the revocation contravenes the FFDCA and the public interest and stands in tension with the relief granted by a sister circuit. The Court should deny Petitioners' motion.

BACKGROUND

A. Statutory and regulatory background

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

Under the FFDCA, EPA establishes "tolerances," which are maximum levels of pesticide residue allowed in or on food. 21 U.S.C. § 346a. EPA may establish or leave in place a tolerance for a pesticide *only* if it determines that the tolerance is "safe," and must revoke or modify an existing tolerance if EPA determines that the tolerance is not "safe." *Id.* § 346a(b)(2)(A)(i). Under the FFDCA, "safe" means a "reasonable certainty that no harm will result from aggregate exposure" to pesticide chemical residues, including "all anticipated dietary exposures and all other exposures for which there is reliable information" (for example, drinking water). *Id.* § 346a(b)(2)(A)(ii). Additionally, EPA must assess the risk of the pesticide residues to infants and children utilizing a presumptive tenfold margin of safety for threshold effects unless a lower margin will be safe. 21 U.S.C. § 346a(b)(2)(C).

2. The Federal Insecticide, Fungicide, and Rodenticide Act

EPA also regulates pesticides under FIFRA. FIFRA requires EPA approval of pesticides prior to distribution or sale and establishes a registration regime for regulating their use. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). In contrast to the FFDCA's risk-only safety standard, FIFRA's "unreasonable adverse effects" standard means "any unreasonable risk to man or the environment," taking into consideration both risks and benefits of the pesticide. *Id.* § 136(bb).

FIFRA directs EPA to re-evaluate the registrations of all currently registered pesticides every 15 years. *Id.* § 136a(g)(1)(A). During "registration review," EPA must ensure that each pesticide registration continues to satisfy FIFRA's "unreasonable adverse effects" standard, taking into account new scientific information and changes to risk-assessment procedures, methods, and data requirements. 40 C.F.R. §§ 155.40(a)(1), 155.53(a); 7 U.S.C. § 136a(g). EPA may propose measures to mitigate identified risks, such as label or registration changes. *See* 40 C.F.R. § 155.58(b).

Where EPA determines that a pesticide does not meet the requirements for registration, EPA can request that registrants submit requests to voluntarily cancel

their pesticides or certain uses under 7 U.S.C. § 136d(f), or initiate cancellation proceedings under § 136d(b).

B. Factual background

1. Prior Ninth Circuit litigation

In 2007, public interest groups petitioned EPA to revoke all chlorpyrifos tolerances. EPA failed to issue a formal response to the petition, and the U.S. Court of Appeals for the Ninth Circuit ordered EPA to respond to the petition by October 31, 2015. *In re Pesticide Action Network N. Am. v. EPA,* 798 F.3d 809, 815 (9th Cir. 2015). EPA published for comment a proposed rule revoking all chlorpyrifos tolerances. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (Nov. 6, 2015). The Ninth Circuit then ordered EPA to complete its final action on the petition by March 31, 2017. *In re Pesticide Action Network N. Am. v. EPA,* 840 F.3d 1014, 1015 (9th Cir. 2016). EPA denied the petition, departing from its proposal and leaving the tolerances in effect. 82 Fed. Reg. 16581 (Apr. 5, 2017). In response to another Ninth Circuit order, EPA issued a final order denying all objections. 84 Fed. Reg. 35555 (July 24, 2019); *League of United Latin Am. Citizens v. EPA*, 922 F.3d 443 (9th Cir. 2019) (en banc) (*"LULAC"*).

On April 29, 2021, the Ninth Circuit vacated EPA's denial of the original petition and objections and concluded that, based on the existing record, "the only reasonable conclusion the EPA could draw is that the present tolerances are not

safe within the meaning of the FFDCA." *LULAC v. Regan*, 996 F.3d 673, 700 (9th Cir. 2021) (*"LULAC II"*). The Ninth Circuit chided EPA for taking "nearly 14 years to publish a legally sufficient response to the 2007 Petition," which was an "egregious delay [that] exposed a generation of American children to unsafe levels of chlorpyrifos." *Id.* at 703. The Ninth Circuit expressly precluded EPA from additional fact finding, as "further delay would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself." *Id.* at 702; *see also id.* at 678 (denying petition based on ongoing registration review was a "total abdication of the EPA's statutory duty under the FFDCA").

The Ninth Circuit instructed EPA to publish a final response to the 2007 petition within 60 days after the issuance of its mandate, without notice and comment, "that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703.

2. The Proposed Interim Decision under Registration Review

On a separate regulatory track, in December 2020, prior to the *LULAC II* decision, EPA released the Proposed Registration Review Interim Decision for Chlorpyrifos ("PID") (Long Decl. Ex. B). The PID concluded that aggregate exposure (including exposures in food, drinking water, and residential settings) from all currently-registered uses of chlorpyrifos was unsafe. *Id.* at 19. To reduce

aggregate exposures to safe levels, EPA proposed that chlorpyrifos applications be limited to eleven "high-benefit" uses, and further restricted with respect to geographic areas and application rates. *Id.* at 40-41. EPA proposed cancelling all other existing uses under FIFRA. *Id.* at 40. Multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses. *See* Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 Fed. Reg. 11222, 11246 (Feb. 28, 2022) (the "Denial Order") (Long Decl. Ex. FF). Carrying out the modifications proposed in the PID would require use cancellations and label amendments. *Id.* at 11244. No registrants submitted voluntary cancellation requests or label amendments for their registrations. *Id.* at 11246. EPA has not yet issued a final interim decision for chlorpyrifos. *Id.* at 11233.

3. EPA's revocation of all chlorpyrifos tolerances

In response to *LULAC II*, on August 30, 2021, EPA published a Final Rule revoking all tolerances for chlorpyrifos. 86 Fed. Reg. 48315 (Long Decl. Ex. A). EPA set an expiration date of February 28, 2022 for the tolerances. *See id.* On February 28, 2022, EPA published the Denial Order in the Federal Register, responding to objections to the revocation. 87 Fed. Reg. 11222.

As EPA explained in the Final Rule, chlorpyrifos affects the nervous system by inhibiting acetylcholinesterase ("AChE"), an enzyme necessary for the proper

functioning of the nervous system. *Id.* at 11231. EPA's decision relied on the effect of AChE inhibition for assessing risks from chlorpyrifos and retention of the 10X safety factor to account for scientific uncertainties around the potential for adverse neurodevelopmental outcomes in infants and children. *Id.* at 11237. EPA considered aggregate exposures that would occur in food, drinking water, and residential settings due to currently registered uses. *Id.* at 11237-38. EPA's analysis of registered uses demonstrated that concentrations of chlorpyrifos and its drinking water metabolite in certain sources of drinking water would exceed the maximum safe levels for residues in drinking water, leading to unsafe aggregate exposures. *Id.* Because aggregate exposures to chlorpyrifos exceeded safe levels, EPA revoked all chlorpyrifos tolerances. *Id.* at 11238.

EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not submitted. Decl. of Timothy Kiely ¶ 26. Those proceedings will address existing stocks.[1] *Id.*

[1] Existing stocks are stocks of a registered pesticide product that were in the United States and packaged, labeled, and released for shipment prior to the effective date of the product's cancellation. *See* Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362 (June 26, 1991).

ARGUMENT

To obtain a stay, movants must establish their likelihood of success on the merits, the likelihood of irreparable harm without a stay, that the balance of equities tips in their favor, and that a stay is in the public interest. *Nken v. Holder*, 556 U.S. 418, 426, 434 (2009). Petitioners fail to meet this standard.

I. Petitioners are not likely to succeed on the merits.

To begin with, the Court still does not have before it a proper petition. *See* Resps.' Mot. to Dismiss. Parties can only seek judicial review of a final order under § 346(g)(2)(C) and regulations subject to that order. Because EPA's Denial Order issues on March 14, 2022, 40 C.F.R. § 23.10, the Court lacks jurisdiction unless a proper petition is filed on or after that date. Even if the Court had jurisdiction, a stay is not warranted.

A. EPA cannot conclude that chlorpyrifos is safe.

EPA's *sole* statutory criteria for establishing or revoking a tolerance is whether the residue is "safe." 21 U.S.C. § 346a(b)(2)(A)(i); *see also LULAC II*, 996 F.3d at 696 (amendments to the FFDCA "explicitly prohibit the EPA from balancing safety against other considerations, including economic or policy concerns."). After an exhaustive assessment of a multitude of studies, EPA determined that it cannot conclude that chlorpyrifos is safe, particularly for infants and children, because aggregate exposures to chlorpyrifos exceeded safe levels.

Exposure to chlorpyrifos can lead to neurotoxicity, *i.e.,* damage to the brain and other parts of the nervous system. 87 Fed. Reg. at 11231. A large body of evidence shows an association between chlorpyrifos exposure and adverse neurodevelopmental outcomes in infants and children. *Id.* Laboratory animal studies, epidemiology data, and mechanistic studies all show evidence of a negative effect on the developing brain, including cognitive, anxiety and emotion, social interactions, and neuromotor functions. *Id.*

Petitioners attempt to undercut these findings by importing FIFRA's "unreasonable adverse effects" standard—which considers economic and social costs and benefits—into the FFDCA's safety standard. *See* Mot. at 20-21 (arguing that EPA's safety decision should have considered the "interests" of growers and Gharda in the continued use of chlorpyrifos). This fails because Congress treated pesticides used on food differently. The FFDCA imposes "an uncompromisable limitation: the pesticide must be determined to be safe for human beings." *LULAC II*, 996 F.3d at 678. Petitioners cannot rewrite statutes to include considerations Congress precluded.

B. EPA reasonably assessed "aggregate" exposure from "all anticipated" exposures under the FFDCA.

Petitioners argue that EPA erred by evaluating all registered uses of chlorpyrifos and that, instead, EPA was required to devise a subset of registrations that could be safe under the FFDCA, based on the subset of 11 geographically and

rate-restricted uses identified in a *proposed* determination (the PID) prepared for EPA's registration review under FIFRA. Mot. at 15-16. Petitioners are wrong.

First, EPA was not required to make a "tolerance-by-tolerance examination." Petitioners' contrary contention (at 15-16) ignores the FFDCA's direction to EPA to assess "*aggregate* exposure to the pesticide chemical residue" based on "*all* anticipated dietary exposures and *all* other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added); *see also LULAC II*, 996 F.3d at 703. Evaluating exposures from the uses associated with only one tolerance at a time would disregard exposures from other uses, contrary to the FFDCA.

Second, the FFDCA requires EPA to assess *all anticipated exposures* in making its safety determination. 21 U.S.C. § 346a(a)(2)(A)(ii). It is reasonable for EPA to consider all registered uses when determining which exposures are "anticipated." *See* General Principles For Performing Aggregate Exposure and Risk Assessments (Nov. 28, 2001) (Ex. A) at 45 ("The starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide."). There are currently 25 chlorpyrifos registrants and 76 total chlorpyrifos registrations. Kiely Decl. ¶ 5. *None* of the registrants, including Gharda, have submitted a request to voluntarily cancel their registrations. *Id.* ¶¶ 22-24; 87 Fed.

Reg. at 11245-46, 11267. Thus, at the time of the Final Rule, EPA could not reasonably conclude that there would be no anticipated exposures associated with those registered products. *Id.* at 11246.

Third, Petitioners' argument that EPA was obligated to conduct a tolerance-by-tolerance analysis imports FIFRA's standard for registering pesticides into the FFDCA. FIFRA and the FFDCA are different statutes with separate requirements. Registration review under FIFRA assesses all registrations of a particular pesticide. 7 U.S.C. § 136a(g). As it did in the PID, EPA may propose label modifications and cancellations in order to meet FIFRA's unreasonable adverse effects standard. 40 C.F.R. § 155.56. When registrants comply with EPA's proposed mitigation by voluntarily cancelling registrations or adopting use restrictions on product labels, then EPA's finding that a pesticide meets the FIFRA registration standard is based on the uses that remain and no longer includes the uses that are cancelled or amended. But, in assessing the safety of a tolerance under the FFDCA, EPA must consider whether anticipated exposures from proposed and registered uses are safe, not whether there are changes that could be made to registrations under FIFRA to make the uses safe.

Fourth, Petitioners' claim that EPA's prior practice has been to conduct a tolerance-by-tolerance analysis is wrong. Mot. at 16 (citing Seethapathi Decl. Ex. 4, Reiss Decl. ¶ 17). Petitioners base this assertion on the Agency's approach to

registering a new product under FIFRA—not the separate and distinct process for making a safety determination under the FFDCA. *See* Reiss Decl. ¶ 17 ("[T]he Agency routinely conducts assessments that presume what the use pattern will be upon a *registration decision*. This is fundamental to the Agency *registration process*.") (emphasis added). EPA has previously explained its position that the FFDCA "does not compel EPA to determine the appropriate subset [of tolerances] that would meet the safety standard." Carbofuran; Order Denying FMC's Objections and Requests for Hearing, 74 Fed. Reg. 59608, 59675 (Nov. 18, 2009). Indeed, EPA's "general policy" when more than one tolerance is unsafe is *not* to independently select the subset of uses that meets the safety standard. *Id.*

Fifth, the PID was a *proposed* determination as part of a registration review—a separate, ongoing process under FIFRA—and not, as Petitioners claim (at 1), a final "finding that EPA's Designated Safe Uses are safe for everyone." *See supra* at 7; 87 Fed. Reg. at 11246. Some commenters, including cranberry and banana growers, argued that their crops should be included among the 11 considered uses; others, including advocacy and environmental groups, argued that a safety determination supporting even those limited 11 uses would contravene the available science. *Id.* at 11246, 11249. EPA has not yet fully considered these comments and will not issue a final interim decision until later this year. Kiely Decl. ¶ 9; *see also LULAC II*, 996 F.3d at 678. Contrary to Petitioners' claim (at 2,

11, 17), EPA did not make a final safety finding in the Final Rule or Denial Order for the subset of 11 uses. *See* 86 Fed. Reg. at 48333; 87 Fed. Reg. at 11241 ("[T]he Agency could support a safety determination for the very limited and specific subset of uses identified in the [PID]. The problem is that at the time of the final rule, the Agency did not have a basis for assuming that uses would be limited.").

Sixth, EPA could not have determined chlorpyrifos tolerances were safe based on the subset of 11 uses within the Ninth Circuit's 60-day deadline without, at a minimum, voluntary cancellation requests by all registrants of the other uses. 87 Fed. Reg. at 11246. The FFDCA does not provide an independent legal basis for EPA to selectively consider exposures associated with existing tolerances to ensure that "aggregate exposures" will be safe. Nor do Petitioners explain how the Court is to make a final safety finding for the 11 uses—which it must do to leave tolerances in place—when EPA has not done so. EPA did enter into good-faith negotiations with each of the technical registrants,[2] including Gharda, but none ever submitted a voluntary cancellation request under FIFRA to cancel other uses of chlorpyrifos. 87 Fed. Reg. at 11247-48. Nor did any registrants submit

[2] "Technical" or "manufacturing use products" are intended and labeled for formulation and repackaging into other pesticide products. *See* 40 C.F.R. § 158.300.

proposed revised labels that reflect cancelled uses, restrict remaining uses to certain geographic areas, and reduce application rates. *Id.* at 11246.

Instead, Gharda repeatedly sought unreasonable cancellation terms that could not be reconciled with EPA's obligations under the FFDCA. In its first post-*LULAC II* letter, Gharda stated that it was "willing to negotiate and execute an agreement with EPA" containing at least nine separate terms, including allowing continued uses on several other crops; phasing out the production, sale, and distribution for chlorpyrifos products for certain uses through 2026; and obtaining existing stock orders for additional time for those phased-out uses. Seethapathi Decl. Ex. 3, Ex. B at 1-2. In its second post-*LULAC II* letter, Gharda "commit[ted] to voluntarily cancel all currently approved agricultural uses" besides the subset of 11 uses, subject to nine other conditions, including allowing use of chlorpyrifos on cotton in Texas (which was not proposed in the PID) and the import of all finished technical product in the United States and overseas to be processed and sold for all currently registered uses. *Id.*, Ex. C at 1-2. In its final letter, dated July 6, 2021, Gharda proposed allowing the formulation and distribution for all current uses through June 2022 and the use of existing stocks through June 2023, instead of EPA's proposals of February and August 2022. *Id.,* Ex. H at 2; Kiely Decl. ¶ 18. EPA had concerns about, and did not agree to, those proposed terms because it could not make a safety finding for chlorpyrifos. Kiely Decl. ¶¶ 16-18. Without

voluntary cancellation requests in-hand from *any* registrants and with the Ninth Circuit's 60-day deadline approaching, EPA reasonably made a safety decision based upon an assessment of the registrations that actually existed. 87 Fed. Reg. at 11248. Petitioners' suggestion (at 16) that EPA should have simply "adjusted" all chlorpyrifos registrations outside the subset of 11 uses ignores that involuntary cancellation proceedings can last up to two years. Kiely Decl. ¶ 26.

Finally, Gharda's suggestion that EPA did not permit it to meaningfully participate in the revocation process rings hollow. Since the petition to revoke chlorpyrifos tolerances was filed nearly 15 years ago, EPA has solicited comments on revocation multiple times. After years of administrative process in response to the 2007 petition, in which registrants participated, and in light of the scientific record EPA developed indicating chlorpyrifos is unsafe at current exposures, the Ninth Circuit said enough is enough and directed EPA to modify or revoke the chlorpyrifos tolerances within 60 days and without notice and comment. *LULAC II*, 996 F.3d at 702. No additional notice of its decision to revoke tolerances was required. *See* 21 U.S.C. § 346a(d)(4)(A)(i) (authorizing EPA to issue a "final regulation" without notice and comment in response to a petition to revoke). Gharda is not without a remedy. Gharda and the other registrants may at any time request voluntary cancellation or modification of their registrations and petition

EPA to establish new tolerances. Instead, Gharda is unjustifiably pursuing a stay of the revocation of tolerances for *all* uses.

C. The FFDCA does not require EPA to cancel uses before revoking tolerances.

Although the bulk of Petitioners' merits arguments focus on the subset of 11 uses identified in the PID, they ask the Court to stay the revocation of *all* tolerances until EPA issues an "appropriate" existing stocks order. Mot. at 6, 14. Petitioners fail, however, to explain how the Court is to conclude, as a scientific matter, that *all* uses are safe under the FFDCA. Instead, Petitioners point to the FFDCA's direction that "the Administrator shall coordinate such action with any related necessary action under [FIFRA]." Mot. at 15-16 (quoting 21 U.S.C. § 346a(*l*)(1)). But Petitioners ignore that Congress directed EPA to coordinate the revocations of tolerances with FIFRA "[t]o the extent practicable." 21 U.S.C. § 346a(*l*)(1). Thus, contrary to Petitioners' contention (at 21), the FFDCA does not require EPA to cancel registrations or address existing stocks before revoking tolerances. Indeed, while the Ninth Circuit instructed EPA to revoke or modify the tolerances within 60 days, it directed EPA to modify or cancel related FIFRA registrations for food use "in a timely fashion." *LULAC II*, 996 F.3d at 704.

EPA has asked all chlorpyrifos registrants to voluntarily cancel their registered food uses and intends to commence involuntary cancellation proceedings for all registrations for which voluntary cancellation requests are not

submitted. Kiely Decl. ¶ 26. Those proceedings will address existing stocks. *Id.* Petitioners apparently assume that they are entitled to lengthy existing stocks periods, but FIFRA permits the continued sale or use of existing stocks periods only if they are "not inconsistent with the purposes of this [Act]," 7 U.S.C. § 136d(a)(1), which specify no "unreasonable risk to man." *See supra* p. 3. Given the potential impacts to infants and children, a lengthy existing stocks period may not be consistent with FIFRA.

In sum, Petitioners have not demonstrated likelihood of success on the merits.

II. Petitioners have not demonstrated irreparable harm.

A party seeking a stay must demonstrate that the irreparable harm claimed "is certain and great and of such imminence that there is a clear and present need for equitable relief" to prevent irreparable harm. *Iowa Utils. Bd. v. FCC,* 109 F.3d 418, 425 (8th Cir. 1996). Monetary loss alone is insufficient, unless the loss threatens the very existence of the movant's business. *Packard Elevator v. ICC*, 782 F.2d 112, 115 (8th Cir. 1986) ("[E]conomic loss does not, in and of itself, constitute irreparable harm"); *see also Wis. Gas. Co. v. Fed. Energy Regul. Comm'n*, 758 F.2d 669 (D.C. Cir. 1985) (same). Petitioners must "substantiate the claim that irreparable injury is 'likely' to occur." *Packard Elevator*, 782 F.2d at 115. Petitioners have failed to demonstrate irreparable harm.

A. Growers have not demonstrated irreparable harm.

While Petitioners argue that vast numbers of family farms will incur severe economic losses, they do not establish that those losses are certain or are of a magnitude sufficient to warrant a stay.

Petitioners estimate losses of around $82 million for sugarbeet grower members alone and that these losses threaten the viability of those businesses. Mot. at 23. That figure dramatically overstates possible costs to family farms. *See* Decl. of Neil Anderson ¶ 20. EPA's expert economists estimate that total likely losses across all sugarbeet growers—taking into account both additional costs of alternatives and reductions in yield—are around just *ten percent* of Petitioners' estimate. *Id.* (potential costs of $2.2 to $31.5 million, with likely costs of $8.6 million); EPA Revised Benefits of Agricultural Uses of Chlorpyrifos (Nov. 18, 2020) ("Benefits Document") (Long Decl. Ex. E) at 48-49. In support of their claim that the losses threaten the viability of their businesses, Petitioners point only to a paragraph in a declaration on behalf of the American Crystal Sugar Company ("ACSC") claiming that impacts to its sugarbeet processing business would threaten the Company's existence. Mot. at 23 (citing Pets.' Att. 2, Hastings Decl. ¶ 27). ACSC's claim is based on the incorrect assumption that 20% of Minnesota and 10% of North Dakota sugarbeet acreage could be "lost." *See* Benefits Document at 49 (explaining percentages as acres *severely affected* by sugarbeet

root maggot rather than a percentage of *all sugarbeet acreage* throughout each state). EPA did not conclude that acreage would be "lost"; rather, EPA's analysis modeled yield losses of 45% for such affected acres. *Id.*; Anderson Decl. ¶ 24. Even if that assertion were correct, ACSC fails to explain why those reductions in yield during the pendency of this litigation would put the Company out of business, particularly when it has withstood similar variations in past years. Anderson Decl. ¶ 26.

Total estimated likely losses from reduced yield or increased costs of alternatives across the entire subset of 11 uses is around $53 million—or *just under 0.1%* of those growers' expected revenue. *Id.* ¶¶ 15-16. In addition, an EPA analysis of the impacts of revoking the tolerance found that, on the vast majority of farms, including small farms, losses are likely to be less than one percent of gross annual revenue. *Id.* ¶ 17. EPA estimated that only around 1,900 small farms, or 0.13% of all small farms growing crops, will experience losses greater than 3% gross revenue per-acre. *Id.* Even that number likely is an overestimate because growers produce multiple crops, including some that are not susceptible to pests controlled by chlorpyrifos. *Id.* ¶ 19; *see, e.g.,* Pet. Att. 2, Ex. H at ¶ 5 (sugarbeets are 22.5% of total acreage). And, if growers experience significant yield losses due to inadequate pest control, Petitioners have failed to allege that they will not be compensated by federal crop insurance for the majority of those losses.

Petitioners' alleged losses therefore do not rise to the level of harm justifying a stay.

Further, growers typically do not experience large pest pressures every year, or on every acre of their farm. For example, borers are not currently a major pest for cherries. Anderson Decl. ¶ 31. And, even in heavily infested peach orchards in the southeastern United States, only about 20% of trees are affected by borers. *Id.* ¶ 30; Benefits Document at 24. Thus, even though adequate alternatives are not available for use on peaches and cherries, allegations of tremendous harm to those growers are speculative.

Petitioners point to a lack of alternatives to chlorpyrifos, but this too falls short. In most cases, there are suitable alternatives to chlorpyrifos. *See* Anderson Decl. ¶ 27. In any event, these anticipated regulatory compliance costs are not the type of harm that courts recognize as warranting a stay—otherwise irreparable injury would essentially be read out of the standard in regulatory cases. *See, e.g., Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980) ("[I]njury resulting from attempted compliance with government regulation ordinarily is not irreparable harm.").

B. Gharda has not demonstrated irreparable harm.

Because Gharda does not claim that EPA's revocation of chlorpyrifos tolerances threatens the existence of its business, it has not shown irreparable

harm. *See Packard Elevator*, 782 F.2d at 115. Moreover, Gharda has failed to minimize its alleged economic harms. Gharda took a calculated business risk by increasing production of chlorpyrifos products in 2021 when the future regulatory status of chlorpyrifos was uncertain. 87 Fed. Reg. at 11266. That its gamble did not pay off does not constitute the type of harm that can form the basis for a stay.

Gharda also claims that it will experience reputational harm due to the stigma attached to EPA's purportedly "unfounded" statement that the revocation of chlorpyrifos will help to ensure children and others "are protected from the potentially dangerous consequences of this pesticide." *See* Seethapathi Decl. ¶ 51. Gharda's claim lacks merit. Although EPA's scientific analysis of chlorpyrifos is complicated, its conclusion is not: "Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe." 87 Fed. Reg. at 11270; *see also supra* pp. 8-9 (discussing potential impacts of chlorpyrifos to infants and children). Moreover, Gharda cannot distinguish reputational harm from the revocation versus harm from the Ninth Circuit's conclusion that existing chlorpyrifos exposures were unsafe for infants and children. *See CTS Corp. v. EPA,* 759 F.3d 52, 58 (D.C. Cir. 2014).

For these reasons, Petitioners have not shown irreparable harm absent a stay.

III. A stay is not in the public interest.

The public interest and balance of harms also weigh strongly in favor of denying Petitioners' stay request. *See Nken*, 556 U.S. at 435 (stay factors "merge when the Government is the opposing party"). Congress determined that the public interest here is safety and instructed EPA to revoke tolerances unless it concludes that current uses are safe. *See* H.R. Rep. No. 104-669(II) (July 23, 1996) (Ex. B) at 40 (replacing FFDCA requirement to consider "the necessity for production of an adequate, wholesome, and economical food supply" and "the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture" with a pure safety standard). Petitioners now ask this Court to do what Congress forbade: leave all tolerances in place even though the expert agency cannot conclude that they are safe. What is more, excusing Petitioners from complying with the Final Rule pending judicial review could result in harm to those exposed to chlorpyrifos through its continued use on food crops. That exposure through food is not the sole source of exposure does not diminish these harms: the FFDCA seeks to address their collective contribution, which cannot be addressed without regulating pesticide uses on food.

Granting Petitioners' stay request would also undermine judicial process and comity among sister circuits. Specifically, a stay would stand in considerable

tension with the Ninth Circuit's order to modify tolerances only if EPA finds they are safe.

CONCLUSION

For the foregoing reasons, Petitioners' motion should be denied.

Respectfully submitted,

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March 11, 2022
DJ #1-22109

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 5,194 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ *Laura Glickman*
LAURA GLICKMAN
Counsel for Respondents

EXHIBIT 5

Petition for Review, *RRVSGA*, No. 22-1422 (8th Cir. Feb. 28, 2022), Entry ID 5131400

In the United States Court of Appeals

FOR THE EIGHTH CIRCUIT

No. 22-1422

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITION FOR REVIEW

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and 8th Cir. R. 26.1.A,

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International Inc.** states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

Summary of Grounds for Petition

Petitioners Red River Valley Sugarbeet Growers Association, US Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of

Wheat Growers, Cherry Marketing Institute, Florida Fruit and Vegetable Association, and Georgia Fruit and Vegetable Growers Association, National Cotton Council of America and Gharda Chemicals International, Inc. hereby petition the United States Court of Appeals for the Eighth Circuit for review of (1) the U.S. Environmental Protection Agency's ("EPA") final rule entitled "Chlorpyrifos; Tolerance Revocations," issued on August 30, 2021, published at 86 Fed. Reg. 48,315 (the "Final Rule") (Att. 1, Long Decl. Ex. A); (2) EPA's constructive denial of Petitioners' requests for an administrative stay of the Final Rule; and (3) EPA's order denying Petitioners' objections to the Final Rule and confirming denial of Petitioners' requests for an administrative stay of the Final Rule, entitled "Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule" issued on February 22, 2022 and published at 87 Fed. Reg. 11222 ("EPA's Denial") (Att. 1, Long Decl. Ex. FF). As a result of EPA's Denial, the Final Rule takes effect on today's date, February 28, 2022.

Petitioners previously filed a petition for review of EPA's Final Rule in this Court on February 9, 2022, Case No. 22-1294. Petitioners

described the irreparable harm they have and will continue to suffer as a result of the Final Rule and sought a partial stay of that rule to allow continued use of chlorpyrifos for certain limited uses that EPA found to be safe ("EPA's Designated Safe Uses"). Petitioners also sought a partial stay of the tolerance expiration date for all other crop uses of chlorpyrifos until EPA issues an appropriate existing stocks order for those uses. Petitioners' motion to stay remains pending.

Now that EPA has released an order ruling on Petitioners' objections and requests for an administrative stay, Petitioners file this second petition to confirm that they are challenging (1) the Final Rule, (2) EPA's constructive denial of their requests for an administrative stay of the Final Rule, and (3) EPA's decisions in EPA's Denial overruling their objections to the Final Rule and confirming denial of Petitioners' requests to stay the Final Rule. EPA's constructive denial of Petitioners' requests for administrative stay and rejection of Petitioners' objections and requests to stay the Final Rule are arbitrary and capricious and contrary to law, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et*

seq., for the same reasons set forth in Petitioners' petition and partial motion to stay in Case No. 22-1294.

This Court has jurisdiction to consider this petition under 21 U.S.C. § 346a(h)(1), and has authority to stay implementation of the Final Rule under 5 U.S.C. § 705.[1] A stay of the Final Rule is necessary to prevent irreparable harm, as set forth in the declarations submitted in support of this petition. *See* Att. 2, Exs. A-W and Declaration of Ram Seethapathi on Behalf of Petitioner Gharda Chemicals International, Inc.

Given the significant overlap of the issues raised by both petitions, Petitioners will soon be filing a motion to have this matter consolidated with Case No. 22-1294.

[1] In a notice filed pursuant to FRAP 28(j) in Case No. 22-1294, EPA suggested that Petitioners would have to wait 14 days after publication of EPA's Denial in the Federal Register before Petitioners could challenge it. Respondents' Rule 28(j) Notice, Doc. 5130160 at 1. That assertion is contrary to, *inter alia*, the FFDCA judicial review provision in 21 U.S.C. § 346a(h)(1). EPA cannot delay judicial review of the Final Rule, which is now in effect.

February 28, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have, on this day, served by certified mail, return receipt requested, a copy of the foregoing document upon the following parties:

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Dated: February 28, 2022

s/ Nash E. Long
Nash E. Long

EXHIBIT 6

Petition for Review, *RRVSGA*, No. 22-1530 (8th Cir. Mar. 14, 2022), Entry ID 5136561

In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 22-1530

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION; U.S. BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION; SOUTHERN MINNESOTA BEET SUGAR COOPERATIVE; AMERICAN CRYSTAL SUGAR COMPANY; MINN-DAK FARMERS COOPERATIVE; AMERICAN FARM BUREAU FEDERATION; AMERICAN SOYBEAN ASSOCIATION; IOWA SOYBEAN ASSOCIATION; MINNESOTA SOYBEAN GROWERS ASSOCIATION; MISSOURI SOYBEAN ASSOCIATION; NEBRASKA SOYBEAN ASSOCIATION; SOUTH DAKOTA SOYBEAN ASSOCIATION; NORTH DAKOTA SOYBEAN GROWERS ASSOCIATION; NATIONAL ASSOCIATION OF WHEAT GROWERS; CHERRY MARKETING INSTITUTE; FLORIDA FRUIT AND VEGETABLE ASSOCIATION; GEORGIA FRUIT AND VEGETABLE GROWERS ASSOCIATION; NATIONAL COTTON COUNCIL OF AMERICA; AND GHARDA CHEMICALS INTERNATIONAL, INC.,

Petitioners,

v.

MICHAEL S. REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

On Petition for Review from the
U.S. Environmental Protection Agency

PETITION FOR REVIEW

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and 8th Cir. R. 26.1.A,

1. **Red River Valley Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

2. **U.S. Beet Sugar Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

3. **American Sugarbeet Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

4. **Southern Minnesota Beet Sugar Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

5. **American Crystal Sugar Company** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

6. **Minn-Dak Farmers Cooperative** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

7. **American Farm Bureau Federation** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

8. **American Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

9. **Iowa Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

10. **Minnesota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

11. **Missouri Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

12. **Nebraska Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

13. **South Dakota Soybean Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

14. **North Dakota Soybean Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

15. **National Association of Wheat Growers** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

16. **Cherry Marketing Institute** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

17. **Florida Fruit and Vegetable Association** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

18. **Georgia Fruit and Vegetable Growers Association** states that it is a not for profit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

19. **National Cotton Council of America** states that it is a not for profit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

20. **Gharda Chemicals International Inc.** states that it is a Delaware corporation, that it is a wholly owned subsidiary of its parent corporation, Gharda Chemicals Ltd., and that no other corporation holds 10% or more of the stock of Gharda Chemicals International, Inc.

Petitioners Red River Valley Sugarbeet Growers Association, US Beet Sugar Association, American Sugarbeet Growers Association, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, Minn-Dak Farmers Cooperative, American Farm Bureau Federation, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, North Dakota Soybean Growers Association, National Association of Wheat Growers, Cherry Marketing Institute, Florida Fruit and

Vegetable Association, and Georgia Fruit and Vegetable Growers Association, National Cotton Council of America and Gharda Chemicals International, Inc. are hereinafter referred to as "Petitioners."

Summary of Grounds for Petition

Petitioners continue to seek review of a final rule promulgated by EPA on August 30, 2021 and effective on February 28, 2022. "Chlorpyrifos; Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) ("Final Rule") (Att. 1). And because Petitioners are likely to succeed on the merits and the Final Rule has caused and will cause them irreparable harm, Petitioners continue to seek a partial stay of the Final Rule.

Petitioners first sought such relief in a petition (No. 22-1294) filed on February 9, 2022, Doc. ID 5126162 (the "First Petition") and a motion for partial stay filed on February 10, 2022, Doc. ID 5126280 (the "First Motion to Stay"). Petitioners carefully crafted their request for a stay to align with EPA's scientific findings and with EPA's legal obligations. For example, Petitioners sought a stay of the Final Rule consistent with EPA's December 2020 Proposed Interim Decision for Chlorpyrifos ("PID"), 22-1294 Doc. ID 5126162 at 31, in which EPA's

expert scientists concluded that eleven crop uses (alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugarbeet, strawberry, and wheat) in specifically designated regions are safe ("EPA's Designated Safe Uses"). As set forth in EPA's PID, EPA's Designated Safe Uses are as follows:

Agricultural Uses Proposed for Retention in Chlorpyrifos Labels with an FQPA Safety Fact of 10X		
No.	**Agricultural Commodity**	**States for Retention**
1	Alfalfa	AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WY
2	Apple	AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV
3	Asparagus	MI
4	Cherry (tart)	MI
5	Citrus	AL, FL, GA, NC, SC, TX
6	Cotton	AL, FL, GA, NC, SC, VA
7	Peach	AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV
8	Soybean	AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY
9	Strawberry	OR
10	Sugar beet	IA, ID, IL, MI, MN, ND, OR, WA, WI
11A 11B	Wheat (spring) Wheat (winter)	CO, KS, MO, MT, ND, SD, WY CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY

PID (22-1294 Doc. ID 5126162 at 70-71)

Petitioners' First Motion to Stay remains pending. To date, EPA has resisted review of the Final Rule through a series of procedural maneuvers. First, EPA contended that it had not made any final decisions that could be reviewed, only to reveal those final decisions one business day later by signing a 193-page order denying all of Petitioners' objections and requests. *See* Respondents' Motion to Dismiss, Doc. ID 5129068 at 6; Respondents' Rule 28(j) Notice, Doc. ID 5130160 at 1. Those final decisions were published in the Federal Register on February 28, 2022, the same day the Final Rule took effect. "Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule," 87 Fed. Reg. 11,222 (Feb. 28, 2022) ("EPA's Denial") (Att. 2).

On that same day, February 28, 2022, Petitioners filed a second petition for review incorporating all issues raised in the First Petition as well as a challenge to EPA's Denial. Petition No. 22-1422, Doc. ID 5131400 (the "Second Petition"). Petitioners also updated the First Motion to Stay in light of EPA's Denial, and filed a Renewed Motion for Partial Stay in Case No. 22-1422. Doc. ID 5132688 ("the Renewed

Motion to Stay"). Petitioners' Renewed Motion to Stay sought the same relief as the First Motion to Stay.

In the midst of this briefing, EPA has now advanced a new argument that, to Petitioners' knowledge, had never before been made: EPA contends that under 40 C.F.R. § 23.10, federal courts do not have jurisdiction to review a final rule, published and in effect, until 14 days had expired following the rule's publication in the Federal Register. Respondents' Reply on their Motion to Dismiss, Case No. 22-1294, Doc. ID 5133911 at 6.

That is not the law. 40 C.F.R. § 23.10 creates no jurisdictional bar to review of any of the issues raised by Petitioners in the pending petitions for review of: (1) the Final Rule published on Aug. 30, 2021; (2) the constructive denial of Petitioners' requests for administrative stay; and (3) the decisions announced in EPA's Denial on February 28, 2022. Congress determines the jurisdiction of the federal courts, not agencies. *Cf. Karcher v. May*, 484 U.S. 72, 77 (1987) ("The power of federal courts to hear and decide cases is defined by Article III of the Constitution and by the federal statutes enacted thereunder."). Section 408(h)(1) of the FFDCA provides for judicial review of "any order" on

objections to a final tolerance rule, like EPA's Denial, "within 60 days *after publication* of such order." 21 U.S.C. § 346a(h)(1) (emphasis added). EPA's Denial was published in the Federal Register on February 28, 2022, and as tolerance expiration took effect that same day, there can be no dispute that it is a final, reviewable order under the FFDCA.

EPA's attempt to shield EPA's Denial and the underlying Final Rule from this Court's review by invoking 40 C.F.R. § 23.10 is unavailing. The purpose of Section 23.10, as with similar EPA timing regulations, was to bring greater fairness to so-called "races to the courthouse," in which litigants relied on elaborate schemes to be the first to learn of and file a petition for review of a final rule in their preferred forum. *See* Judicial Review Under EPA-Administered Statutes; Races to the Courthouse, 50 Fed. Reg. 7268, 7268 (Feb. 21, 1985). This issue was largely eliminated with Congress's enactment of Pub. L. 100-236, which created the random selection process for deciding the forum to hear multiple petitions filed in different circuits. *See* 28 U.S.C. § 2112(a)(3); *see also* S. Rep.'t No. 100–263. The regulation has no application here, where (i) all interested parties are

plainly on notice of the Final Rule and EPA's Denial, (ii) Petitioners' petition for review of EPA's Final Rule has been pending for ***over a month*** in Case No. 22-1294 and (iii) Petitioners have and continue to suffer irreparable harm as a result of the Final Rule. There is simply no authority—and EPA cites none—for EPA's claim that EPA's regulation deprives the Court of jurisdiction conferred by Congress to redress a final agency order that is unquestionably already in effect and causing irreparable harm. This is yet another attempt by EPA to frustrate and delay resolution of the Petition.

Nevertheless, EPA has asserted that this Court lacks jurisdiction over the Second Petition because it was filed fewer than 14 days after publication of EPA's Denial in the Federal Register. Respondents' Reply in Support of their Mot. to Dismiss, No. 22-1294, Doc. ID 5133911 at 6. In order to remove any doubt about this Court's ability to proceed, Petitioners hereby file this third petition for review, incorporating the Second Petition and its attachments in their entirety. This third petition for review also incorporates and renews the Renewed Motion for Stay, Doc. ID 5132688.

Given the significant overlap of the three pending petitions, consolidation of the three petitions into one action is appropriate. Petitioners will soon present a request to consolidate the three pending petitions into one action, after determining whether that request can be made jointly with EPA.

The filing of this third petition and consolidation of the three petitions into one action moots all jurisdictional, claims-processing, exhaustion and procedural arguments EPA has raised in its attempt to avoid dealing with the merits of Petitioners' claims. Petitioners' claims, as set forth in each of its petitions and motions to stay, are based upon EPA's own science. Petitioners' claims raise a straight-forward question of statutory interpretation—a fact EPA cannot dispute:

> EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document [i.e., EPA's Designated Safe Uses]. …. [A]s a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time of the Final Rule. Ultimately, this issue comes down to whether EPA properly interpreted its obligation under the FFDCA in assessing aggregate exposure to chlorpyrifos, and that is ultimately a question of law and not one of fact.

EPA's Denial, 87 Fed. Reg. at 11241. Thus, the Court does not need to decide which uses of chlorpyrifos are safe. EPA has already identified the uses it considers safe, applying the relevant safety standards of the FFDCA and FQPA. EPA did so in specifying EPA's Designated Safe Uses in the PID published in 2020, in reaffirming the findings of the PID in the Final Rule released in 2021, and in confirming the validity of "its own scientific conclusions and findings" from the PID in EPA's Denial in 2022.

The Court should consolidate this petition with the two pending petitions, deny EPA's motion to dismiss the first petition as moot, and proceed to rule on the pending motion to stay, renewed by Doc. ID 5132688.

Statement of Issues for Review

Petitioners incorporate by reference the issues for review identified in their Second Petition. Namely, Petitioners hereby petition the United States Court of Appeals for the Eighth Circuit for review of (1) EPA's final rule entitled "Chlorpyrifos; Tolerance Revocations," issued on August 30, 2021, published at 86 Fed. Reg. 48,315 (the "Final

Rule") (Att. 1)[1]; (2) EPA's constructive denial of Petitioners' requests for an administrative stay of the Final Rule; and (3) EPA's order denying Petitioners' objections to the Final Rule and confirming denial of Petitioners' requests for an administrative stay of the Final Rule, entitled "Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule" issued on February 22, 2022 and published at 87 Fed. Reg. 11222 ("EPA's Denial") (Att. 2).[2] As a result of EPA's Denial, the Final Rule took effect on February 28, 2022.

Petitioners previously filed petitions for review of EPA's Final Rule in this Court on February 9, 2022, Case No. 22-1294 and on February 28, 2022, Case No. 22-1422. Petitioners described there the irreparable harm they have and will continue to suffer as a result of the Final Rule and sought a partial stay of that rule to allow continued use of chlorpyrifos for certain limited uses that EPA found to be safe ("EPA's Designated Safe Uses"). Petitioners also sought a partial stay

[1] Attachment 1 hereto is the same as Att. 1, Long Decl. Ex. A, Doc. ID 5131400 at 7, in Case No. 22-1422.

[2] Attachment 2 hereto is the same as Att. 1, Long Decl. Ex. FF, Doc. ID 5131400 at 706, in Case No. 22-1422.

of the tolerance expiration date for all other crop uses of chlorpyrifos until EPA issues an appropriate existing stocks order for those uses. Petitioners' motion to stay remains pending.

Now that 14 days have elapsed following publication of EPA's Denial in the Federal Register, Petitioners file this third petition incorporating by reference its Second Petition. Petitioners hereby renew their challenge of (1) the Final Rule, (2) EPA's constructive denial of their requests for an administrative stay of the Final Rule, and (3) EPA's decisions in EPA's Denial overruling their objections to the Final Rule and confirming denial of Petitioners' requests to stay the Final Rule. EPA's constructive denial of Petitioners' requests for administrative stay and rejection of Petitioners' objections and requests to stay the Final Rule are arbitrary and capricious and contrary to law, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.*, for the same reasons previously set forth by Petitioners. *See* Petition 22-1294, Doc. ID 5126162; Partial Motion to Stay in 22-1294, Doc. ID 5126280; Petition 22-1422, Doc. ID 5131400; Renewed Partial Motion to Stay in 22-1422, Doc. ID 5132688.

This Court has jurisdiction to consider this petition under 21 U.S.C. § 346a(h)(1), and has authority to stay implementation of the Final Rule under 5 U.S.C. § 705.[3] A stay of the Final Rule is necessary to prevent irreparable harm, as set forth in the declarations submitted in support of the Second Petition, which are incorporated herein by reference. *See* Petition 22-1422, Att. 2, Exs. A-W (Doc. ID 5131400) and Declaration of Ram Seethapathi on Behalf of Petitioner Gharda Chemicals International, Inc. (Doc. ID 5133345).

Given the significant overlap of the issues raised by both petitions, Petitioners will soon be filing a motion to have this matter consolidated with Case Nos. 22-1294 and 22-1422. Petitioners have a pending motion to consolidate Case Nos. 22-1294 and 22-1422, which EPA does not oppose. *See* Petitioners' Mot. to Consolidate, Doc. ID 5131564; EPA Response to Mot. to Consolidate, Doc. ID 5133354.

[3] EPA concedes that this Court has jurisdiction to review petitions concerning the Final Rule and/or EPA's Denial filed on or after today's date: March 14, 2022. Respondents' Reply on their Motion to Dismiss, Doc. ID 5133911 at 6.

Conclusion

With the filing of this petition, the Court can have no doubt about its jurisdiction to review the Final Rule and to rule on Petitioners' Renewed Motion to Stay. The Court should (1) deny as moot Respondents' Motion to Dismiss, Case No. 22-1294, Doc. ID 5129068, (2) consolidate all three petitions together for briefing and resolution by the Court, and (3) proceed to rule on Petitioners' Renewed Motion to Stay.

March 14, 2022

Respectfully submitted,

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Vegetable Association, and Georgia Fruit and Vegetable Growers Association, and National Cotton Council of America

CERTIFICATE OF SERVICE

I hereby certify that I have, on this day, served by certified mail, return receipt requested, a copy of the foregoing document upon the following parties:

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Dated: March 14, 2022

s/ Nash E. Long
Nash E. Long

EXHIBIT 7

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

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No: 22-1422

Red River Valley Sugarbeet Growers Association, et al.

Petitioners

v.

Michael S. Regan, Administrator, U.S. Environmental Protection Agency and U.S. Environmental Protection Agency

Respondents

League of United Latin American Citizens, et al.

Amici Curiae

No: 22-1530

Red River Valley Sugarbeet Growers Association, et al.

Petitioners

v.

Michael S. Regan, U.S. Environmental Protection Agency and U.S. Environmental Protection Agency

Respondents

Petition for Review of an Order of the Environmental Protection Administration
(EPA-HQ-OPP-2021-0523)
(EPA-HQ-OPP-2021-0523)

ORDER

The joint motion to consolidate Nos. 22-1422 and 22-1530 is granted. The parties' proposed briefing schedule is also granted. Petitioners' brief is due May 18, 2022; respondents'

brief is due July 22, 2022; and Petitioners' reply brief is due September 2, 2022. Extensions of this briefing schedule will not be granted absent extraordinary circumstances.

April 21, 2022

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans