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. 22-1294

Respondents' Motion to Dismiss

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Code of Federal Regulations

Federal Registers

Legislative History

INTRODUCTION

Petitioners Red River Valley Sugarbeet Growers Association, *et al*. ("Petitioners"), seek judicial review of EPA's action entitled "Final Rule for Chlorpyrifos Tolerance Revocations," 86 Fed. Reg. 48,315 (Aug. 30, 2021) (hereinafter "Final Rule"), and of EPA's failure to act to stay the Final Rule, but this Court does not have jurisdiction over the petition. EPA issued the Final Rule under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), in response to an administrative petition, 21 U.S.C. § 346a(d)(4). Actions issued by EPA under § 346a(d)(4) are not immediately reviewable. Instead, Congress required that parties seeking to challenge such regulations first exhaust administrative remedies by filing objections with the Agency under 21 U.S.C. § 346a(g). Only *after* a party has exhausted its administrative remedies under § 346a(g) *and* EPA has issued a final order under § 346a(g)(2)(C) may the party seek judicial review of the order and any regulations subject to the final order. 21 U.S.C. § 346a(h)(1) (authorizing judicial review of "any order issued under [§ 346a(g)(2)(C)] . . . or any regulation that is the subject of such an order"). EPA has not issued its final order here, so this Court lacks jurisdiction to review the Petition.

Petitioners do not dispute that EPA has not issued a final order under § 346a(g)(2)(C) concluding the objections process. Moreover, Petitioners have not identified any statutory or regulatory authority that would allow them to

circumvent the limits Congress placed on jurisdiction under § 346a(h). It would be premature for this Court to consider the merits of EPA's Final Rule (or issue a stay as requested by Petitioners) before EPA issues its decision concluding the objections process, which EPA intends to do by February 28, 2022. Thus, the Petition for Review should be dismissed.

BACKGROUND

A. Statutory and Regulatory Background

The FFDCA authorizes EPA to establish "tolerances," which are maximum levels of pesticide residue allowed in or on food. 21 U.S.C. § 346a. Without a tolerance or exemption, pesticide residues in or on food are considered unsafe. *Id.* § 346a(a)(1). EPA "may establish or leave in effect a tolerance for a pesticide only if the Administrator determines that the tolerance is safe." *Id.* § 346a(b)(2)(A)(i). Conversely, EPA must "modify or revoke a tolerance if EPA determines that the tolerance is not safe." *Id.*

In 1996, Congress amended the FFDCA to create a new safety standard for pesticide residues, requiring EPA to determine that there is a "reasonable certainty that no harm will result" from "aggregate exposure" to pesticide chemical residues, including "all anticipated dietary exposures and other exposures" for which reliable information exists, in order to establish or leave a tolerance in effect. *Id.* § 346a(b)(2)(A)(ii). In addition, 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).

The FFDCA sets forth a detailed and specific process for establishing, modifying or revoking tolerances. EPA may promulgate a tolerance, on its own initiative, as a regulation under § 346a(e). Congress also authorized any person to petition EPA to issue a regulation "establishing, modifying, or revoking" a tolerance. *Id.* § 346a(d)(1)(A). In response to such a petition, EPA has several options. It may issue (1) a final regulation establishing, modifying, or revoking a tolerance; (2) a proposed regulation establishing, modifying, or revoking a tolerance; or (3) a denial of the petition. *Id.* § 346a(d)(4)(A)(i).

Congress further established an administrative process to consider objections to a regulation or an order issued under § 346a(d)(4) granting or denying a petition to establish, modify, or revoke a tolerance. Under § 346a(g)(2), any person may file written objections with EPA and may also request an evidentiary hearing on those objections. *Id.* § 346a(g)(2)(A)–(B). After considering any objections and holding any hearing, if deemed necessary, EPA must issue a final decision in the form of an order with respect to the objections. *Id.* § 346a(g)(2)(C).

Importantly, Congress provided specific requirements for judicial review of agency actions. It provided for exclusive judicial review in the United States courts of appeals of certain actions under the FFDCA. *Id.* § 346a(h). Most

important here, Congress delineated specific actions that are subject to judicial review, and EPA actions under § 346a(d)(4) responding to a petition to establish, modify, or revoke a tolerance are *not* directly reviewable. *See id*. Instead, Congress required parties aggrieved by such a petition response to first file an objection petition pursuant to Section 346a(g)(2)(C), and specified, as relevant here, that it is only EPA's final order responding to such an objections petition that is subject to judicial review (along with the regulation to which that final order relates). *Id.* § 346a(h)(1). Moreover, Congress precluded judicial review under any other provision of law as to issues that are reviewable under the FFDCA. *Id*. § 346a(h)(5). Finally, a party seeking judicial review must file a petition within 60 days of publication of the final order. *Id.* § 346a(h)(1).

B. Factual Background

1. *League of United Latin American Citizens v. Regan*

In 2007, several public interest groups including League of United Latin American Citizens ("LULAC") and others petitioned EPA under § 346a(d)(1) to revoke all existing chlorpyrifos tolerances. In 2017, EPA denied the LULAC petition after public comment. Like the Petitioners here, the LULAC petitioners prematurely sought judicial review of EPA's 2017 denial in the U.S. Circuit Court of Appeals for the Ninth Circuit. A panel of the Ninth Circuit vacated the 2017 petition denial and ordered EPA to revoke all chlorpyrifos tolerances within 60

days. *League of United Latin Am. Citizens v. EPA ("LULAC")*, 899 F.3d 814 (9th Cir. 2018). However, EPA sought rehearing en banc of the Ninth Circuit's decision on the grounds that the court lacked jurisdiction to review the 2017 denial pending an order concluding the statutorily-mandated objections process. *LULAC*, 914 F.3d 1189 (9th Cir. 2019). The Ninth Circuit granted rehearing en banc effectively vacating the panel's order. *LULAC*, 914 F.3d 1189 (9th Cir. 2019); *Advisory Committee Notes*, 9th Cir. R. 35-1 to 35-3. The Ninth Circuit sitting en banc treated the petition for review as one for mandamus relief and ordered EPA to respond to the objections to its 2017 denial within 90 days, without reaching any of the other issues in the case. *LULAC*, 922 F.3d 443 (9th Cir. 2019).

In 2019, EPA issued a final decision under § 346a(g)(2)(C) denying the LULAC petitioners' objections. In response, LULAC filed a petition for review of the 2019 order. At the outset of that proceeding, the Ninth Circuit sitting en banc dismissed the challenges to the 2017 denial as moot. *LULAC v. EPA*, 940 F.3d 1126, 1127 (9th Cir. 2019). Following briefing and oral argument on the merits of petitioners' challenges to EPA's denial of the original petition and the objections petition, on April 29, 2021, a Ninth Circuit panel vacated EPA's actions 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. EPA*, 996 F.3d 673, 680–700 (9th Cir. 2021). The court

instructed EPA to publish a final response to the 2007 petition within 60 days after the issuance of the court's mandate, without notice and comment. *Id.* at 702–703. The court further ordered that EPA's response "must be a final regulation that [1] either revokes all chlorpyrifos tolerances or [2] modifies chlorpyrifos tolerances *and* makes the requisite safety findings based on aggregate exposure, including with respect to infants and children." *Id.* at 703.

2. EPA's final rule revoking all tolerances for chlorpyrifos

On August 30, 2021, consistent with the court's order in *LULAC*, 996 F.3d at 703, EPA published the Final Rule in the Federal Register, revoking all tolerances for chlorpyrifos based on EPA's conclusion that aggregate exposures to chlorpyrifos were not safe. 86 Fed. Reg. 48,315. Petitioner Gharda and others filed objections to the Final Rule pursuant to 21 U.S.C. § 346a(g)(2)(A). EPA has not yet issued a final decision on the objections, although EPA intends to issue one by February 28, 2022. *See id.* § 346a(g)(2)(C); EPA's Opp. to Pets' Mot. to Stay, Decl. of Dr. M. E. Reaves at ¶ 25.

ARGUMENT

THE COURT LACKS JURISDICTION BECAUSE EPA HAS NOT ISSUED A FINAL DECISION UNDER 21 U.S.C. § 346a(g)(2)(C).

The Court should dismiss the petition and deny Petitioners' request for a stay because it lacks jurisdiction under the relevant FFDCA judicial review

provision, 21 U.S.C. § 346a(h). In § 346a(h), Congress did not authorize immediate judicial review for regulations like the Final Rule at issue here. Instead, Congress required that parties first file objections with the agency. *See id.* § 346a(g) (setting forth the objections process). Section 346a(h)(1) provides judicial review of regulations like the Final Rule only *after* a party has exhausted its administrative remedies *and* EPA has issued a final order under § 346a(g)(2)(C) on the objections. *Id.* § 346a(h)(1). Because, as explained below, § 346a(h)(1) says in "sweeping and direct" language that no jurisdiction exists until after EPA has issued a final order on an objection, a final order under § 346a(g)(2)(C) is a jurisdictional prerequisite and cannot be waived. *Ace Prop. & Cas. Ins. Co. v. Fed. Crop Ins. Corp.*, 440 F.3d 992, 996–97 (8th Cir. 2006). Further, Petitioners cannot evade the jurisdictional prerequisite of an order under § 346a(g)(2)(C) by fashioning their claim as one for mandamus relief.

A. The jurisdictional grant in 21 U.S.C. § 346(h)(1) extends only to a regulation that is the subject of an order under § 346(g)(2)(C).

As this Court has noted, whether "a statute requiring plaintiffs to exhaust administrative remedies" is jurisdictional depends on "the intent of Congress as evinced by the language used." *Ace*, 440 F.3d at 996. Only a statutory prerequisite that is "sweeping and direct" will be considered jurisdictional. *Id.* at 997 (quoting *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975)). If the language indicates either

that "there is no federal jurisdiction prior to exhaustion" or that exhaustion is "an element of the underlying claim," it is jurisdictional. *Id.* The text of § 346a(h) requires an order under § 346a(g)(2)(C) for federal jurisdiction to exist and thus sets forth a clear jurisdictional prerequisite.

Section 346a(h) provides:

> (1) Petition
>
> In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or *any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review* by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.
>
> (2) Record and jurisdiction
>
> * * * Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.
>
> * * *
>
> (5) Application
>
> Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

Id. § 346a(h).

Section 346a(h)(1) makes clear that the only actions subject to judicial review include: (1) "any regulation issued under subsection (e)(1)(C), or (2) any order issued under subsection (f)(1)(C) or (g)(2)(C), or (3) any regulation that is the subject of such an order." *Id*. at § 346a(h)(1). *See Natural Res. Def. Council v. Johnson*, 461 F.3d 164, 172 (2d Cir. 2006) (the FFDCA "contains no single, overarching provision governing judicial review—instead subjecting discrete agency actions to specialized review provisions.") (quotations omitted). Congress carefully enumerated those actions that are subject to exclusive judicial review under § 346a(h)(1), making clear that a regulation issued under § 346a(d)(4)(i) in response to a petition, such as the Final Rule, is not included unless it is the subject of an order under § 346a(g)(2)(C). As the Supreme Court has stressed, when a statute names only specific agency actions for judicial review, "[c]ourts are required to give effect to Congress' express inclusions and exclusions, not disregard them." *Nat'l Ass'n of Mfrs. v. DOD*, 138 S. Ct. 617, 631 (2018). Thus, an order under § 346a(g)(2) concluding the objections process is required before a court may exercise jurisdiction.

Additional textual signals in § 346a(h) confirm Congress's clear intent to limit a court's jurisdiction. Section 346a(h) is entitled "Judicial Review." Subsection (h)(1) expressly identifies which orders and regulations may be the

subject of a petition for review and does not include actions under § 346a(d)(4). Additionally, subsection (h)(2), captioned "Record and jurisdiction," makes "the filing of such a petition"—*i.e.*, a petition for review of an order specifically enumerated in section 346a(h)(1)—an express condition of the Court's exercise of "exclusive jurisdiction." Lastly, § 346a(h)(5) states that "[a]ny issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law."

Aside from its plain text, the legislative history of the FFDCA shows that Congress's choice to exclude from judicial review regulations establishing, modifying, or revoking a tolerance *except* those that are the subject of an order under § 346a(g)(2)(C) was intentional. Prior versions of the FFDCA permitted certain actions by EPA to be subject to *either* further administrative review or judicial review. *See* 21 U.S.C. § 346a(e), (i) (1982) (revised in 1996); *see Nat'l Coal. Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 879 (D.C. Cir. 1987) (quoting 21 U.S.C. § 346a(e) (1982 version)). In 1996, Congress amended the statute in the Food Quality Protection Act and eliminated the opportunity for judicial review without the completion of the administrative process. Food Quality Protection Act of 1996, Pub. L. No. 104–170, 110 Stat. 1489, 1525.

Analyzing the FFDCA's amended jurisdictional provision, the Second Circuit in *Johnson* recognized its carefully constructed limiting language:

> By specifically referencing Section 346a(g)(2)(C), Section 346a(h)(1) permits review of those orders issued pursuant to Section 346a(g). Section 346a(g), in turn, permits objections to orders issued pursuant to Section 346a(d)(4), which resolve petitions to establish, modify, or revoke a tolerance under Section 346a(d)(1). Thus, *if it is or was possible to obtain review under the administrative review procedures of Section 346a(g), then Section 346a(h) limits judicial review to the courts of appeals and forecloses such review prior to the exhaustion of administrative remedies*.

461 F.3d at 173 (emphasis added).

Although a Ninth Circuit panel reviewing a premature challenge to EPA's 2017 denial of the initial 2007 petition to revoke chlorpyrifos concluded that § 346a(h)'s exhaustion requirements were not jurisdictional, that decision was effectively vacated by an order granting rehearing en banc. *LULAC*, 914 F.3d 1189 (9th Cir. 2019); *Advisory Committee Notes*, 9th Cir. R. 35-1 to 35-3; *see also In re Pesticide Action Network of N. Am.*, 863 F.3d 1131, 1132-33 (9th Cir. 2017) (recognizing § 346a(h)'s exhaustion requirements). The plain text of § 346a(h) demonstrates that a final order under § 346a(g)(2)(C) is a jurisdictional prerequisite.

Because EPA has not yet issued an order under § 346a(g)(2)(C), this Court lacks subject-matter jurisdiction and the petition should be dismissed.

B. Petitioners provide no basis for this Court to ignore the express limits on jurisdiction.

Petitioners do not appear to dispute that § 346a(h)(1) limits judicial review to only those regulations that are the subject of a final order under § 346a(g)(2)(C).

See Petition for Review ("Pet.") at 30, Dkt ID # 5126162 (acknowledging that it is EPA's "final decision" under § 346a(g)(2)(C) that "an objector may challenge in court"). Indeed, by seeking mandamus relief, Petitioners tacitly admit that this Court lacks jurisdiction to review the Final Rule absent an order under § 346a(g)(2)(C) on the pending objections. Nonetheless, they argue that the Court should ignore the express limitations of § 346a(h)(1) because awaiting EPA's final order under § 346a(g)(2)(C) would "foreclose[e] judicial review" of the revocation of the tolerances, exhaustion would be futile, and petitioners would be irreparably harmed. Pet. at 30. None of Petitioners' arguments provides a basis for this Court to ignore § 346a(h)(1)'s jurisdictional prerequisite of an order under § 346a(g)(2)(C), as subject-matter jurisdiction cannot be waived. Even if the exhaustion requirement in § 346a(h)(1) is not jurisdictional, however, it is still a statutorily mandated claims-processing rule that must be enforced, if raised, as is the case here. *United States v. Houck*, 2 F.4th 1082, 1084 (8th Cir. 2021).

The requirement that a party wishing to challenge a regulation issued under § 346a(d)(4) obtain an order under § 346(g)(2)(C) is not a mere procedural step. Rather, the jurisdictional grant in § 346a(h)(1) authorizing review of a "regulation" is limited to a "regulation that is subject to such an order" under § 346a(g)(2)(C). In other words, it is only a regulation subject to an order under § 346a(g)(2)(C) that is among the "classes of [actions] . . . falling within a court's adjudicatory

authority." *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004) (discussing jurisdiction). Absent an order under § 346a(g)(2)(C), the Final Rule is simply not within the FFDCA's jurisdictional grant and subject-matter jurisdiction is lacking.

As already discussed, Congress made clear in express terms that judicial review of any order or regulation issued pursuant to the FFDCA's petition process would have to await the conclusion of the administrative objections process. Therefore, Petitioners' contention that awaiting a final order concluding the objections process would "foreclose" judicial review is a non sequitur. Section 346a(h)(1) provides for judicial review of the Final Rule *after* the conclusion of the objections process, upon the issuance of an order under § 346a(g)(2)(C). And EPA intends to issue that order by the end of this month, at which point Petitioners will have an opportunity for judicial review.

Petitioners' reliance on the D.C Circuit's decision in *Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017), invokes another inapt comparison. *See* Pet. at 11. In that case, the D.C. Circuit held that EPA had erred by granting a stay of a final rule issued under the Clean Air Act because it concluded that EPA had exceeded the limits that Congress had placed on such stays. Here, it is Petitioners who are trying to compel the Court to issue a stay of the Final Rule in contravention of Congress's clearly expressed intent that judicial review should

await a final decision by EPA concluding the administrative process. Neither the FFDCA nor the decision in *Clean Air Council* supports Petitioners' position.[1]

Nor can Petitioners' claim that § 346a(h)'s express jurisdictional limits can be waived because requiring exhaustion would be futile. As noted, even if § 346a(h)(1)'s exhaustion requirement were not jurisdictional, it would still be a mandatory claims processing rule that should be enforced. *See Houck*, 2 F.4th at 1084–85. Even if the Court could waive the mandatory exhaustion requirement in § 346a(h)(1), an administrative remedy is futile only "if there is doubt about whether the agency could grant effective relief." *Ace*, 440 F.3d at 1000. The question is not whether the agency *will* grant relief, but whether it could grant effective relief. Petitioners do not dispute that EPA has the authority to resolve objections under the FFDCA and that a stay or modification of the Final Rule would resolve their concerns. Thus, Petitioners cannot claim futility.

Insofar as Petitioners contend that they are seeking review of EPA's failure to respond to their administrative objections and stay request, that does not provide a route around § 346a(h)(1)'s express jurisdictional prerequisite of an order under

---

[1] Nor are Petitioners aided by their reference to FDA regulations that EPA looks to for evaluating stay requests under the FFDCA. *See* Pet. at 12 n.5. Under 21 C.F.R. § 10.45(d), the agency's final decision on a stay request is a final, reviewable action. EPA has not yet issued a final decision on the administrative stay request pending before it, and therefore there is no "final action" for this Court to review.

§ 346a(g)(2)(C) either. *See Degnan v. Burwell*, 765 F.3d 805, 810 (8th Cir. 2014) (denying mandamus jurisdiction where the claimants could seek relief by exhausting their administrative remedies) (citation omitted). These limits would be meaningless if a party could avoid them merely by arguing that the agency failed to act to grant administrative relief. EPA has not unreasonably delayed in responding to objections to the Final Rule, which was only issued in August 2021. Although EPA has not yet issued an order in response to the objections, it intends to do so by February 28, 2022.[2] *See* Reaves Decl. at ¶ 25.

CONCLUSION

Because a final rule under 21 U.S.C. § 346a(d)(4)(A)(i) is not within the jurisdiction of this Court to review until EPA issues a final decision under § 346a(g)(2), which it has not done, the Court must dismiss the petition. Even if § 346a(h)(1)'s exhaustion requirement is not jurisdictional, it is still a mandatory statutory requirement that should be enforced and Petitioners fail to show otherwise.

[2] EPA reserves the right to file a further response to Petitioners' request for mandamus if the Court orders a response. 8th Cir. R. 21A; Fed. R. App. P. 21.

Respectfully submitted,

/s/ *Laura Glickman*

TODD KIM
Assistant Attorney General
LAURA GLICKMAN
JESSICA O'DONNELL
Attorneys
Environment and Natural Resources Division
U.S. Department of Justice
Post Office Box 7411
Washington, D.C. 20044
(202) 514-6390
Fax: (202) 514-8865
laura.glickman@usdoj.gov

/s/ *Joshua M. Jones*

SAYLER A. FLEMING
United States Attorney
JOSHUA M. JONES, # 61988MO
Assistant United States Attorney
Thomas F. Eagleton U.S. Courthouse
111 South Tenth Street, 20th Floor
St. Louis, MO 63102
(314) 539-2310
Fax: (314) 539-2287
joshua.m.jones@usdoj.gov

Of Counsel:

ANGELA HUSKEY
AARON NEWELL
Attorneys
U.S. Environmental Protection Agency

February 18, 2022
DJ #1-22091

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 3,611 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