Michael E. Gans *Clerk of Court* VOICE (314) 244-2400 FAX (314) 244-2780 www.ca8.uscourts.gov

February 10, 2022

Mr. Nash E. Long III HUNTON & WILLIAMS Suite 3500 101S. Tryon Street Charlotte, NC 28280 Mr. Donald C. McLean ARENT & FOX 1717 K Street, N.W. Washington, DC 20036-5342

RE: 22-1294 RRVSG Assoc., et al v. Michael Regan, et al

Dear Counsel:

We have received a petition for review of an order of the Environmental Protection Agency in the above case, together with payment in the amount of \$500 for the docket fee.

Counsel in the case must supply the clerk with an Appearance Form. Counsel may download or fill out an Appearance Form on the "Forms" page on our web site at www.ca8.uscourts.gov.

The petition has been filed and docketed. A copy of the petition is hereby served upon the respondent in accordance with Federal Rule of Appellate Procedure, 15(c).

Your attention is invited to the briefing schedule pertaining to administrative agency cases, a copy of which will be sent under separate Notice of Docket Activity. The clerk's office provides a number of practice aids and materials to assist you in preparing the record and briefs. You can download the materials from our website, the address of which is shown above. Counsel for both sides should familiarize themselves with the material and immediately confer regarding the briefing schedule and contents of the appendix.

On June 1, 2007, the Eighth Circuit implemented the appellate version of CM/ECF. Electronic filing is now mandatory for attorneys and voluntary for pro se litigants proceeding without an attorney. Information about electronic filing can be found at the court's web site www.ca8.uscourts.gov. In order to become an authorized Eighth Circuit filer, you must register with the PACER Service Center at https://www.pacer.gov/psco/cgi-bin/cmecf/ea-regform.pl. Questions about CM/ECF may be addressed to the Clerk's office.

Michael E. Gans Clerk of Court

CAH

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Enclosure(s)

cc: Ms. Sayler Anne Ault Fleming Ms. Kathleen Roth Heilman Mr. Todd Kim Mr. Matthew Z. Leopold Ms. Erica Nicole Peterson Mr. Brent A. Rosser Ms. Martha R. Steincamp

District Court/Agency Case Number(s): EPA-HQ-OPP-2021-0523

Caption For Case Number: 22-1294

Red River Valley Sugarbeet Growers Association; United States 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; Gharda Chemicals International, Inc.

Petitioners

v.

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

Respondents

Addresses For Case Participants: 22-1294

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FILED

FEB 0 9 2022

In the United States Court of Appeals For the Eighth Circuit No.

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.

PETITION FOR REVIEW OF EPA'S FAILURE TO GRANT AN ADMINISTRATIVE STAY OF FINAL RULE REVOKING ALL TOLERANCES FOR CHLORPYRIFOS AND FOR REVIEW OF THE FINAL RULE OR, ALTERNATIVELY, PETITION FOR A WRIT OF MANDAMUS

RECEIVED

FEB 0.9 CCP U.S. COURT OF APPEALS EIGHTH CIRCUIT NASH E. LONG BRENT A. ROSSER HUNTON ANDREWS KURTH LLP 101 S. Tryon Street, Suite 3500 Charlotte, NC 28280 (704) 378-4728 <u>nlong@huntonak.com</u> brosser@huntonak.com

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Attorneys for Petitioner Gharda Chemicals International, Inc.

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure Petitioners submit the following corporate disclosure statement:

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.

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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

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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.

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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.

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NATURE OF THE CASE

The insecticide chlorpyrifos is a major crop protection tool that growers throughout the Midwest and around the country have relied upon for decades. In an arbitrary and capricious final rule, the U.S. Environmental Protection Agency ("EPA" or the "Agency") has ordered what will effectively end the use of chlorpyrifos on food crops as of February 28, 2022. To date, and despite mounting irreparable harm to the petitioners in this matter and others in the agricultural community, EPA has failed to respond to requests for an administrative stay of and objections to the final rule. Petitioners seek (1) to stop EPA from implementing certain portions of the final rule, thereby allowing continued use of chlorpyrifos consistent with EPA's safety findings, until judicial review is completed and (2) judicial review of portions of the final rule that conflict with those safety findings.

SUMMARY OF GROUNDS FOR PETITION

On August 30, 2021, EPA issued a final rule revoking all tolerances for the pesticide chlorpyrifos. *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. Tolerances are maximum levels of pesticide residues allowed in or on food and are

regulated under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Food Quality Protection Act ("FQPA"). EPA issued the Final Rule in response to an April 29, 2021 order of the U.S. Court of Appeals for the Ninth Circuit in *League of United Latin American Citizens v. Regan*, 996 F.3d 673, 678 (9th Cir. 2021) ("*LULAC*"), instructing EPA "either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "or, if it was unable to make a safety finding, to revoke all chlorpyrifos tolerances."

Just months before the Ninth Circuit's ruling, EPA's expert scientists issued a December 2020 Proposed Interim Decision for Chlorpyrifos ("PID"), Long Decl. Ex. B, in which they 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"). The aggregate value of these crops to the U.S. economy is more than \$59 billion annually.¹ As set forth in EPA's PID, EPA's Designated Safe Uses are as follows:

¹ USDA, National Agricultural Statistics Service, <u>www.nass.usda.gov</u>.

Agricultural Uses Proposed for Retention in Chlorpyrifos					
Labels with an FQPA Safety Factor of 10X					
No.	Agricultural	States for Retention			
	Commodity				
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	Wheat (spring)	CO, KS, MO, MT, ND, SD, WY			
11B	Wheat (winter)	CO, IA, KS, MN, MO, MT, ND, NE, OK,			
		SD, TX, WY			

PID at 40–41 (Long Decl. Ex. B). Rather than modify tolerances consistent with its finding that EPA's Designated Safe Uses are safe, EPA's Final Rule revoked *all* tolerances for chlorpyrifos. EPA did not have any new data or scientific analyses to support this decision. Instead, EPA's Final Rule announced—without notice and comment—a new interpretation of the law that allowed EPA to claim that its safety findings did not matter. On that basis, EPA's Final Rule eliminated chlorpyrifos tolerances for all commodities effective six months from the date of publication—on **February 28, 2022**. 86 Fed. Reg. at 48,336 (Long Decl. Ex. A).

Grower Petitioners² are a coalition of growers and grower groups who rely on chlorpyrifos to meet their crop protection needs. Petitioner Gharda Chemicals International, Inc. ("Gharda") is the holder of an EPA registration for chlorpyrifos and the primary supplier of chlorpyrifos for agricultural use in the United States. Grower Petitioners and Gharda together are referred to herein as the "Petitioners." In the over five months since the Final Rule was published, EPA has received numerous objections to the Final Rule from Petitioners and others urging EPA to reconsider the Final Rule

² Grower Petitioners are comprised of Petitioners Red River Valley Sugarbeet Growers Association, United States 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, and National Cotton Council.

and, at a minimum, to stay tolerance expirations pending administrative and judicial review of the Final Rule. The stay petitions challenged EPA's arbitrary and capricious revocation of chlorpyrifos tolerances as contrary to EPA's own finding that EPA's Designated Safe Uses are safe. The stay also challenged EPA's failure to coordinate any revocation action with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), including through an appropriate existing stocks order. Petitioners detailed the extraordinary irreparable harms they have and will continue to suffer as a result of the Final Rule, which will devastate the economic livelihood of many growers and wreak havoc on the already stressed agricultural supply chain.

Although the FFDCA expressly authorized EPA to stay the Final Rule and the stay petitions readily satisfied EPA's standard for a stay, EPA has chosen not to act on them. 21 U.S.C. § 346a(g)(1); *Infra* at 24– 28. Tolerance revocation is now imminent. Once tolerances expire on February 28, 2022, food containing chlorpyrifos residues from applications after that date will be deemed "adulterated" under the

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FFDCA and may not be moved in interstate commerce. 21 U.S.C. §§ 331, 342.

EPA's inaction on the stay petitions up until the eve of tolerance expiration is tantamount to a denial. Indeed, EPA has stated publicly as recently as January 4, 2022 that tolerances for chlorpyrifos "will be revoked on February 28, 2022" and that the Agency intends to proceed with cancellation of associated food use registrations. EPA's Response to American Soybean Association's Objections and Request to Stay Tolerance Revocations: Chlorpyrifos (Long Decl. Ex. S). Legal consequences flow from EPA's inaction on the stay requests. The State of Minnesota, for example, has already suspended chlorpyrifos use on food crops as of January 1, 2022, as a result of the Final Rule. *See* Supplemental Declaration of Ram Seethapathi ("Supp. Seethapathi Decl.") ¶¶ 5–6, Ex. 1.

Pursuant to Rule 15 of the Federal Rules of Appellate Procedure, Petitioners hereby petition this Court for review of (1) EPA's failure to grant their stay petitions and (2) the Final Rule. Petitioners also move this Court to stay implementation of parts of the Final Rule. Specifically, the Final Rule should be stayed as to EPA's Designated Safe Uses. *See supra* at 3. This Court should also stay the tolerance expiration date for all other crop uses of chlorpyrifos until EPA issues an appropriate existing stocks order for those uses.

Alternatively, this Court should issue a writ of mandamus directing EPA to act on the objections and stay requests immediately.

STATEMENT OF JURISDICTION AND APPLICABLE LAW

Petitioners have standing to seek review of EPA's constructive denial of their stay petitions and EPA's Final Rule. Article III standing requires: (1) a "concrete and particularized" and "actual or imminent" "injury in fact"; (2) that is "fairly traceable" to the conduct complained of; and (3) that will be "redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citations omitted). An association has standing to sue on its members' behalf "when its members would otherwise have standing . . . the interests at stake are germane to the organization's purpose," and the claim and requested relief do not require the individual members' participation in the lawsuit. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000). "[W]here one plaintiff establishes standing to

sue, the standing of other plaintiffs is immaterial to jurisdiction." Jones
v. Gale, 470 F.3d 1261, 1265 (8th Cir. 2006); Nat'l Wildlife Fed'n v.
Agric. Stabilization & Conservation Serv., 955 F.2d 1199, 1203 (8th Cir. 1992). "[A] regulated party generally has standing to challenge an
agency action regulating its behavior." Ameren Servs. Co. v. FERC, 893
F.3d 786, 792 (D.C. Cir. 2018).

The Grower Petitioners, on their own behalf or on behalf of their members, demonstrate a "concrete and particularized" and "actual or imminent" injury in fact because they currently use chlorpyrifos as a critical pest control tool for sugarbeets, soybeans, and other crops, and would continue to do so absent EPA's revocation. See, e.g., Hastings Decl. ¶¶ 4, 9–26 (Att. 2, Ex. G); Metzger Decl. ¶¶ 4, 9–22 (Att. 2, Ex. I); Scott Decl. ¶¶ 6–19 (Att. 2, Ex. K); Scholz Decl. ¶¶ 4–16 (Att. 2, Ex. S); see also Lujan, 504 U.S. at 560; Ameren Servs., 893 F.3d at 791. This injury is imminent because as of February 28, 2022, there will be no tolerances for chlorpyrifos in effect, 86 Fed. Reg. at 48,334, and any commodity treated with chlorpyrifos after that date will be "adulterated," 21 U.S.C. §§ 342(a), 346a(a)(1), and subject to seizure, id. § 334(a)(1). Also, any grower who applies chlorpyrifos to commodities in

interstate commerce after February 28, 2022 would be subject to criminal sanctions. *See id.* §§ 331, 333. The inability to lawfully apply chlorpyrifos after February 28, 2022 will cause the growers represented by Grower Petitioners financial harm from reduced crop yields due to the increase in pest pressure, *see, e.g.*, Hastings Decl. ¶¶ 4, 9–26 (Att. 2, Ex. G), Baldwin Decl. ¶¶ 10–15 (Att. 2, Ex. B), as well reputational harm, *see, e.g.*, Metzger Decl. ¶ 20 (Att 2., Ex. I), Scott Decl. ¶ 17 (Att. 2, Ex. K).

Petitioner Gharda also has standing as the chlorpyrifos registrant. A number of cases recognize injury in fact based on a party's interest in its federal permit. *See Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 870 (8th Cir. 2013) (injury based on members' interest in Clean Water Act permits); *Coteau Props. Co. v. Dep't of Interior*, 53 F.3d 1466, 1472 (8th Cir. 1995) (applicant for surface mining permit had standing). Gharda similarly has a "concrete and particularized" interest in the tolerances and the harm to that interest is "actual or imminent," *Lujan*, 504 U.S. at 560, because the tolerances provide the necessary authorizations for Gharda to manufacture and sell chlorpyrifos for use on food, 7 U.S.C. § 136(bb), and absent action from this Court, those authorizations will terminate on February 28, 2022. These concrete injuries are directly caused by EPA's action in the Final Rule revoking tolerances for EPA's Designated Safe Uses, and would be remedied by a decision from this Court staying or vacating the Final Rule with respect to those uses and providing appropriate existing stocks relief. *See Lujan*, 504 U.S. at 560–61.

This Court has authority to review Petitioners' challenge to the Final Rule under FFDCA § 408(h)(1). 21 U.S.C. § 346a(h)(1) ("any person . . . adversely affected by" an order on objections to a final rule revoking tolerances "may obtain judicial review . . . in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business"). This action properly lies here because most of the Petitioners reside within the Eighth Circuit. Eleven of the nineteen Grower Petitioners³ are all based in States located within the

³ These eleven Petitioners are Red River Valley Sugarbeet Growers Association, Minn-Dak Farmers Cooperative, Southern Minnesota Beet Sugar Cooperative, American Crystal Sugar Company, American Soybean Association, Iowa Soybean Association, Minnesota Soybean Growers Association, Missouri Soybean Association, Nebraska Soybean Association, South Dakota Soybean Association, and North Dakota Soybean Growers Association.

Eighth Circuit. *See id.* An additional five Petitioners⁴ have members located within the Eighth Circuit. A large share of the crops adversely affected by the revocation of chlorpyrifos tolerances are grown within the Eighth Circuit.

Because the FFDCA provides for jurisdiction in this Court for Petitioners' challenge to the Final Rule, this Court also has jurisdiction to review EPA's failure to stay that rule. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (agency's decision to stay final rule is "tantamount to amending or revoking [the] rule").

EPA's inaction on the stay petitions is a reviewable, final agency action. *See id.* EPA has shown no willingness to act on the stay requests and in fact has expressed intent to move ahead with tolerance revocation despite the pending stay petitions. Legal consequences flow from EPA's refusal to stay the Final Rule, as some States (*e.g.*, Minnesota) have already suspended use of chlorpyrifos because of the Final Rule. Supp. Seethapathi Decl. Ex. 1. EPA's inaction represents the final agency position on this issue, has the status of law, and has an

⁴ These five Petitioners are U.S. Beet Sugar Association, American Sugarbeet Growers Association, American Farm Bureau Federation, National Association of Wheat Growers, and National Cotton Council.

immediate and direct effect on the parties. *See Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (agency action is "final" if (1) it "mark[s] the consummation" of the agency's decision-making process" and (2) is one by which "rights or obligations have been determined, or from which legal consequences will flow"); *Friedman v. FAA*, 841 F.3d 537, 542 (D.C. Cir. 2016) ("[T]he applicable test [for finality] is not whether there are further administrative proceedings available, but rather whether the impact of the order is sufficiently final to warrant review in the context of the particular case.").⁵ This Court should therefore review EPA's refusal to grant a stay, and enter a partial stay of the Final Rule in order to prevent irreparable harm to Petitioners.

Additionally, this Court should waive any administrative exhaustion requirements under the FFDCA because further administrative remedies would be futile and only perpetuate the irreparable harm from the Final Rule. After staying the Final Rule as requested by Petitioners, this Court should proceed to review the Final Rule on the merits as to EPA's Designated Safe Uses.

⁵ Indeed, under the Food and Drug Administration regulation EPA applies in evaluating stay petitions, a decision on a stay petition is a final, reviewable agency action. 21 C.F.R. § 10.45(d).

Alternatively, this Court has authority to issue a writ of mandamus compelling EPA to act on the stay petitions and objections pursuant to the All Writs Act, 28 U.S.C. § 1651 (authorizing federal courts to issue all writs appropriate "in aid of their respective jurisdictions") and Section 706(1) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1). This Court has jurisdiction to issue such a writ to end EPA's delay in ruling on the objections because Petitioners' challenges to EPA's action on the objections (and the underlying Final Rule) lie in this Court. 21 U.S.C. § 346a(h)(1).

STATEMENT OF THE CASE

I. LEGAL STANDARDS

The FFDCA requires EPA to set food safety "tolerances," which are maximum levels of pesticide residues allowed in or on food. 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.* c 346a(b)(2)(A)(i). Food containing pesticide residues that exceed an established tolerance level is deemed "adulterated" under the FFDCA and may not be moved in interstate commerce. *Id.* §§ 331, 342. In

considering whether to establish, modify, or revoke a tolerance, EPA must consider, among other things, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue." *Id.* § 346a(b)(2)(D)(i).

A tolerance is deemed "safe" under the FFDCA if "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). This includes exposure from food, drinking water, and in residential settings, but does not include occupational exposure. In assessing reasonable certainty of no harm, EPA is to apply an additional tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" but EPA has discretion to apply a different margin of safety if there is "reliable data" to support that determination. *Id.* § 346a(b)(2)(C)(ii).

EPA also regulates pesticides under FIFRA. FIFRA requires EPA registration of a pesticide before it can be marketed, sold, or distributed in the United States. 7 U.S.C. § 136a(a). A registration operates as a

product-specific license. In approving a pesticide registration, EPA must review and approve the pesticide's label, which governs a pesticide's use, including the specific crops on which the pesticide may be lawfully used. *Id.* § 136j(a)(2)(G). EPA will not register a pesticide unless scientific data and other information show that its use in accordance with its label will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D).

For pesticides used on food, the "unreasonable adverse effects" standard incorporates FFDCA's "reasonable certainty of no harm" safety standard. *Id.* § 136(bb). Thus, when EPA registers a pesticide for use on food, it must determine that doing so will not cause higher amounts of pesticide residue on food commodities than the approved tolerances allow. Additionally, the FFDCA mandates that when revoking a tolerance, EPA "shall coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(l)(1). That related action may cancel the pesticide's registration and enter an "existing stocks" order to "permit the continued sale and use of existing stocks" of the pesticide whose registration is cancelled. 7 U.S.C. § 136d(a), (b).

II. BACKGROUND

A. The Vital Importance of Chlorpyrifos and Its Decades of Safe Use In the United States

Chlorpyrifos is a vitally important agricultural tool, protecting over fifty valuable U.S. food crops (*e.g.*, soybeans, wheat, sugarbeets, cherries and other fruits and vegetables) from destruction due to insect pests. The total benefit of chlorpyrifos to U.S. growers is upwards of over a hundred million dollars annually, not including crop loss from lack of suitable alternatives. EPA, Revised Benefits of Agricultural Uses of Chlorpyrifos at 5, 7, EPA-HQ-OPP-2008-0850-0969 (Nov. 18, 2020) ("Revised Benefits"), Long Decl. Ex. E. Chlorpyrifos has value to growers in protecting their crops and income, as well as to consumers who enjoy affordable, healthy, and high quality produce throughout the year.

EPA has recognized chlorpyrifos's critical importance as an insect pest management tool due to its broad-spectrum efficacy, favorable environmental characteristics, and affordability for growers. EPA has recognized that chlorpyrifos is the leading active ingredient to control a broad spectrum of difficult-to-control insect pests, and for some destructive pests it is the only effective pest management tool available. Revised Benefits at 2 (Long Decl. Ex. E).

Chlorpyrifos is supported by decades of scientific study. Since it was first registered in 1965, EPA has reviewed chlorpyrifos several times to ensure that it continues to meet applicable safety standards under FIFRA and the FFDCA. In 2006, EPA reauthorized all existing agricultural uses and determined that all chlorpyrifos food tolerances are "safe," meaning there is "a reasonable certainty that no harm will result from aggregate exposure" to chlorpyrifos. 21 U.S.C. § 346a(b)(2)(A)(ii). That decision remained undisturbed until the Final Rule.

In 2007, a group of nongovernmental organizations petitioned EPA to revoke all chlorpyrifos tolerances. In response to the administrative petition, EPA accelerated registration review of chlorpyrifos, a fifteenyear scientific reassessment of all registered pesticides required by FIFRA. 7 U.S.C. § 136a(g). During this process, EPA reviews available data and information and conducts a number of risk assessments. EPA makes these assessments available for public comment, reviews and responds to comments, conducts further scientific analyses, and revises its assessments, as necessary. Registration review culminates in EPA issuing a proposed decision, which EPA also makes available for public comment before issuing a final decision. *See* 40 C.F.R. § 155.58.

B. EPA's 2020 Proposed Interim Decision as to EPA's Designated Safe Uses

On December 7, 2020, as part of EPA's registration review of chlorpyrifos, EPA published its PID.⁶ 85 Fed. Reg. 78,849 (Dec. 7, 2020). The PID is supported by EPA's September 21, 2020 Third Revised Human Health Risk Assessment (the "2020 RHHRA"), Long Decl. Ex. C, which in turn relies on, among other documents, a September 15, 2020, Updated Chlorpyrifos Refined Drinking Water Assessment (the "2020 DWA"), Long Decl. Ex. D. EPA's PID and its underlying assessments reflect a fulsome, measured, and well-reasoned evaluation by EPA's expert scientists of potential human health and drinking water risks of chlorpyrifos with respect to EPA's Designated Safe Uses.

EPA's PID relied on the 2020 DWA, which updated and refined the Agency's 2016 DWA. The 2020 DWA is one of the most sophisticated drinking water analyses EPA has conducted and relied on

⁶ Registration review of chlorpyrifos is ongoing and scheduled to be completed by October 2022.

EPA's most cutting edge and highly refined methods for assessing drinking water risks.⁷ See Declaration of Donald C. McLean ("McLean Decl.") Ex. D, Reiss Decl. at ¶¶ 9–11. In the 2020 DWA, EPA focused on the eleven crop uses that comprise EPA's Designated Safe Uses. 2020 DWA at 1, 9, 17, 19–21 (Long Decl. Ex. D). The 2020 DWA focused on select regions of the country where estimated drinking water concentrations are below the drinking water level of concern. *Id.* at 27– 28.

In the 2020 RHHRA and PID, EPA conducted an assessment of potential risk to human health from aggregate exposure to chlorpyrifos residues, taking into account all anticipated dietary exposures from food, drinking water, and residential sources, pursuant to FFDCA Section 408(b). EPA determined that there were *no* potential risks of concern from exposure to chlorpyrifos in food or residential uses alone. 2020 RHHRA at 12 (Long Decl. Ex. C); PID at 14, 18 (Long Decl. Ex. B). EPA determined that risks from drinking water exposure exceeded safe levels taking into account *all* registered uses but, relying on its 2020

⁷ EPA subjected the 2020 DWA to peer review by nine EPA expert scientists, an unprecedented level of peer review for an assessment of its kind. *See* Reiss Decl. at ¶ 12 (McLean Decl. Ex. D).

DWA, EPA found that risks were *below* the drinking water level of concern benchmark anticipating use only on EPA's Designated Safe Uses. PID at 18 (Long Decl. Ex. B).

In its 2020 RHHRA and PID, EPA presented two approaches for assessing potential risks: (i) application of a 10X FQPA safety factor and limiting use of chlorpyrifos to EPA's Designated Safe Uses, or (ii) application of a 1X FQPA safety factor, which would allow for the retention of all currently registered uses. Regarding the first approach, EPA was unequivocal that "the agency has determined" that limiting use to EPA's Designated Safe Uses "*will not pose potential risks of concerns with an FQPA safety factor of 10X.*" *Id.* at 40 (emphasis added).

C. Petitioner Gharda's Discussions with EPA Concerning a Potential Voluntary Narrowing of Chlorpyrifos Uses

In April 2021, EPA approached Gharda about a possible agreement to voluntarily cancel some uses of chlorpyrifos. Seethapathi Decl. at ¶ 21 (McLean Decl. Ex. C). In these initial discussions, EPA urged Gharda to accept a voluntary phase-out of the uses other than EPA's Designated Safe Uses. *Id*.

On April 29, 2021, the Ninth Circuit issued a decision in LULAC, which concerned EPA's handling of the 2007 administrative petition. The Ninth Circuit held that EPA's denial of objections to a 2017 order denying the administrative petition was at odds with the FFDCA because EPA did not make an affirmative finding that chlorpyrifos tolerances were "safe" in response to the petition. LULAC, 996 F.3d 673 (9th Cir. 2021). The Ninth Circuit ordered EPA "either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe," "or to revoke all chlorpyrifos tolerances." *Id.* at 678. (emphasis added). In making this ruling the court expressly recognized the importance of the PID. The court specifically referenced the PID in observing that EPA "may modify chlorpyrifos registrations rather than cancelling them." Id. at 703. The court also ordered EPA to "correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of 21 U.S.C. § 346a(a)(1)." Id. at 678.

After the Ninth Circuit decision in *LULAC*, EPA continued discussions with Gharda about a potential voluntary narrowing of chlorpyrifos uses. Seethapathi Decl. ¶ 23 (McLean Decl. Ex. C). These discussions culminated in Gharda's *written commitment* to EPA to voluntarily cancel all uses of chlorpyrifos except EPA's Designated Safe Uses. *Id.* ¶ 24. In turn, Gharda requested that EPA allow for an orderly phase-out of existing stocks for all other uses. *Id.* EPA responded with a written proposal to Gharda for a multi-year phase-out of existing stocks for all other uses. *Id.* ¶¶ 25, 29. These discussions continued until, days before it issued the Final Rule, EPA abruptly terminated them. *Id.* ¶¶ 30–35.

D. EPA's Final Rule Revoking All Tolerances for Chlorpyrifos For All Crop Uses

Without undergoing notice and comment, EPA announced the Final Rule in August 2021. 86 Fed. Reg. 48,315 (Long Decl. Ex. A). In the Final Rule, EPA stated that it is revoking all food use tolerances for chlorpyrifos. *Id.* at 48,317. EPA stated that, "taking into consideration the currently registered uses for chlorpyrifos," it is unable to make *any* safety finding under the FFDCA. *Id.* at 48,315, 48,317. EPA did not rely on any new data or scientific analyses in reaching this conclusion. In fact, the scientific analysis in the Final Rule is largely consistent with the Agency's scientific findings in the PID. As to the aggregate exposure assessment, EPA confirmed in the Final Rule, as it had found in the PID, that "exposures from food and non-occupational exposures individually or together do not exceed EPA's levels of concern." *Id.* at 48,333. EPA agreed that it is only drinking water exposures, when combined with food and nonoccupational (residential) exposures, that create risks of concern. *Id.* As to drinking water, the Final Rule acknowledged EPA's findings in the PID that drinking water exposures do not exceed levels of concern when assuming use on only EPA's Designated Safe Uses. *Id.*

Nevertheless, and despite admitting that "there may be limited combinations of uses *that could be safe*," EPA claimed that because it is required to assess aggregate exposure taking into account all "currently registered uses," and based on the 2016 DWA, it could not find that aggregate exposures to chlorpyrifos are safe. *Id*. The Agency stated, without explanation, that it lacked "effective mitigation upon which to base a reduced aggregate exposure calculation." *Id*. The Final Rule stated that the tolerances would expire six months later, on February 28, 2022. *Id*. at 48,334.

E. Petitioners File Objections to and Seek an Administrative Stay of the Final Rule

Petitioners timely submitted objections to the Final Rule, pursuant to the Section 408(g) of the FFDCA. 21 U.S.C. § 346a(g)(2)(A). In light of the significant, immediate, and irreparable injuries Petitioners have and will continue to suffer as a result of the revocation of tolerances, several Petitioners also sought a stay of the Final Rule pending EPA's review of the objections and any judicial review of EPA's decision on the objections. *See, e.g.*, Long Decl. Exs. F–I, L–V; Gharda Objections and Stay Petition (McLean Decl. Exs. A–B). Petitioners' stay requests met all requirements set forth for an administrative stay of the Final Rule and the FFDCA explicitly authorizes such a stay. *Infra* at 24–28; 21 U.S.C. § 346a(g)(1).

EPA has failed to act on the stay requests, but has signaled publicly that it intends to carry out the expiration of tolerances and corresponding cancellation of food use registrations under FIFRA, despite the ongoing administrative objections process. Long Decl. Ex. S.

Following issuance of the Final Rule, Gharda initiated the annual process to renew its state registrations of chlorpyrifos. Supp. Seethapathi Decl. ¶ 5. Because of the Final Rule, Minnesota and Wisconsin declined to renew Gharda's State registration for chlorpyrifos products for use on food in 2022. *Id.* ¶ 6 (Supp. Seethapathi Decl.Ex. 1). As a result, as of January 1, 2022, Gharda has been unable to distribute or sell its chlorpyrifos products registered for use on food/feed in those states—even though chlorpyrifos tolerances will remain lawfully in place until February 28, 2022 under the Final Rule. *Id.* ¶ 5.

ISSUES FOR REVIEW

I. EPA'S FAILURE TO STAY THE RULE AS TO EPA'S DESIGNATED SAFE USES IS ARBITRARY AND CAPRICIOUS, CONTRARY TO LAW, AND VIOLATES DUE PROCESS RIGHTS

EPA has failed to act on Petitioners' requests to stay the Final

Rule, which have now been pending before the Agency for over three months despite the imminent tolerance expiration date. This amounts to constructive denial of Petitioners' administrative stay requests. Petitioners' requests for administrative stay of the Final Rule met all requirements for a stay. Petitioners' administrative stay petitions demonstrated the irreparable harms to Petitioners from the Final Rule, were in good faith and were not frivolous, were supported by sound public policy grounds, and demonstrated that a stay was not outweighed by public interests. 21 C.F.R. § 10.35(e). EPA's failure to grant the stay petitions in these circumstances was arbitrary and capricious and violated due process.

First, Petitioners' administrative stay petitions demonstrated the irreparable harm that they would suffer under the Final Rule. For example, the request filed by Petitioner U.S. Beet Sugar Association and the American Sugarbeet Growers Association detailed the substantial and unrecoverable economic losses that sugarbeet farmers would suffer without the ability to use chlorpyrifos. American Sugarbeet Growers Association/U.S. Beet Sugar Association – Request for a Stay of Decision (Long Decl. Ex. G). Chlorpyrifos, these Petitioners explained, is the most effective means of controlling sugarbeet root maggots and flies. Without the ability to use chlorpyrifos, sugarbeet growers represented by three farming cooperative Petitioners could experience significant crop yield losses, at a value of up to nearly \$82 million per year. See Hastings Decl. ¶¶ 20-21 (Att. 2, Ex. G) (estimating \$34.43 million in losses for members); Geselius Decl. ¶ 22 (Att. 2, Ex. F) (estimating up to \$30 million in losses for members); Metzger Decl. ¶ 18 (Att. 2, Ex. I) (estimating up to \$17.5 million in losses for members).

Similarly, Petitioner Gharda explained that revocation of all tolerances will result in the loss of its EPA registration for chlorpyrifos, in which it has a legally protectable property interest. Gharda Stay Petition at 5-6 (McLean Decl. Ex. B). Revocation of all tolerances will also cause Gharda devastating economic harm from lost sales and lost investment in significant quantities of existing inventory it is unable to exhaust. *Id.* at 6–7. Revocation of all tolerances will also cause Gharda reputational harm as a result of EPA's arbitrary action against chlorpyrifos, loss of customer and public good will, and potentially lost market share. *Id.* at 7–9.

Second, Petitioners' requests for administrative stay raised sound public policy challenges to the Final Rule, were made in good faith, and were not frivolous. Petitioners pointed out that EPA's Final Rule ignored EPA's own safety findings in the PID, ignored Gharda's commitment to limit registration of chlorpyrifos to EPA's Designated Safe Uses, and rested on a justification (alleged occupational exposure by farmworkers) that was not a consideration permitted by the FFDCA. *See id.* at 9–11. Petitioner Gharda challenged the EPA's failure to issue an existing stocks order, in disregard of the Agency's duty under FIFRA. *Id.* at 3, 10–11. Each of these errors were arbitrary and capricious, which more than satisfies the low bar for an administrative stay.

Finally, Petitioners' requests for administrative stay demonstrated that a stay is in the public interest. Petitioners made a strong showing that a stay would provide critical relief to the family farmers raising sugarbeets, soybeans, and the other high-benefit crops at issue here. See, e.g., Long Decl. Exs. B, I, M. These growers would be significantly harmed by the loss of chlorpyrifos to control the insects that will attack their crops. Id. No public health or public interest considerations outweigh the need for a stay. There are no public health or other public interests that would be adversely affected by a stay of the revocation of the tolerances as to EPA's Designated Safe Uses. There is no concern for food safety with respect to these crops. Petitioners relied upon EPA's own safety findings to point out that EPA's Designated Safe Uses met all relevant safety standards. See, *e.g.*, *Id.* Exs. F–G, L–N, R.

Although Petitioners met all requirements for an administrative stay, EPA refused to grant their requests. EPA's constructive denial of Petitioners' requests for administrative stay was arbitrary, capricious, contrary to law, and violated due process. The Court should review EPA's failure to grant Petitioners the requested stay, and should itself partially stay implementation of the Final Rule with respect to EPA's Designated Safe Uses for the reasons set forth in Petitioners' motion to stay accompanying Motion to Stay. 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.⁸

II. THIS COURT SHOULD WAIVE ADMINISTRATIVE EXHAUSTION AND REVIEW THE FINAL RULE AS TO EPA'S DESIGNATED SAFE USES

This Court should waive administrative exhaustion under the FFDCA and review EPA's revocation of tolerances for EPA's Designated Safe Uses on the same grounds articulated above. Waiver of administrative exhaustion requirements is necessary here for three reasons: (1) to prevent EPA from thwarting judicial review by delaying a decision on the objections, (2) to prevent irreparable harm to

⁸ Petitioner Gharda reserves its rights as to its objections to the Final Rule's revocation of tolerances for chlorpyrifos uses other than EPA's Designated Safe Uses.

Petitioners, and (3) because exhaustion of administrative remedies would be futile.

Parties objecting to an EPA decision to revoke tolerances must generally file objections. 21 U.S.C. § 346a(g)(2). EPA is required to respond to objections "as soon as practicable," *id.* § 346a(g)(2)(C); 40 C.F.R. § 178.30. The objections lead to a "final decision" by EPA that an objector may challenge in court. 21 U.S.C. §§ 346a(g)(2)(C), 346a(h)(1); 40 C.F.R. § 180.30(a)(6).

Petitioners have complied with the FFDCA by timely filing objections with EPA, but EPA has refused to act on them. This Court should waive the requirement that judicial review follow EPA's action on the objections to prevent EPA from foreclosing judicial review by refusing to act on the objections while the revocations go into effect.

The Court should also waive any exhaustion requirement here because further administrative procedures would be futile. *See In Home Health, Inc. v. Shalala,* 272 F.3d 554, 560 (8th Cir. 2001) (exhaustion may be excused where "further administrative procedures would be futile"); *see also Ace Prop. & Cas. Ins. Co. v. Fed. Crop Ins. Corp.,* 440 F.3d 992, 1000 (8th Cir. 2006). EPA appears entrenched in its position and has shown no willingness to reconsider the Final Rule. In fact, the Agency has expressed publicly as recently as January 4, 2022 that tolerances "will be revoked" on February 28, 2022, and that it intends to proceed with cancellation of associated food use registrations. Long Decl. Ex. S. Any review of the pending objections and stay requests will thus be *pro forma* at best.

Exhaustion waiver is also warranted here because delaying judicial review until tolerance revocation takes effect will cause irreparable harm. *See In Home Health*, 272 F.3d at 560 (exhaustion may be waived where it would cause irreparable harm). EPA has made clear its intent to avoid acting on the objections and stay petitions until tolerance expiration is inevitable or has already occurred, at which time the harms from the Final Rule will already be felt. Delaying judicial review to await EPA's resolution of the objections would thus only perpetuate the irreparable harms from the Final Rule. This Court's immediate review is necessary to prevent Petitioners from suffering unrecoverable economic harm and other irreparable losses from the revocation of chlorpyrifos tolerances. Because EPA does not intend to timely resolve the stay petitions, further administrative procedures would be futile, and the harm presented in the stay petitions is immediate and irreparable, this Court should waive administrative exhaustion under the FFDCA and review EPA's Final Rule as to EPA's Designated Safe Uses. This Court should also waive exhaustion and review EPA's failure to issue an appropriate existing stocks order for all remaining uses.

III. IN THE ALTERNATIVE, A WRIT OF MANDAMUS IS WARRANTED TO COMPEL EPA TO ACT IMMEDIATELY ON PETITIONERS' OBJECTIONS AND STAY PETITIONS

EPA has unreasonably delayed by failing to act on the objections to and petitions to stay the Final Rule. The APA authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). For a writ of mandamus to issue: (1) the petitioner must demonstrate it has "no other adequate means to attain" the desired relief; (2) that "entitlement to the writ is clear and indisputable"; and (3) "that the writ is appropriate under the circumstances." *In re Kemp*, 894 F.3d 900, 905 (8th Cir. 2018) (quotations omitted). Courts apply a six-factor test for determining when an agency delay is unreasonable under 5 U.S.C. § 706(1): (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Telecomm. Research & Action Ctr. v. FCC ("TRAC"), 750 F.2d 70, 75

(D.C. Cir. 1984) (citations omitted).

Tolerances are set to expire within a matter of weeks and EPA has shown no willingness to reconsider its position or to stay implementation of the Final Rule, despite the irreparable harms it has caused. While there is no statutory deadline for EPA to act, without a stay of the Final Rule, Petitioners face catastrophic economic and other irreparable harms. Thus, EPA's delay violates the "rule of reason" and significantly prejudices the Petitioners' interests. *See id*.

In light of EPA's obvious intent to avoid acting on the objections and stay petitions until tolerance expiration is inevitable or has already occurred, by which time the irreparable harms from the Final Rule will already be irreversible, the *TRAC* factors support issuance of a writ of mandamus compelling EPA to immediately act on the objections and stay petitions.

IV. CONCLUSION

For these reasons, and because of the irreparable injuries Petitioners have and will continue to suffer as a result of the nearimminent revocation of all tolerances, the Final Rule should be stayed as to EPA's Designated Safe Uses, pending review of the Final Rule on the merits. This Court should also stay the tolerance expiration date for all other crop uses of chlorpyrifos until the Agency provides an appropriate existing stocks order for those uses.

If this Court does not grant a stay pending review of the Final Rule, it should at a minimum issue a writ of mandamus directing EPA to act on the objections and stay requests immediately, so as to allow Petitioners and other interested parties to seek judicial review of that action and the underlying Final Rule before the harms from the Final Rule become so irreparable as to render such review futile.

Respectfully submitted this 9th day of February, 2022,

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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

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