In the United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 22-1294

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, et al.,

Petitioners,

v.

MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, et al.,

Respondents.

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

REPLY IN SUPPORT OF PETITIONERS' MOTION FOR A PARTIAL STAY PENDING REVIEW

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EPA's Final Rule disregarded the facts, the law, and its own scientific findings at the expense of thousands of family farmers. EPA's response to Petitioners' motion to stay continues that trend, attempting to re-write both the FFDCA and the regulatory history. EPA's unlawful actions will cause severe irreparable harm to Petitioners. The Court should grant Petitioners' stay request.

ARGUMENT

I. This Court Has Jurisdiction.

EPA's response confirms this Court has jurisdiction. EPA forecasts denials of Petitioners' objections and stay requests by February 28, 2022 (the Final Rule's effective date), followed by cancellation of chlorpyrifos registrations. Resp. at 9, 17; Reaves Decl. ¶25. This tells the Court all it needs to know. EPA has constructively denied Petitioners' requests to stay the Final Rule and is running out the clock until it takes effect.

EPA "cannot simply end-run judicial review by sitting on its hands." *Byrd v. Haas*, 17 F.4th 692, 697–98 (6th Cir. 2021). Judicial review of EPA's decisions is required to prevent the imminent and irreparable harm described in the Petition and supporting declarations.

Mot. at 21–25. For these reasons, as well as those in Petitioners' forthcoming opposition to EPA's motion to dismiss, this Court should reject EPA's attempt to evade judicial review and grant Petitioners' stay request.[1]

II. Petitioners Are Likely to Succeed on the Merits.

A. The Court faces a legal question, not a scientific debate.

EPA's response confirms the key facts establishing Petitioners' likelihood of success on the merits:

- EPA's 2020 PID concluded that 11 uses (EPA's Designated Safe Uses) are safe and present no public health risk, Resp. at 7;
- EPA's Final Rule did not find any basis to conclude these uses are unsafe, *id.* at 8; and
- EPA's sole reason for rejecting the identified safe uses was a newfound interpretation of the FFDCA that prevents modifying tolerances to narrow permissible uses, *id.* at 11–17.

The Reaves Declaration makes clear that EPA—to this day—has not varied from its conclusion that EPA's Designated Safe Uses are indeed

[1] When EPA issues its decision rejecting Petitioners' objections and upholding the revocation of all tolerances—the result EPA telegraphs here—Petitioners will petition for review of that decision and the underlying Final Rule in this Court.

safe. Reaves Decl. ¶¶ 16, 24. This case therefore requires no resolution of scientific issues.[2] Rather, this case presents a simple legal question: does the FFDCA prohibit EPA from narrowing uses of a pesticide to those it considers safe, or instead must EPA reject ***all*** uses of a pesticide if ***any*** use could be unsafe?

The plain text of the FFDCA answers this question. EPA must employ a tolerance-by-tolerance approach for revocation: examining the data to determine whether "a tolerance" is safe. Mot. at 15–17; 21 U.S.C. § 346a(b)(2)(C). To be sure, EPA must assess safety for the individual tolerance by considering "aggregate exposure" to the pesticide residue, including "all anticipated dietary exposures." 21 U.S.C. § 346a(b)(2)(A)(ii)). In other words, EPA must examine a tolerance's safety in the context of other relevant exposures. But

[2] Petitioners rely upon the Final Rule, which confirmed EPA's prior safety findings. EPA's suggestion that it cannot find chlorpyrifos safe based on alleged evidence of neurodevelopmental impacts, Resp. at 10-11, is contradicted by the Final Rule itself. 48 Fed. Reg. at 48,324 ("EPA remains unable to make a causal linkage between chlorpyrifos exposure and the [neurodevelopmental] outcomes reported"). Proposed Amici's brief, which similarly re-argues EPA's scientific findings, is also beside the point.

Congress never required EPA to conduct this assessment for the "universe of proposed and approved uses for the pesticide." Resp. at 12.

EPA's new interpretation that all tolerances must rise or fall together reads key text out of the statute. Congress authorized EPA to "modify" an existing tolerance, as well as to "leave in effect" or "revoke" a tolerance. 21 U.S.C. § 346a(b)(2)(A)(i). Congress intended modification to include narrowing permissible uses, as it expressly prohibited "expanding the tolerance to cover additional foods" through modification. *Id.* § 346a(b)(1). By expressly prohibiting ***expansion*** of uses through modification, while leaving open the ***reduction*** of uses through modification, Congress clearly intended to allow EPA the option of narrowing uses through modification of tolerances—precisely what EPA did in the PID.

EPA's newfound interpretation would also produce absurd results. EPA has established over 75 different tolerances for chlorpyrifos in or on agricultural commodities. 40 C.F.R. § 180.342. Similarly, dozens of different tolerances exist for a host of other pesticides. *See, e.g.*, *id.* § 180.339 (MCPA); *id.* § 180.332 (Metribuzin). If all tolerances must rise or fall together, then EPA would have to revoke all tolerances for any

pesticide every time it concluded an individual tolerance was unsafe. That makes no sense. *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("interpretations of a statute which would produce absurd results are to be avoided").

B. EPA's litigation position conflicts with its established interpretation.

Prior to the Final Rule, EPA never construed FFDCA and FIFRA to prohibit narrowing of permissible uses in making a safety determination. EPA's established practice is to modify both tolerances and associated food use registrations to conform to its safety findings. For example, EPA increased the Imidacloprid tolerances for citrus fruits and coffee while revoking tolerances for apples and okra, among other crops, and made the associated label changes. Imidacloprid PID (Jan. 2020) 58–71.[3] In doing so, EPA acknowledged it had authority under the FFDCA to make needed tolerance changes. *Id.* at 58. EPA included similar language in the PID here: "The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances." Long Decl. Ex. B at 62. EPA would not have contemplated

[3] https://www.epa.gov/sites/default/files/2020-01/documents/imidacloprid_pid_signed_1.2 2.2020.pdf.

making "needed changes" if the only decision allowed was a yes/no decision covering all tolerances.

In attempting to rewrite history, EPA misquotes its Carbofuran Order. *Compare* Resp. at 14 ("when one tolerance is unsafe, *all* tolerances are equally unsafe . . .") (emphasis in original, internal quotation marks omitted) *with* 74 Fed. Reg. at 59,675 ("[W]hen one tolerance is unsafe, all tolerances are equally unsafe ***until aggregate exposures have been reduced to acceptable levels.***") (emphasis added). That order goes on to describe EPA's settled practice of working with registrants to narrow permissible uses as part of a safety finding. "EPA's general policy … is not to independently select the subset that meets the standard, but to rely on the pesticide registrant and the public to determine which of the various subsets of tolerances are of sufficient importance to warrant retention." 74 Fed. Reg. at 59,675. EPA then proceeds with its safety finding for the narrowed subset of uses.

That is precisely the process EPA embarked upon here, before abruptly reversing course in the Final Rule. Following *LULAC*, EPA negotiated for months with Gharda on narrowing the permissible uses.

McLean Decl. Ex. A at 56–88. This entire negotiation process assumed a tolerance-by-tolerance assessment could be conducted, considering the aggregate exposures of the anticipated tolerances that would remain. If EPA thought a finding of safety for all currently registered uses was required, then it would not have wasted time and resources on reaching agreement with Gharda on EPA's Designated Safe Uses. *Shell Offshore Inc* ***v.*** *Babbitt*, 238 F.3d 622, 629 (5th Cir 2001) ("existing practice" evidence of agency interpretation). EPA's post-hoc litigation position here contradicts the FFDCA's text and EPA's established interpretation. It must be rejected. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012).

C. EPA's excuses for abandoning its established interpretation ring hollow.

In attempting to excuse its rejection of the plain text of the FFDCA and its abandonment of past practice, EPA suggests it was forced to do so. That EPA makes such claims demonstrates the weakness of its legal arguments and underscores the extent to which the Final Rule departed from settled understanding and practice.

First, EPA claims that it lacked the "proposals" needed for voluntary cancellation, and thus could not limit aggregate exposures to

the 11 uses found safe. Not true. Reaves Decl. ¶21 (citing Gharda proposals). And EPA had not just proposals from Gharda—it had Gharda's commitment to conform its registration to EPA's safety finding. McLean Decl. Ex. A at 73-80 and Ex. C ¶¶29-33.[4] EPA next asserts a voluntary cancellation agreement was not finalized because Gharda sought "unreasonable cancellation terms," such as a phased out production and exhaustion of existing stocks. But ***EPA*** proposed these terms. *Id*. Ex. A at 71 (EPA email to Gharda stating "[EPA is] considering the following dates for existing stocks" and referencing a "12 to 18 month" production phaseout period and use by growers "until exhausted"). As the parties neared an agreement, EPA informed Gharda that it would likely need a written voluntary cancellation agreement quickly to reference it in the Final Rule and thanked Gharda for its "continued patience and engagement." *Id.* at 87. EPA then terminated discussions without explanation.

Second, EPA implies that the Ninth Circuit required it to make a single up-or-down decision for all tolerances—claiming that the relief

[4] EPA's declaration omits additional communications after the "Second Gharda Letter" regarding Gharda's commitment to narrow uses consistent with EPA's safety finding. McLean Decl. Ex. A at 66-88.

Petitioners seek is "in … tension" with the *LULAC* order. Resp. at 2. Not true. The Ninth Circuit told EPA to modify or revoke the tolerances based on the evidence. *LULAC*, 996 F.3d at 703. EPA could have modified the tolerances within 60 days (having already made the necessary safety determinations in the PID) and then canceled FIFRA registrations for other uses within a reasonable time thereafter. This was what Congress expected: for EPA "to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties." H.R. Rep. 104-669(II). This was what the Ninth Circuit ordered. *LULAC*, 996 F.3d at 703–04. And this was what EPA started to do, before reversing course in the Final Rule. McLean Decl. Ex. A at 56–88.

EPA's post-hoc rationalizations for ignoring the law and abandoning its established practice have no basis.

D. EPA cannot ignore the PID.

Because its legal arguments fail, EPA tries to sideline the PID—not by walking back its safety findings, but by questioning their relevance. Those attempts also fail.

First, EPA claims its PID safety findings have nothing to do with the FFDCA. *Id.* at 4, 11-12. Here again, EPA ignores the law and its established interpretation. FIFRA explicitly incorporates the FFDCA safety standard. 7 U.S.C. § 136(bb) ("unreasonable adverse effects" includes dietary risk inconsistent with FFDCA "reasonable certainty of no harm" standard). "Thus," EPA has explained, "Congress set forth a standard in FIFRA under which EPA would assess a pesticide's safety under the FFDCA at the same time it addressed the pesticide's registration or . . . re-examined existing pesticide registrations." EPA Br. at 7, ECF 47, *LULAC*, 996 F.3d 673 (9th Cir. 2021).

Similarly, EPA attempts to disregard the PID as a mere proposal. Resp. at 11. What matters here is not the label EPA puts on a decision, but how it treats that decision. *Cf. FWS v. Sierra Club*, ___ U.S. ___, 141 S. Ct. 777, 786 (2021) (decision is final where agency treats it as such). EPA acknowledged that "a final decision for chlorpyrifos may be issued" based on the PID. Long Decl. Ex. B at 62. And EPA treated the PID as final—relying upon it when negotiating with Gharda on retention of EPA's Designated Safe Uses. McLean Decl. Ex. A at 95. EPA could not have done so if it did not consider the uses safe and

understand it had the authority to "modify" tolerances accordingly. 21 U.S.C. § 346a(b)(2)(A)(i). EPA's attempt to distance itself from the PID is nothing more than a convenient litigating position.

Petitioners are likely to succeed on the merits.

III. Petitioners Demonstrate Irreparable Harm.

EPA does not dispute that Petitioners will suffer harm. Rather, EPA tries to discount the harm's severity. Resp. at 19-20. As demonstrated by the 24 declarations submitted with the Petition, Petitioners established harms that are both irreparable and substantial.

First, Petitioners' economic losses are unrecoverable, which "qualif[ies] as irreparable harm." *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996). Complying with a regulation later held invalid "almost ***always*** produces the irreparable harm of nonrecoverable compliance costs." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment).

Second, Petitioners' irreparable harm is substantial. EPA found the 11 uses of chlorpyrifos at issue here provide "high benefits" to agriculture. Anderson Decl. ¶¶9-10. EPA itself predicts $53 million in

losses for farmers—a substantial figure—from revocation of chlorpyrifos tolerances. Resp. at 20. Although EPA downplays these losses by comparing them to overall business, an entire industry need not be decimated to support a stay. "[W]hen the threatened harm is more than *de minimis*, it is not so much the magnitude but the ***irreparability*** that counts." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 279 (5th Cir. 2012) (emphasis in original; quotations omitted).

Petitioners have also shown substantial harm to individual farmers before the Court, who will suffer tens to hundreds of thousands of dollars in annual losses under the Final Rule. *E.g.* Att. 2, Ex. B (Baldwin Decl.) at ¶14, *id.* Ex. E (Hultgren Decl.) at ¶14, and *id.* Ex. H (Haugrud Decl.) at ¶14. These harms are "highly significant" and "devastating" to farms that are already struggling to remain viable. Att. 2, Ex. B (Baldwin Decl.) at ¶¶14–15; Att. 2, Ex. E (Hultgren Decl.) at ¶¶14–15; Att. 2, Ex. H (Haugrud Decl. ¶14–15). EPA cannot rebut these declarations.

Similarly, Gharda has shown substantial irreparable harm in lost sales and lost investment in significant quantities of existing inventory, which EPA does not contest. Instead, EPA says that because Gharda

has not alleged it will go out of business, its harm cannot be irreparable. Again, that is not the law. *Supra* at Part III. EPA also argues that Gharda's reputational harm is self-inflicted because Gharda decided to produce chlorpyrifos in 2021 when the future regulatory status of chlorpyrifos was uncertain. But EPA led Gharda to believe, until shortly before it issued the Final Rule, that EPA would allow chlorpyrifos for EPA's Designated Safe Uses. McLean Decl. Ex. A at 56–88. EPA cannot blame Gharda for believing EPA was negotiating in good faith.

EPA's suggestion that Gharda could start over with a request to establish new registrations and tolerances is no solution. The process would take years and cost hundreds of thousands of dollars. Ex. A (Stephens Declaration). More importantly, it would do nothing for the Grower Petitioners and their members who need chlorpyrifos in the 2022 growing season, to avoid unrecoverable losses now and pest pressure in the future.

IV. The Public Interest and Balance of Equities Support a Stay.

Petitioners show that the public interest and balance of the equities support a stay. EPA found no harm to human health from

EPA's Designated Safe Uses, whereas denying Petitioners the opportunity to use and supply chlorpyrifos for these discrete uses would cause irreparable harm. Mot. at 25–26. EPA responds that Congress required EPA to revoke tolerances that are not safe. Resp. at 23. Although that general principle may be true, it has no application to Petitioners' request for a partial stay of the Final Rule with respect to EPA's Designated Safe Uses.

CONCLUSION

Petitioners are entitled to the relief sought in their motion.

February 21, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply In Support of Motion for Partial Stay complies with the type-volume limitation of Federal Rule of Appellate Procedure because it contains 2,599 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: February 21, 2022

s/ Nash E. Long
Nash E. Long

CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2022, I electronically filed the foregoing 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. Parties may access this filing through the Court's system.

Dated: February 21, 2022

s/ Nash E. Long
Nash E. Long

EXHIBIT A

Declaration of Stephanie H. Stephens

Declaration of Stephanie H. Stephens

I, Stephanie H. Stephens, declare as follows:

1. I am currently a Principal Scientist at Exponent, Inc. (Exponent). I have worked on pesticide registration issues for consulting companies, pesticide industry, and the United States Department of Agriculture, Animal and Plant Health Inspection Service for 30 years. I am familiar with the facts set forth in this declaration and, if called as a witness, could and would testify competently to these facts under oath.

2. I am making this declaration on behalf of Petitioner Gharda Chemicals International, Inc. (Gharda) in support of Petitioners' Reply in Support of Petitioners' Motion for A Partial Stay Pending Review. I have reviewed Respondents' Opposition to Petitioners' Motion for A Partial Stay Pending Review, in which the U.S. Environmental Protection Agency (EPA) states that "Gharda is not without a remedy. . . . Gharda and the other registrants may at any time request voluntary cancellation or modification of its registrations and petition EPA to establish new tolerances." Resp. at 17. In my decades of experience

with pesticide registration issues, it is my opinion that this is not a viable remedy.

3. On behalf of Gharda, throughout 2021 and through January 2022, I attended numerous discussions between Gharda and personnel from EPA's Office of Pesticide Programs, Pesticide Re-Evaluation Division (EPA OPP PRD). Leading up to EPA's August 2021 Final Rule revoking all tolerances for chlorpyrifos (Final Rule), these discussions focused on a possible voluntary cancellation of selected chlorpyrifos uses and associated tolerances with retention of other crop uses and associated tolerances.

4. After EPA's Final Rule, PRD proposed to Gharda that Gharda could submit an application for new food use(s) and associated tolerance(s). The applicable registration package(s) would be prepared and submitted to EPA's Registration Division (RD), which is responsible for pesticides that are considered conventional chemicals, and would be subject to the fees and timing under the current fee-for-service provisions for pesticide registrations under the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4).[1] I believe this is the

[1] https://www.epa.gov/pria-fees.

regulatory "remedy" EPA's brief is referring to when it states that "Gharda . . . may at any time request voluntary cancellation or modification of its registrations and petition EPA to establish new tolerances." Resp. at 17.

5. In my experience, if Gharda were to submit an application for registration of food uses and associated tolerances while existing food uses and tolerances remained on the label (*i.e.*, before EPA revoked all tolerances and cancelled all food uses), it would take approximately 16 months from the time of submission of the application until possible EPA approval. EPA's fees for retaining U.S. food uses and associated tolerances would be approximately $525,000.

6. If Gharda were to submit applications for registration of new food uses and associated tolerances after EPA revoked all tolerances and cancelled all food uses, it would take approximately 38 months from the time of submission of the applications until possible EPA approval. EPA's fees for reestablishing U.S. food uses and associated tolerances would be approximately $875,000.

7. EPA's proposed path forward, whether done in advance of the cancellation of all food uses and associated tolerances or after all

food uses and associated tolerances are canceled, is not a viable remedy because of the significant timing and associated costs.

I, Stephanie H. Stephens, declare that the forgoing statements are true and correct to the best of my knowledge.

Dated: February 21, 2022

Stephanie H. Stephens

Stephanie H. Stephens