No. 17-71636

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, et al.,

Petitioners,

STATE OF NEW YORK, et al.,

Petitioner-Intervenors,

v.

ANDREW WHEELER, Acting Administrator, United States Environmental Protection Agency, and THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

ON PETITION FOR JUDICIAL REVIEW OF ACTION BY THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

# PETITION FOR *EN BANC* AND PANEL REHEARING

JEFFREY H. WOOD
*Acting Assistant Attorney General*
JONATHAN D. BRIGHTBILL
*Deputy Assistant Attorney General*

PHILLIP R. DUPRÉ
ERICA M. ZILIOLI
*Attorneys, Environmental Defense Section*
*Environment and Natural Resources Div.*
*U.S. Department of Justice*
*P.O. Box 7611*
*Washington, D.C. 20044*
*(202) 616-7501 (Dupré)*
*(202) 514-6390(Zilioli)*
*phillip.r.dupre@usdoj.gov*
*erica.zilioli@usdoj.gov*

*Of Counsel:*
MARK DYNER
*Office of the General Counsel*
*U.S. Environmental Protection Agency*
*William Jefferson Clinton Building, North*
*1200 Pennsylvania Ave., N.W.*
*Washington, D.C. 20460*

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## INTRODUCTION

Respondents United States Environmental Protection Agency ("EPA") and Acting EPA Administrator Andrew Wheeler hereby seek *en banc* and panel rehearing of the Court's August 9, 2018, decision. The decision granted the petition for review of EPA's order entitled "Chlorpyrifos: Order Denying PANNA and NRDC's Petition to Revoke Tolerances," 82 Fed. Reg. 16,581 (Apr. 5, 2017) (hereinafter "Initial Denial Order"). It then directed EPA to revoke the tolerances and cancel the pesticide registrations for chlorpyrifos.

In counsel's judgment, the purposes for rehearing are met here. First, EPA seeks rehearing *en banc* or panel rehearing on the panel's finding of jurisdiction to review the agency action. The Initial Denial Order is not an action Congress granted jurisdiction to review. On this point, the "panel decision conflicts with a decision of [this court] . . . and consideration by the full court is therefore necessary to secure and maintain uniformity of the court's decisions." Fed. R. App. P. 35(b)(1)(A). Specifically, the panel's decision conflicts with *In re PANNA*, 863 F.3d 1131 (9th Cir. 2017), and *Nader v. EPA*, 859 F.2d 747 (9th Cir. 1988).

Second, EPA seeks *en banc* or panel rehearing on the panel's remedy directing EPA to take specific actions upon vacatur of the Initial Denial Order. The "panel decision conflicts with a decision of the United States Supreme Court . . . and consideration by the full court is therefore necessary to secure and maintain uniformity of the court's decisions." Fed. R. App. P. 35(b)(1)(A). The panel's order

limiting EPA's options on remand conflicts with Supreme Court precedent holding that where an agency's order is not sustainable on the record, a court should vacate the underlying decision and remand for further consideration by the agency, rather than directing specific action. *See Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952) ("[T]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the Commission for reconsideration."); *see also Camp v. Pitts*, 411 U.S. 138, 143 (1973).

Third, in the event the Court's decision is not reversed in its entirety, EPA seeks panel rehearing on the requirement that EPA cancel chlorpyrifos registrations under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). The panel "overlooked or misapprehended," Fed. R. App. P. 40(a)(2), that EPA's revocation of tolerances under the Federal Food, Drug, and Cosmetic Act ("FFDCA") would not necessitate cancellation of all registrations under FIFRA. The Court's order to do so also conflicts with procedural requirements governing cancellation of registrations under FIFRA. Accordingly, the Court should either rescind or narrow any relief pursuant to FIFRA.

## BACKGROUND

### I. Statutory and Regulatory Background

EPA regulates pesticides under both the FFDCA and FIFRA. The FFDCA authorizes the establishment of "tolerances," which set maximum levels of pesticide residue in food. 21 U.S.C. § 346a. Without a tolerance, pesticide residues on food are

considered unsafe. *Id.* § 346a(a). EPA may establish a tolerance only if it determines that the tolerance is "safe,"[1] but it must modify or revoke a tolerance if the tolerance is not "safe." *Id.* § 346a(b)(2)(A)(i).

The FFDCA contains a multi-step process for the establishment, modification, or revocation of tolerances. When an administrative petition to establish, modify, or revoke a tolerance is filed, EPA must give "due consideration" to that petition and take one of three actions: (i) issue a final regulation establishing, modifying, or revoking a tolerance; (ii) issue and take comments on a proposed regulation under section 346a(e) and thereafter issue a final regulation; or (iii) issue an initial order denying the petition. *Id.* § 346a(d)(4)(A).

When EPA issues a regulation or initial order under section 346a(d)(4)(A), "any person" may then file written objections with EPA under section 346a(g). *Id.* § 346a(g)(2)(A)-(B). After considering any objections and any hearing, if held, EPA must issue a final order resolving the objections. This order encapsulates its "*[f]inal decision*," *id.* § 346a(g)(2)(C) (emphasis added), which is subject to judicial review in the courts of appeals, *id.* § 346a(h). "Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order . . . ." *Id.* § 346a(h)(2).

FIFRA requires EPA registration of all pesticides prior to their distribution or sale. 7 U.S.C. § 136a(a). EPA must approve an application for a pesticide registration

[1] "Safe" means "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue . . . ." 21 U.S.C. § 346a(b)(2)(A)(ii).

if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(D), defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" *and—if* pesticides are used on food crops—the FFDCA safety standard. 7 U.S.C. § 136(bb). Thus, EPA considers the FFDCA's safety standard under FIFRA when assessing registration of a pesticide for food uses. EPA does not address that standard when registering pesticides with only non-food uses.

Congress established the procedures for involuntary cancellation of a registration in FIFRA, 7 U.S.C. § 136d(b). Under that provision, EPA must first provide the U.S. Department of Agriculture and the FIFRA Scientific Advisory Panel with an opportunity to review a draft notice of intent to cancel and then wait at least 60 days before issuing that notice. 7 U.S.C. § 136d(b). That notice provides registrants and others with an opportunity to request an adjudicatory hearing before cancellation becomes effective. *See id.* § 136d(b), (d); 40 C.F.R. Part 164 subpart B.

## II. Procedural History

In 2007, Pesticide Action Network of North America ("PANNA") and Natural Resources Defense Council ("NRDC") petitioned EPA to revoke all FFDCA tolerances and cancel all FIFRA registrations for chlorpyrifos (hereinafter the "Administrative Petition"). 82 Fed. Reg. at 16,583. EPA then resolved some of the claims raised. *Id.* at 16,583. In September 2014, PANNA and NRDC filed a petition

for a writ of mandamus to force EPA to respond to the remaining claims. *See generally In re PANNA*, No. 14-72794 (9th Cir.). This Court ordered EPA to "issue either a proposed or final revocation rule or a full and final response" to the Administrative Petition by October 31, 2015. *In re PANNA*, 798 F.3d 809, 815 (9th Cir. 2015). In November 2015, EPA proposed to respond to the Administrative Petition by "revok[ing] all chlorpyrifos tolerances . . . ." 82 Fed. Reg. at 16,583. The Court then ordered EPA to take final action by March 31, 2017. *In re PANNA*, 808 F.3d 402, 402-03 (9th Cir. 2015); *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016).

On March 29, 2017, EPA took action. It denied the Administrative Petition pursuant to 21 U.S.C. § 346a(d)(4)(A)(iii). 82 Fed. Reg. at 16,581. PANNA and NRDC then moved for further relief in the mandamus action. *In re PANNA*, Case No. 14-72794, Dkt. No. 55-1 (Apr. 5, 2017). This Court denied the motion. "Now that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by [the FFDCA]." *In re PANNA*, 863 F.3d 1131, 1132-33 (9th Cir. 2017) (citations omitted). Once EPA issues a final order, only then can the Court "consider the merits of EPA's 'final agency action.'" *Id.*

On June 5, 2017, Petitioners filed this Petition for Review. On the same day, Petitioners filed with EPA administrative objections to the Initial Denial Order pursuant to 21 U.S.C. § 346a(g)(2)(A).

## III. Panel Opinion

The panel's divided August 9, 2018, opinion, written by Judge Rakoff, sitting by designation, had three substantive rulings relevant to this rehearing request. *First*, the Court held it had jurisdiction to review EPA's Initial Denial Order. *Second*, on the merits of Petitioners' challenge to the Initial Denial Order, the Court held that EPA had acted unlawfully in maintaining the tolerances for chlorpyrifos because the Initial Denial Order did not make an affirmative safety finding (as the Court concluded was required by the FFDCA), instead finding "significant uncertainty" as to the pesticide's health effects. Slip Op. at 31. *Third*, as to remedy, the Court ordered without substantive discussion that "[t]he EPA's 2017 Order maintaining chlorpyrifos is VACATED, and the case is remanded to the EPA with directions to revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days." Slip Op. at 32.

Judge Fernandez dissented, stating he would dismiss the petition for review for lack of jurisdiction. Slip Op. at 40.

# ARGUMENT

## I. *En Banc* or Panel Rehearing Should Be Granted to Reverse the Panel's Finding of Jurisdiction.

Congress only authorized judicial review of specific agency actions in the FFDCA. *See NRDC v. Johnson*, 461 F.3d 164, 172 (2d Cir. 2006) ("[T]he [F]FDCA contains no single, overarching provision governing judicial review—instead subjecting discrete agency actions to specialized review provisions.") (quotations

omitted). Only EPA's "[f]inal decision," following an objections process in 21 U.S.C. § 346a(g), is subject to judicial review. *Id.* § 346a(h)(1). For those decisions, "the court shall have exclusive jurisdiction to affirm or set aside" the actions. *Id.* § 346a(h)(2). But no language of the FFDCA grants jurisdiction to review an order issued under section 346a(d)(4)—such as the Initial Denial Order here—either before or after the administrative objections process. *See id.*

The FFDCA specifically identifies the administrative actions subject to judicial review: "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." *Id.* § 346a(h)(1). For those actions, an "adversely affected" party may petition the courts of appeals "praying that the order or regulation be set aside . . . ." *Id.* The FFDCA does not grant jurisdiction to review orders issued under section 346a(d)(4), such as the Initial Denial Order. Therefore, there is simply no jurisdiction for review. 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).

The panel's conclusion that section 346a(h)(1) "lacks mandatory language with 'jurisdictional import,'" Slip Op. at 19 (quoting *Sebelius v. Auburn Reg'l Med. Ctr*, 568 U.S. 145, 154 (2013)), is facially at odds with the text of the statute. First, section 346a(h) is entitled "Judicial review." Second, section 346a(h)(1) specifically identifies

which orders may be the subject of a petition for review, and does not include orders issued under section 346a(d)(4). Third, section 346a(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, section 346a(h)(5) states that "[a]ny issue as to which review is or was obtainable under this subsection shall not be subject to judicial review under any other provision of law." Nowhere does the FFDCA provide any jurisdiction for this Court to review a denial order issued under section 346a(d)(4).

Judge Fernandez, in his dissent, explained these jurisdictional requirements:

> Here Congress was very careful and very specific about the class of cases— the limited kind of orders—over which it wished to give the courts of appeals direct review. It made it plain that we could not review the EPA's actions in this specific area until the agency had developed and considered a full record regarding objections and the like. Before that occurred, judicial review was not available; we had no authority whatsoever to consider the issue.

Slip Op. at 36-37.

The Second Circuit similarly recognized the FFDCA's jurisdictional requirements in *Johnson*:

> 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. Although the panel was correct that this was dictum, Slip Op. at 21, "given the extensive analysis of the statute . . . , it is rather persuasive *dictum*." *Matter of Clark*, 738 F.2d 869, 874 n.6 (7th Cir. 1984).

Moreover, the panel's conclusion also conflicts with a prior decision by this Court. *Nader* involved a materially identical judicial review provision under a prior version of the FFDCA.[2] *See* 859 F.2d at 751-52. As here, *Nader* addressed EPA's initial denial of an administrative petition to revoke tolerances.[3] Petitioners sought judicial review of EPA's initial denial order without first going through the administrative objections process. *Id.* at 751. This Court found it lacked jurisdiction to review the initial denial order:

> If the party seeks to invoke judicial review under § 348(g), however, objection under § 348(f) is a prerequisite. By its plain terms, section 348(g) permits judicial review in this court only of orders issued under subsection (f). Subsection (f) permits persons adversely affected by the denial of a petition to file objections with the Administrator and seek a hearing. *The jurisdiction of the court encompasses orders pertaining to administrative objections*, *not the grant or denial of the petition in the first instance*. Had Congress intended to permit direct review of petition denials, it would have

[2] Respondents did not cite *Nader* in their brief, nor was it addressed by the Panel.
[3] *Nader* addressed a prior version of the FFDCA, wherein EPA set tolerances for raw agricultural commodities under 21 U.S.C. § 346a and tolerances for processed food under 21 U.S.C. § 348. When Congress amended the FFDCA in 1996, it collapsed EPA's tolerance-setting authority into a single section (§ 346a, as amended), and imported the administrative objections and judicial review provisions in then-section 348(f) and (g) into the current version of section 346a(g) and (h). *See* 21 U.S.C. § 348(f), (g) (1994), attached at Addendum page A48.

> conferred jurisdiction over orders issued under subsection (c). Subsection (f) would have been superfluous.

*Id.* at 751–52 (emphasis added).

This Court similarly recognized in the antecedent mandamus case that a section 346a(g)(2)(C) order is a necessary prerequisite for judicial review:

> Now that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute. *See* 21 U.S.C. §§ 346a(g)(2), (h)(1); 40 C.F.R. §§ 178.65, 180.30(b). PANNA implicitly recognizes as much by acknowledging that "[f]iling objections *and awaiting their resolution* by the EPA Administrator is a prerequisite to obtaining judicial review" of EPA's final response to the petition. *Only at that point may we consider the merits* of EPA's "final agency action." *See* 5 U.S.C. § 704.

*In re PANNA*, 863 F.3d 1131, 1132-33 (9th Cir. 2017) (emphasis added; some citations omitted).

The panel, however, mistakenly classified the administrative exhaustion requirements in the FFDCA as claims-processing rules. These simply "'require[] that the parties take certain procedural steps at certain specified times.'" Slip Op. at 15 (quoting *Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 435 (2011)). But, unlike section 346a(h)(2) ("the court shall have exclusive jurisdiction to affirm or set aside the order"), those claims-provisions did "not speak in jurisdictional terms or refer in any way to jurisdiction." *Henderson*, 562 U.S. at 438 (quotation omitted). And "obtaining a (g)(2)(C) order," Slip Op. at 17, under the FFDCA is not a mere "procedural step," *id.* at 15. Rather, the resulting (g)(2)(C) order from the objections process is *itself* the action subject to judicial review. Thus, a section 346a(g)(2)(C)

order—as distinguished from a section 346a(d)(4) order—is one of the "classes of [orders] . . . falling within a court's adjudicatory authority." *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004) (discussing jurisdiction).

Indeed, the FFDCA's jurisdictional bar on review of initial denial orders under section 346a(d)(4) is far afield from cases involving true claims-processing rules. Claims-processing rules include statutory deadlines that encourage parties to timely assert their rights. *See* Slip Op. at 18 (citing *Henderson*, 562 U.S. at 438 (180-day deadline to file appeal not jurisdictional), and *Auburn Reg'l Med. Ctr*, 568 U.S. at 154 (same)). But in both *Henderson* and *Auburn Regional Medical Center*, there was no question as to *what* decision was subject to review and whether it could be reviewed *if* timely filed. The issue was whether missing those deadlines would strip the reviewing body of jurisdiction. Here, by contrast, the panel reviewed and set aside an agency action that the Court is not authorized to review under *any* circumstances.[4]

Because an initial decision denying an administrative petition under 21 U.S.C. § 346a(d)(4)(A)(iii) is simply not within the jurisdiction of this Court to review and the panel's decision is inconsistent with this circuit's precedent, rehearing *en banc* is appropriate.

[4] The panel also erred by relying on cases addressing whether exhaustion requirements under one statute prevented a court from exercising jurisdiction under another statute because here, there is no provision granting jurisdiction under another statute. *See* Slip Op. at 18, 20 (citing *Payne v. Peninsula School Dist.*, 653 F.3d 863, 872 (9th Cir. 2011) (*en banc*) and *Verizon Maryland Inc. v. PSC*, 535 U.S. 635 (2002)).

## II. *En Banc* or Panel Rehearing Should Be Granted to Reverse the Panel's Decision Directing EPA to Take Specific Actions.

The panel ultimately ordered EPA to take specific actions—i.e., revoke all FFDCA tolerances for chlorpyrifos pursuant to 21 U.S.C. § 346a(d)(4)(A) and cancel all FIFRA registrations pursuant to 7 U.S.C. § 136d(b). These specific directions limiting EPA's discretion on remand, in the context of these statutes, exceeded the remedial authority granted the courts by Congress. Instead, the panel should have vacated the Initial Denial Order and remanded for further proceedings.

The Supreme Court has repeatedly held that agency action found unlawful should simply be vacated and remanded to the agency for further consideration. *See, e.g.*, *Federal Power Comm'n*, 344 U.S. at 20; *Pitts*, 411 U.S. at 143. The Supreme Court further explained:

> If the record before the agency does not support the agency action [or] if the agency has not considered all relevant factors . . . , the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.

*Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

Indeed, the FFDCA itself expressly limits the remedy this Court may order. "Upon the filing of such a petition, the court shall have exclusive jurisdiction *to affirm or set aside* the order or regulation complained of . . . ." 21 U.S.C. § 346a(h)(2) (emphasis added). This is also the approach to remedy envisioned by the Administrative Procedure Act, which provides the standard of review in this matter.

*See* 5 U.S.C. § 706(2) (reviewing court may "hold unlawful and set aside agency action"); *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008) (standard of review for FFDCA challenges is provided by the APA). Under the APA, "[w]hen a court determines that an agency's action failed to follow Congress's clear mandate the appropriate remedy is to vacate that action." *Cal. Wilderness Coal. v. Dep't of Energy*, 631 F.3d 1072, 1095 (9th Cir. 2011).

The panel erred by directing EPA to take specific actions—revocation of the FFDCA tolerances and cancellation of the FIFRA registrations—within 60 days upon remand. Slip Op. at 32. After a record-based remand such as this, the FFDCA leaves EPA the authority to issue, consistent with the holding of the Court and any further record to be developed, a new or revised response to the Administrative Petition under section 346a(d)(4).[5] For example, rather than a blanket revocation of all tolerances, the FFDCA gives EPA the discretion to deny the petition if finding the FFDCA's safety standard was met. Or, if warranted by a revised safety finding, EPA might merely reduce some or all of the tolerances, or revoke only some of the tolerances. Whatever order or regulation EPA issues would then be subject to objections and requests for hearing pursuant to section 346a(g)(2). Where tolerances are revoked, EPA would separately consider whether cancellation of any—or only

[5] EPA intends to issue a revocation order under section 346(d)(4) if rehearing is denied.

some—of the FIFRA registrations was warranted under the standards applicable to that statute. *See* § III, *supra*.

The panel was merely empowered to vacate the Initial Denial Order and remand for further consideration in light of the panel's holding that EPA may not "decline[] to revoke chlorpyrifos tolerances [without] mak[ing] a finding of reasonable certainty that the tolerances were safe." Slip Op. at 31. Its overbroad order that EPA categorically revoke all tolerances and registrations—issued without any consideration of the statutory scheme or briefing on proper remedy—justifies rehearing.

## III. If Broader Rehearing Is Not Granted, Panel Rehearing Should Be Granted to Modify the Relief Ordered Under FIFRA.

Although the panel found EPA's Initial Denial Order deficient only under the FFDCA, it also ordered EPA to cancel all registrations for chlorpyrifos under FIFRA within 60 days. Slip Op. at 32. The panel reasoned that "[c]hlorpyrifos similarly does not meet the statutory requirement for registration under FIFRA [because FIFRA] incorporates the FFDCA's safety standard." Slip Op. at 32. This is an inaccurate—or at least incomplete—statement. FIFRA incorporates the safety standard of the FFDCA only with respect to *food-use* pesticides. And even where the FFDCA safety standard is applicable under FIFRA, automatic cancellation is not required. Accordingly, at a minimum, the panel should reconsider the remedy—upon which it received no briefing—and decline to order specific actions under FIFRA.

First, the panel could not order revocation under FIFRA on this record. Petitioners argued—and the Court held—that the Initial Denial Order failed to meet the required safety finding under the FFDCA. Even assuming the Court appropriately ordered revocation of the tolerances under the FFDCA, the Court failed to identify any authority to directly order cancellation of the registrations under FIFRA. Before that could occur, EPA must first implement the procedures that apply under FIFRA before cancelling a registration. Specifically, when revoking a tolerance, 21 U.S.C. § 346a(l)(1) directs EPA to coordinate that revocation with any necessary action under FIFRA. EPA has several options and could "seek voluntary cancellation of those uses or amendment of those registrations or may initiate cancellation under section 6 [of FIFRA]." Guilaran Decl. ¶ 6 (attached at A53). The propriety of these alternatives was not before the panel, nor are they foreclosed by its reasoning.

Second, FIFRA precludes EPA from lawfully cancelling registrations within 60 days, as ordered by the panel. FIFRA "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011). EPA must allow the U.S. Department of Agriculture and the FIFRA Scientific Advisory Panel to review any notice of cancellation for 60 days. 7 U.S.C. § 136d(b). And any cancellation does not become effective for 30 days—during which time the registrant may attempt to cure the problem or a person adversely affected may request a formal adjudicatory hearing. *See id.* § 136d(b), (d).

Third, the panel's remedy—premised on an application of the FFDCA's safety standard to FIFRA—was overbroad. Revocation of tolerances under the FFDCA could provide a foundation for cancelling registrations for food uses under FIFRA. But it does not require cancellation of the remaining registrations for non-food uses, such as mosquito control, fire ant mounds, or sod farms. EPA may cancel a pesticide registration when it finds that the pesticide would have "unreasonable adverse effects on the environment," which means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, *or* (2) where use of the pesticide results in residues on food that are unsafe under the FFDCA. 7 U.S.C. § 136(bb).

The first part of the FIFRA definition is the so-called "risk-benefit" standard, which requires EPA to do risk-benefit balancing in deciding whether to register pesticides. That standard is not the same as the FFDCA's "risk only" food safety standard, which applies only to food-use pesticides. Chlorpyrifos products are registered for both food and non-food uses.[6] Accordingly, the Court should not have simply applied the FFDCA standard to conclude that all chlorpyrifos registrations are inconsistent with FIFRA. Instead, the appropriate standard for assessing non-food use pesticides is the "risk-benefit" standard. That was not

[6] Walsh Declaration ¶ 5 (28 chlorpyrifos pesticide products are registered exclusively for non-food uses), attached at A57-58.

before the panel, which should not have extended its ruling to affect non-food use pesticides for which tolerance revocation is not relevant.

## CONCLUSION

For the foregoing reasons, rehearing should be granted.

Respectfully submitted,

JEFFREY H. WOOD
*Acting Assistant Attorney General*
JONATHAN D. BRIGHTBILL
*Deputy Assistant Attorney General*

s/Phillip R. Dupre
PHILLIP R. DUPRÉ
ERICA M. ZILIOLI
*Attorneys, Environmental Defense Section*
*Environment and Natural Resources Div.*
*U.S. Department of Justice*
*P.O. Box 7611*
*Washington, D.C. 20044*
*(202) 616-7501 (Dupré)*
*(202) 514-6390(Zilioli)*
*phillip.r.dupre@usdoj.gov*
*erica.zilioli@usdoj.gov*

*Of Counsel:*
MARK DYNER
*Office of the General Counsel*
*U.S. Environmental Protection Agency*
*William Jefferson Clinton Building, North*
*1200 Pennsylvania Ave., N.W.*
*Washington, D.C. 20460*

SEPTEMBER 24, 2018

**CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)**

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Circuit Rule 40-1(a) because it contains **4,179** words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/Phillip R. Dupré
PHILLIP R. DUPRÉ

## CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on September 24, 2018. I certify that all participants in the case registered as CM/ECF users will receive service via the appellate CM/ECF system.

s/ Phillip R. Dupré
PHILLIP R. DUPRÉ

# ADDENDUM

**FOR PUBLICATION**

# UNITED STATES COURT OF APPEALS
# FOR THE NINTH CIRCUIT

| | |
|---|---|
| LEAGUE OF UNITED LATIN AMERICAN CITIZENS; PESTICIDE ACTION NETWORK NORTH AMERICA; NATURAL RESOURCES DEFENSE COUNCIL; CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION; FARMWORKERS ASSOCIATION OF FLORIDA; FARMWORKER JUSTICE GREENLATINOS; LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATIONAL HISPANIC MEDICAL ASSOCIATION; PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE; UNITED FARM WORKERS,<br>*Petitioners*,<br><br>STATE OF NEW YORK; STATE OF MARYLAND; STATE OF VERMONT; STATE OF WASHINGTON; COMMONWEALTH OF MASSACHUSETTS; DISTRICT OF COLUMBIA; STATE OF CALIFORNIA; STATE OF HAWAII,<br>*Intervenors*,<br><br>v. | No. 17-71636<br><br>OPINION |

ANDREW WHEELER, Acting Administrator of the U.S. Environmental Protection Agency; and U.S. ENVIRONMENTAL PROTECTION AGENCY,

*Respondents.*

On Petition for Review of an Order of the Environmental Protection Agency

Argued and Submitted July 9, 2018
Seattle, Washington

Filed August 9, 2018

Before: Ferdinand F. Fernandez and Jacqueline H. Nguyen, Circuit Judges, and Jed S. Rakoff,* District Judge.

Opinion by Judge Rakoff;
Dissent by Judge Fernandez

* The Honorable Jed S. Rakoff, United States District Judge for the Southern District of New York, sitting by designation.

## SUMMARY**

### Pesticides

The panel granted a petition for review, and vacated the Environmental Protection Agency's ("EPA") 2017 order maintaining a tolerance for the pesticide chlorpyrifos, and remanded to the EPA with directions to revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days.

The Federal Food, Drug, and Cosmetic Act ("FFDCA") authorizes the EPA to regulate the use of pesticides on foods according to specific statutory standards, and grants the EPA a limited authority to establish tolerances for pesticides meeting statutory qualifications. The EPA is subject to safety standards in exercising its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

The EPA argued that FFDCA's section 346a(g)(2)'s administrative process deprived this Court of jurisdiction until the EPA issues a response to petitioner's administrative objections under section 346a(g)(2)(C), which it has not done to date.

The panel held that section 346a(h)(1) of the FFDCA does not "clearly state" that obtaining a section (g)(2)(C) order in response to administrative objections is a jurisdictional requirement. The panel held that section 346a(h)(1) contains no jurisdictional label, is structured as a

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

limitation on the parties rather than the court, and only references an exhaustion process that is outlined in a separate section of the statute.

The panel held that in light of the strong individual interests against requiring exhaustion and weak institutional interests in favor of it, petitioners need not exhaust their administrative objections and were not precluded from raising issues on the merits.

Turning to the merits, the panel held that there was no justification for the EPA's decision in its 2017 order to maintain a tolerance for chlorpyrifos in the face of scientific evidence that its residue on food causes neurodevelopmental damage to children. The panel further held that the EPA cannot refuse to act because of possible contradiction in the future by evidence. The panel held that the EPA was in direct contravention of the FFDCA and FIFRA.

Judge Fernandez dissented. Judge Fernandez would hold that there is no jurisdiction over the petition for review under FFDCA and FIFRA, and dismiss the petition.

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**COUNSEL**

Patti A. Goldman (argued), Marisa C. Ordonia, and Kristen L. Boyles, Earthjustice, Seattle, Washington, for Petitioners.

Frederick A. Brodie (argued), Assistant Solicitor General; Andrea Oser, Deputy Solicitor General; Barbara D. Underwood, Attorney General; Office of the Attorney General, Albany, New York; Brian E. Frosh, Attorney General; Steven M. Sullivan, Solicitor General; Office of the Attorney General, Baltimore, Maryland; Thomas J. Donovan Jr., Attorney General; Nicholas F. Persampieri, Assistant Attorney General; Office of the Attorney General, Montpelier, Vermont; Robert W. Ferguson, Attorney General; William R. Sherman, Counsel for Environmental Protection; Attorney General's Office, Seattle, Washington; Maura Healey, Attorney General; I. Andrew Goldberg, Assistant Attorney General; Environmental Protection Division, Office of the Attorney General, Boston, Massachusetts; Karl A. Racine, Attorney General; Brian R. Caldwell, Assistant Attorney General; Office of the Attorney General, Washington, D.C.; Xavier Becerra, Attorney General; Susan S. Fiering, Supervising Deputy Attorney General; Reed Sato, Deputy Attorney General; Office of the Attorney General, Sacramento, California; Russell A. Suzuki, Acting Attorney General; Wade H. Hargrove III, Deputy Attorney General; Health and Human Services Division, Department of the Attorney General, Honolulu, Hawaii; for Intervenors.

Phillip R. Dupré (argued) and Erica M. Zilioli, Attorneys, Environmental Defense Section; Jeffrey H. Wood, Acting Assistant Attorney General; Environment and Natural Resources Division, United States Department of Justice, Washington, D.C.; Mark Dyner, Office of the General

Counsel, United States Environmental Protection Agency, Washington, D.C.; for Respondents.

Donald C. McLean, Stanley H. Abramson, Kathleen R. Heilman, and Sylvia G. Costelloe, Arent Fox LLP, Washington, D.C., for Amicus Curiae Dow Agrosciences LLC.

Susan J. Kraham and Edward Lloyd, Columbia Environmental Clinic, Morningside Heights Legal Services, New York, New York, for Amicus Curiae Congressman Henry Waxman.

Shaun A. Goho, Emmett Environmental Law & Policy Clinic, Harvard Law School, Cambridge, Massachusetts, for Amici Curiae Health Professional Organizations.

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**OPINION**

RAKOFF, District Judge:

Over nearly two decades, the U.S. Environmental Protection Agency ("EPA") has documented the likely adverse effects of foods containing the residue of the pesticide chlorpyrifos on the physical and mental development of American infants and children, often lasting into adulthood. In such circumstances, federal law commands that the EPA ban such a pesticide from use on food products unless "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide." 21 U.S.C. § 346a(b)(2)(A)(ii). Yet, over the past decade and more, the EPA has stalled on banning chlorpyrifos, first by largely ignoring a petition properly filed pursuant to law seeking such a ban, then by temporizing in response to repeated orders by this Court to respond to the petition, and, finally, in its latest tactic, by denying outright our jurisdiction to review the ultimate denial of the petition, even while offering no defense on the merits. If Congress's statutory mandates are to mean anything, the time has come to put a stop to this patent evasion.

Petitioners seek review of an EPA order issued March 29, 2017 (the "2017 Order" or "Order") that denied a 2007 petition to revoke "tolerances," i.e. limited allowances, for the use of chlorpyrifos on food products. Petitioners argue that the EPA does not have the authority to maintain the tolerances for chlorpyrifos under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which authorizes the EPA to "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"—with "safe," in turn, defined to mean that the EPA "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the

pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(A)(i)–(ii). Respondent, the EPA, has never made any such determination and, indeed, has itself long questioned the safety of permitting chlorpyrifos to be used within the allowed tolerances. The EPA, therefore, does not defend the 2017 Order on the merits. Instead, the EPA argues that, despite petitioners having properly-filed administrative objections to the 2017 Order more than a year ago, and despite the statutory requirement that the EPA respond to such objections "as soon as practicable," the EPA's utter failure to respond to the objections deprives us of jurisdiction to adjudicate whether the EPA exceeded its statutory authority in refusing to ban use of chlorpyrifos on food products.

We hold that obtaining a response to objections before seeking review by this Court is a claim-processing rule that does not restrict federal jurisdiction, and that can, and here should, be excused. There being no other reason not to do so, we grant the petition on the merits.

## BACKGROUND

### A. *The Statutory Framework*

The FFDCA authorizes the EPA to regulate the use of pesticides on foods according to specific statutory criteria. 21 U.S.C. §§ 301–399i. The FFDCA prescribes that food with "any pesticide chemical residue . . . shall be deemed unsafe" and barred from movement in interstate commerce. *Id.* § 346a(a)(1). However, it grants the EPA a limited authority to establish tolerances for pesticides meeting statutory qualifications, enabling foods bearing residues of those pesticides within these tolerances to move in interstate commerce. *See id.* § 346a(a), (a)(4), (b)(1).

The EPA's ability to establish tolerances depends on a safety finding. "The Administrator may establish or leave in effect a tolerance . . . only if the Administrator determines that the tolerance is safe." *Id.* § 346a(b)(2)(A)(i). A tolerance qualifies as safe if "the Administrator has determined that 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) (emphasis added). To make such a determination, the EPA must perform a safety analysis to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" and "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children. *Id.* § 346(b)(2)(C)(ii)(I)–(II). Furthermore, even after establishing a tolerance, the EPA bears continuous responsibility to ensure that the tolerance continues to satisfy the FFDCA's safety standard; the FFDCA provides that the Administrator may "leave in effect a tolerance . . . only if the Administrator determines that the tolerance is safe" and "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* § 346a(b)(2)(A)(i).

The EPA is subject to these same safety standards in exercising its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *See* 7 U.S.C. § 136a(a). The EPA Administrator must register a pesticide—which is a requirement for pesticides to be distributed or sold—when, among other qualifications, the pesticide does not have "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5) (D). FIFRA incorporates the FFDCA's safety standard into the definition of "unreasonable adverse effects" to include "a human dietary risk from residues that result from a use of a

pesticide in or on any food inconsistent with the standard under [the FFDCA]." *Id.* § 136(bb). FIFRA requires the EPA to reevaluate pesticides periodically after approval. *Id.*

While the EPA can act on its own initiative to establish, modify or revoke a tolerance under the FFDCA, 21 U.S.C. § 346a(e)(1), "[a]ny person may file . . . a petition proposing the issuance of [such] a regulation." *Id.* § 346a(d)(1). After "due consideration," the EPA Administrator must issue either a proposed or final regulation or an order denying the petition. *Id.* § 346a(d)(4)(A). After this response, "any person may file objections thereto with the Administrator." *Id.* § 346a(g)(2)(A). The FFDCA directs that the Administrator "shall issue an order [known as a "g(2)(C) order"] stating the action taken upon each . . . objection" "[a]s soon as practicable." *Id.* § 346a(g)(2)(C). "[A]ny person who will be adversely affected" by that order or the underlying regulation "may obtain judicial review by filing in the United States Court of Appeals" a petition for review. *Id.* § 346a(h)(1).

B. *The History of this Litigation*

This case arises from a 2007 petition filed under 21 U.S.C. § 346a(d) proposing that the EPA revoke tolerances for the pesticide chlorpyrifos (the "2007 Petition" or the "Petition"). Chlorpyrifos, an organophosphate pesticide initially developed as a nerve gas during World War II, was approved in 1965 in the United States as a pesticide for agricultural, residential, and commercial purposes. Chlorpyrifos kills insects by suppressing acetelycholinestrerase, an enzyme that acts as a neurotransmitter in various organisms, including humans. The EPA has set chlorpyrifos residue tolerances for 80 food crops, including fruits, nuts, and vegetables. *See* 40 C.F.R. § 180.342. The 2007 Petition, filed by the Pesticide Action

Network North America ("PANNA") and the Natural Resources Defense Council ("NRDC"), presented scientific studies showing that children and infants who had been exposed prenatally to low doses of chlorpyrifos suffer harms such as reduced IQ, attention deficit disorders, and delayed motor development, that last into adulthood.

Prior to the Petition's filing, the EPA already had concerns about chlorpyrifos. After reviewing the registration for chlorpyrifos in 1998 under the amended FFDCA's heightened safety standards that required considering cumulative exposure and the specific risks to children, the EPA cancelled all residential uses. Although the EPA continued to allow the use of chlorpyrifos as a pesticide on food crops, *see* 40 C.F.R. § 180.342, it required that "risk mitigation measures" be implemented while a full reassessment of chlorpyrifos was undertaken, as continued usage of chlorpyrifos without additional precautions "would present risks inconsistent with FIFRA." EPA 738-R-01-007 "Interim Reregistration Eligibility Decision for Chlorpyrifos" (Feb. 2002)). This "interim reregistration" also announced future plans to reduce or revoke entirely chlorpyrifos tolerance levels for certain crops, citing "acute dietary risks" for "infants, all children, and nursing females." *Id*.

Despite these earlier expressions of concern, the EPA failed to take any decisive action in response to the 2007 Petition, notwithstanding that the EPA's own internal studies continued to document serious safety risks associated with chlorpyrifos use, particularly for children. A 2008 EPA Science Issue Paper, reviewing existing scientific studies, "preliminarily concluded that chlorpyrifos likely played a role" in low birth rate and delays in infant mental development observed in human cohort studies. A Science

Advisory Panel convened in 2008 concurred that chlorpyrifos exposures "can lead to neurochemical and behavioral alterations [in the young] that persist into adulthood." A Science Advisory Panel convened in 2011 found "persuasive" evidence "that there are enduring effects on the Central Nervous System . . . from chlorpyrifos exposure at or above 1.0 mg/kg," and that chlorpyrifos exposure is associated with adverse neurodevelopmental effects in children, including abnormal reflexes, pervasive development disorder, and attention and behavior problems.

Yet, even after all of these EPA studies, by 2012 the EPA still had not responded to the 2007 Petition. PANNA and NRDC thereupon petitioned this Court for a writ of mandamus to force the EPA to take action. We initially dismissed the mandamus petition, without prejudice to its renewal, based on the EPA's representation that it had a "concrete timeline for final agency action" to be taken on the 2007 Petition by February 2014. *In re PANNA*, 532 F. App'x 649, 651 (9th Cir. 2013). When the EPA failed to respond to the 2007 Petition by September 2014, PANNA and NRDC again petitioned for mandamus, which we granted, ordering the EPA to issue a final response on the 2007 Petition by October 2015. *In re PANNA*, 798 F.3d 809, 815 (9th Cir. 2015).[1] We found the EPA's delay in responding to the 2007 Petition "egregious," especially "[i]n view of [the] EPA's own assessment of the dangers to human health posed by this pesticide," noting that the EPA had recently "reported that chlorpyrifos poses such a significant threat to water supplies that a nationwide ban on the pesticide may be justified." *Id.* at 811, 814.

[1] Unless otherwise indicated, case quotations omit all internal quotation marks, alterations, footnotes, and citations.

Notwithstanding the deadline set by this Court, the EPA did not initially respond to the 2007 Petition until November 2015, when it issued a proposed rule revoking all tolerances for chlorpyrifos. Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080 (Nov. 6, 2015); *see* 21 U.S.C. § 346a(d)(4)(A)(ii). Describing the various scientific studies' "consistency of finding neurodevelopmental effects" as "striking," *id.* at 69,090, the EPA stated that it was "unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of [21 U.S.C. § 346a(b)(2)(A)(i)]" *id.* at 69,080.

Yet the EPA still equivocated and delayed. Accordingly, in December 2015, we ordered the EPA "to take final action by December 30, 2016 on its proposed revocation rule." *In re PANNA*, 808 F.3d 402, 402 (9th Cir. 2015). In June 2016, the EPA requested a six-month extension to continue scientific analysis, a request we characterized as "another variation on a theme of partial reports, missed deadlines, and vague promises of future action that has been repeated for the past nine years." *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016). We found that a six-month delay was "not justified" in light of the previous time extensions and the EPA's "continued failure to respond to the pressing health concerns presented by chlorpyrifos," but granted a three-month extension to March 2017. *Id.*

In the meantime, the EPA issued a 2016 Risk Assessment concluding that estimated dietary exposure to chlorpyrifos at existing tolerances exceeded what was acceptable for all population groups analyzed, with the highest risks for young children. The Risk Assessment found that scientific literature "as a whole provides evidence of long-lasting neurodevelopmental disorders" linked to chlorpyrifos exposure, with any remaining scientific

uncertainties insufficient to "undermine or reduce the confidence in the findings of the epidemiology studies." The EPA concluded that its analysis of chlorpyrifos "continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard" and that "expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard." Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment, 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016).

Then, in the Order at issue in this case, the EPA reversed its position and denied the 2007 Petition on the merits, leaving chlorpyrifos tolerances in effect. Chlorpyrifos; Order Denying PANNA and NRDC's Petition To Revoke Tolerances, 82 Fed. Reg. 16,581 (Apr. 5, 2017). The Order did not refute the agency's previous scientific findings on chlorpyrifos or its conclusion that chlorpyrifos violated the FFDCA safety standard. Instead, the EPA stated that it would not revoke tolerances as "the science addressing neurodevelopmental effects remains unresolved." *Id.* at 16,583. The EPA stated that it would not complete "any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution," *id.*, and claimed to have "discretion to determine the schedule" for reviewing the existing chlorpyrifos tolerances as long as it completed the chlorpyrifos registration review by FIFRA's deadline of October 1, 2022, *id.* at 16,590.

PANNA and NRDC moved for further mandamus relief in this Court, arguing that the 2017 Order failed to respond adequately to the 2007 Petition. We denied their motion as premature because the EPA had "done what we ordered it to do," i.e. responded to the 2007 Petition, since the 2017 Order formally denied it. *In re PANNA*, 863 F.3d 1131, 1132 (9th

Cir. 2017). Petitioners then petitioned this Court for review of the 2017 Order. Petitioners concurrently filed objections in the EPA's administrative review process. Thereafter, we permitted several states that had also filed objections to the Order to intervene in this matter.

The EPA does not defend this suit on the merits, but argues that § 346a(g)(2)'s administrative process deprives this Court of jurisdiction until the EPA issues a response to petitioners' administrative objections, *see* § 346a(g)(2)(C), which it has not done to date.

## DISCUSSION

### A. *Jurisdiction*

The term "jurisdiction" refers specifically to "a court's adjudicatory authority." *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 160 (2010). Therefore, "a rule should not be referred to as jurisdictional unless it governs a court's adjudicatory capacity, that is, its subject-matter or personal jurisdiction." *Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 435 (2011). In other words, "jurisdictional statutes speak to the power of the court rather than to the rights or obligations of the parties." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 274 (1994).

The Supreme Court has emphasized the necessity of observing "the important distinctions between jurisdictional prescriptions and claim-processing rules." *Reed Elsevier*, 559 U.S. at 161. Claim-processing rules "seek to promote the orderly progress of litigation by requiring that the parties take certain procedural steps at certain specified times." *Henderson*, 562 U.S. at 435. Claim-processing rules may be "important and mandatory," but, as they do not "govern[] a

court's adjudicatory capacity," they can be waived by the parties or the court. *Id.*

The Supreme Court has adopted a "bright line" test for determining when to classify statutory restrictions as jurisdictional. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 516 (2006). A rule qualifies as jurisdictional only if "Congress has clearly stated that the rule is jurisdictional." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013). "[A]bsent such a clear statement," the Supreme Court has cautioned, "courts should treat the restriction as nonjurisdictional in character," with the specific goal of "ward[ing] off profligate use of the term 'jurisdiction.'" *Id.* In considering whether Congress has spoken clearly, courts consider both the language of the statute and its "context, including . . . [past judicial] interpretation[s] of similar provisions." *Reed Elsevier*, 559 U.S. at 168.

"[T]hreshold requirements that claimants must complete, or exhaust, before filing a lawsuit" are typically "treated as nonjurisdictional." *Id.* at 166. Accordingly, "we have rarely found exhaustion statutes to be a jurisdictional bar." *McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 978 (9th Cir. 2002) (holding that requirement of "exhaust[ing] all administrative appeal procedures . . . before [a] person may bring an action in a court" was not jurisdictional); *see also Anderson v. Babbitt*, 230 F.3d 1158, 1162 (9th Cir. 2000) (same for provision that "[n]o decision which at the time of its rendition is subject to [administrative] appeal . . . shall be considered final so as to be agency action subject to judicial review"); *Rumbles v. Hill*, 182 F.3d 1064, 1067 (9th Cir. 1999) (same for provision that "[n]o action shall be brought . . . until such administrative remedies as are available are exhausted"),

*overruled on other grounds by Booth v. Churner*, 532 U.S. 731 (2001).

Section 346a(h)(1), the FFDCA's judicial review provision, provides:

> 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.

The (g)(2)(C) order referenced above is the order "stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted," which the EPA must issue at the conclusion of the administrative objections process outlined in § 346a(g)(2). *Id.* § 346a(g)(2)(C).

We must consider whether § 346a(h)(1) "clearly states" that obtaining a (g)(2)(C) order in response to administrative objections is a jurisdictional requirement. It does not. Section 346a(h)(1) "is written as a restriction on the rights of plaintiffs to bring suit, rather than as a limitation on the power of the federal courts to hear the suit." *Payne v.*

*Peninsula Sch. Dist.*, 653 F.3d 863, 869 (9th Cir. 2011) (en banc). It delineates the process for a party to obtain judicial review, by filing suit in one of two venues within a specified time, not the adjudicatory capacity of those courts.

In *Henderson*, the Supreme Court evaluated a similarly structured provision, which provided that, "to obtain [judicial] review" of a final decision of the Board of Veterans' Appeals, "a person adversely affected . . . shall file a notice of appeal with the Court." 562 U.S. at 438. The Court found this language did "not suggest, much less provide clear evidence, that the provision was meant to carry jurisdictional consequences." *Id.* Similarly, in *Payne*, we held that an exhaustion requirement providing that "before the filing of a civil action . . . , the [administrative] procedures . . . shall be exhausted" was not a jurisdictional limit on the courts, but a requirement for plaintiffs that could be waived. 653 F.3d at 867, 869. Like the provision evaluated in *Payne*, the focus of § 346a(h)(1) on the requirements for petitioners "strongly suggests that the restriction may be enforced by defendants but that the exhaustion requirement may be waived or forfeited." *Id.* at 869.

Further, § 346a(h)(1) "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the [federal] courts." *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982). The word "jurisdiction" never appears. The reference to the United States Courts of Appeals "simply clarifies that, when determining in which court of competent jurisdiction they will file their claim, . . . litigants have a choice of venue." *Merritt v. Countrywide Fin. Corp.*, 759 F.3d 1023, 1038 (9th Cir. 2012) (classifying provision that an action "may be brought in any United States district court, or in any other court of competent jurisdiction" as

non-jurisdictional claim-processing rule despite its being labeled "Jurisdiction of courts; limitations on actions").

Section 346a(h)(1) similarly lacks mandatory language with "jurisdictional import." *Auburn Reg'l Med. Ctr.*, 568 U.S. at 154. It merely provides that a person "*may* obtain judicial review." 21 U.S.C. § 346a(h)(1) (emphasis added). In *Auburn Regional Medical Center*, the Supreme Court evaluated a provision with similar language, which instructed that a health care provider "may obtain a hearing" by the Provider Reimbursement Review Board if "such provider files a request for a hearing within 180 days after notice of the intermediary's final determination." 568 U.S. at 154. The Court held that the provision did "not speak in jurisdictional terms" in part because it lacked "words with jurisdictional import" like "the mandatory word 'shall.'" *Id.* Similarly, this Court has held that "permissive, non-mandatory language such as . . . . 'may file' . . . weighs considerably against a finding that [the provision] is jurisdictional." *Merritt*, 759 F.3d at 1037.

Aside from listing a (g)(2)(C) order as one of the orders available for judicial review, § 346a(h)(1) provides no indication that the administrative process required to produce a (g)(2)(C) order is a condition of the courts' jurisdiction. The objections process itself is detailed in Section 346a(g)(2), a separate provision focused entirely on administrative processes rather than on judicial review. The Supreme Court has repeatedly found that a requirement's "appear[ance] as an entirely separate provision" from the one concerning judicial review is a significant indicator of lack of Congressional intent to make that requirement jurisdictional. *Zipes*, 455 U.S. at 393–94; *see also Reed Elsevier*, 559 U.S. at 164; *Arbaugh*, 546 U.S. at 515.

The fact that (g)(2)(C) orders issued at the conclusion of administrative objections appear on § 346a(h)(1)'s list of orders for judicial review, while (d)(4)(A) orders issued in response to petitions do not, is not in itself suggestive as to whether obtaining a (g)(2)(C) order is a jurisdictional limitation. In evaluating statutes that similarly list administrative actions available for judicial review, the Supreme Court has observed that "[t]he mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others." *Verizon Md., Inc. v. Pub. Serv. Comm'n*, 535 U.S. 635, 643 (2002). "The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977).

The Dissent finds the language of § 346a(h)(5) suggestive of a Congressional intent to "preclude[] possible bypassing of the § 346a(g)(2) provisions." Dissent at 37. We disagree. Section 346a(h)(5) provides 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." This is a limitation on the availability of judicial review under *other* statutory provisions, not a pronouncement as to the internal requirements of § 346a(h)(1) jurisdiction. Similarly, *NRDC v. Johnson*, 461 F.3d 164 (2006), the Second Circuit case cited by the Dissent to support its position that § 346a(h)(5) limits this Court's jurisdiction, is inapposite. In that case, the Second Circuit held that "Section 346a(h) limits judicial review *to the courts of appeals*," rejecting an attempt by plaintiffs to challenge a tolerance by filing directly in federal *district* court under the APA, rather than filing in a federal appellate court pursuant to § 346a(h)(1). *Id.* at 173 (emphasis added). While *Johnson* also stated that § 346a(h) "forecloses such

[appellate court] review prior to the exhaustion of administrative remedies," *id.*, this was pure dictum and particularly inapposite here, since the question of whether such exhaustion was jurisdictional was not presented in that case, which expressly was concerned only with whether "decisions to leave tolerances in effect are reviewable in the district courts." *Id.* at 167.

We are also mindful what it would mean for future review of EPA decisions if we were to find obtaining a (g)(2)(C) order to be a jurisdictional requirement. In seeking to "bring some discipline" to the classification of provisions as jurisdictional, the Supreme Court has repeatedly considered how the classification of the rule in question would impact future claims. *See Auburn Reg'l Med. Ctr.*, 568 U.S. at 153–54 (examining "what it would mean" for the review process if a provision were found jurisdictional); *see also Henderson*, 562 U.S. at 434 (addressing the "considerable practical importance" that attaches to the jurisdictional label, including how jurisdictional rules "may . . . result in the waste of judicial resources and may unfairly prejudice litigants"). The impact of a jurisdictional finding must be considered within the context of the administrative process Congress was establishing in the relevant statute, and the values that process was meant to protect. For example, in *Henderson*, the Supreme Court addressed the impact of a jurisdictional finding on the process established by Congress for adjudicating veterans' benefits claims considering the "solicitude of Congress for veterans" reflected in the review scheme. *Id.*

Applying this analysis to the present case, a jurisdictional finding would mean that under no circumstances could persons obtain judicial review of a denial of a petition prior to an EPA response to an

administrative objection, even under exigent circumstances where the EPA was unwilling or unable to act. The EPA could evade judicial review simply by declining to issue a (g)(2)(c) order in response to an objection, requiring petitioners to seek writs of mandamus to order EPA action on objections. The history of this very case vividly illustrates this danger.

The language Congress used hardly suggests an intention to allow this scenario. Section 346a(g)(2) instructs the EPA to respond "as soon as practicable" to objections filed. Providing only a brief administrative review process makes sense. By the time an administrative objection is filed, the EPA has already fully considered the petition at issue and issued either a "final regulation" or, as here, "an order denying the petition." 21 U.S.C. § 346a(d)(4)(A)(iii).

Furthermore, § 346a(h)(1) provides direct access to the Courts of Appeals to challenge such EPA determinations. Broad, efficient, and prompt access to judicial review is consistent with the other values expressed by the statutory scheme: prioritizing public involvement in monitoring tolerances, as evidenced by the § 346a(d) petition process; and requiring quick EPA responses to changing scientific evidence, as evidenced by the EPA's continuing obligation to ensure that tolerances remain in compliance with the FFDCA's safety standards. *See* § 346a(b)(2)(A)(i).

We have recognized that "determining what has and what has not been exhausted . . . may prove an inexact science" and that "questions about whether administrative proceedings would be futile, or whether dismissal of a suit would be consistent with the general purposes of exhaustion, are better addressed through a fact-specific assessment of the affirmative defense than through an inquiry about whether the court has the power to decide the case at all." *Payne*,

653 F.3d at 870. Finding that a (g)(2)(C) order is a jurisdictional prerequisite would mean that courts would have no ability to analyze whether the administrative process was serving an important role in furthering the development of necessary evidence or was of little value for the issue in question, no matter the significance or the urgency of the question awaiting judicial review.

The EPA makes three main arguments that § 346a(g)(2)(C) is in fact jurisdictional. None are persuasive.

First, the EPA argues that a 1996 amendment to the language of the FFDCA's judicial review provision changing the reviewable orders listed in § 346a(h)(1), indicated a Congressional intent to condition jurisdiction over any orders not listed in Section 346a(h)(1) on their completion of the administrative appeals process. The EPA provides no support for this account of Congressional motivation, which it loosely suggests was a response to a D.C. Circuit decision from nearly a decade earlier finding that the language in the prior version did not require completing an administrative hearing process before filing for judicial review. In fact, the legislative history indicates that the amended statute "retain[ed] most of the existing provisions" regarding judicial review. H.R. Rep. No. 104-669(II), at 49 (1996). But even assuming that Congress's intent with this amendment was to have orders issued in response to petitions go through the § 346a(g)(2) administrative objections process prior to judicial review, that does not bear on the relevant question here, whether Congress intended the new rule as a claims-processing rule or a jurisdictional limitation on the courts.

Second, the EPA argues that the structure of the administrative objections process itself indicates that the process was intended as a jurisdictional requirement, rather

than a claims-processing rule. This argument relies almost entirely on the similarity between § 346a(g)(2)'s objections process and an administrative appeal process that we found jurisdictional in *Gallo Cattle Co. v. United States Department of Agriculture*, 159 F.3d 1194 (9th Cir. 1998). However, *Gallo* was premised on a view of statutory exhaustion that is inconsistent with subsequent Supreme Court precedent and later decisions in this circuit. *Compare id.* at 1197 ("[S]tatutorily-provided exhaustion requirements deprive the court of jurisdiction . . . ."), *with McBride*, 290 F.3d at 980 ("[N]ot all statutory exhaustion requirements are created equal. Only statutory exhaustion requirements containing sweeping and direct language deprive a federal court of jurisdiction."). We have specifically cautioned against reliance on prior cases like *Gallo*, "decided without the benefit of the Supreme Court's recent admonitions against profligate use of the term jurisdictional." *Merritt*, 759 F.3d at 1039. Moreover, even without this change in case law, *Gallo* would be inapposite. Unlike § 346a(h)(1), the provision evaluated in *Gallo* was explicitly jurisdictional, providing that "[t]he district courts of the United States . . . *are hereby vested with jurisdiction* to review [the administrative] ruling." *Gallo*, 159 F.3d at 1197 (emphasis added).

Finally, the EPA argues that this Court's statement in its most recent decision in the prior mandamus action forecloses this conclusion. It does not. That decision denied PANNA and the NRDC's petition for further mandamus relief because it was premised on the ground that the 2017 Order failed to meet the requirements for a final order. Rejecting that view and finding that the 2017 Order was a final denial of the 2007 Petition, this Court instructed PANNA and the NRDC that "[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining

judicial review of [the] EPA's final response to the petition. Only at that point may we consider the merits of [the] EPA's final agency action." *In re PANNA*, 863 F.3d at 1133. Aside from the fact that none of this language spoke to the jurisdictional issue but only to the issue of exhaustion, the instant appeal is clearly in a different posture. In compliance with our prior ruling, petitioners filed their objections, but the EPA has failed to issue a timely (g)(2)(c) order in response.

In sum, we hold that § 346a(h)(1) is not jurisdictional. It contains no jurisdictional label, is structured as a limitation on the parties rather than the courts, and only references an exhaustion process that is outlined in a separate section of the statute.

B. *Exhaustion*

Where, as here, exhaustion of administrative remedies is not jurisdictional, we "must determine whether to excuse the faulty exhaustion and reach the merits, or require the petitioner to exhaust . . . administrative remedies before proceeding in court." *Rivera v. Ashcroft*, 394 F.3d 1129, 1139 (9th Cir. 2004), *superseded by statute on other grounds as stated in Iasu v. Smith*, 511 F.3d 881, 886 (9th Cir. 2007). "In determining whether exhaustion is required, federal courts must balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." *McCarthy v. Madigan*, 503 U.S. 140, 146 (1992), *superseded by statute on other grounds as stated in Booth*, 532 U.S. 731.

The Supreme Court has identified the two key institutional interests favoring exhaustion as "the twin purposes of protecting administrative agency authority and

promoting judicial efficiency." *Id.* at 145. Not all cases implicate these interests to an equal degree. Exhaustion protects an agency's authority "when the action under review involves exercise of the agency's discretionary power or when the agency proceedings in question allow the agency to apply its special expertise." *Id.* Exhaustion also protects an agency's authority by providing the agency "an opportunity to correct its own mistakes with respect to the programs it administers." *Woodford v. Ngo*, 548 U.S. 81, 89 (2006). "[E]xhaustion principles apply with special force when frequent and deliberate flouting of administrative processes could weaken an agency's effectiveness by encouraging disregard of its procedures." *McCarthy*, 503 U.S. at 145.

The institutional interest in requiring exhaustion to protect agency authority appears particularly weak in the present case. The challenged action, permitting the use of chlorpyrifos on food products, does not involve exercise of the EPA's general discretion, but must take place in compliance with strict statutory directives. The questions presented in this appeal are in no way factual or procedural questions implicating the agency's "special expertise." This is not a situation, for example, where the EPA determined a pesticide was safe and the science underlying that determination is challenged. Rather, the purely legal questions here concern the statutory requirements of the FFDCA, and, accordingly, are suited to judicial determination. The crux of petitioners' challenge is that the EPA has found that chlorpyrifos is not safe and therefore cannot maintain a tolerance for it.

Allowing the petition to proceed would not reward failure to properly exhaust administrative remedies. "Proper exhaustion demands compliance with an agency's deadlines

and other critical procedural rules because no adjudicative system can function effectively without imposing some orderly structure on the course of its proceedings." *Woodford*, 548 U.S. at 90–91.

Here, petitioners timely submitted objections to the order denying the 2007 petition to revoke tolerances, fulfilling all of their exhaustion obligations except for the one not within their control—obtaining the EPA's response to the objections. Petitioners' objections were filed 13 months ago, and the key issue therein—whether the EPA was statutorily obligated to revoke the tolerance for chlorpyrifos—was first raised to the EPA over a decade ago in the 2007 Petition. This timeline has provided the EPA more than ample opportunity to correct any mistakes on its own. But, despite the statutory requirement that the EPA respond to the objections "as soon as practicable," it has failed to do so. The history of this litigation supports the inference that the EPA is engaging in yet more delay tactics to avoid our reaching the merits of the sole statutory issue raised here: whether chlorpyrifos must be banned from use on food products because the EPA has not determined that there is a "reasonable certainty" that no harm will result from its use, even under the established tolerances.

The second institutional interest identified by the Supreme Court as potentially favoring exhaustion, judicial economy, counsels against requiring further administrative exhaustion in this instance. Exhaustion offers the greatest support for judicial efficiency where it either permits the agency to "correct its own errors" such that the "judicial controversy may well be mooted, or at least piecemeal appeals may be avoided," or where administrative review "may produce a useful record for subsequent judicial consideration, especially in a complex or technical factual

context." *McCarthy*, 503 U.S. at 145. Here, it is just the opposite. Since 2012, we have issued five separate decisions related to the EPA's inaction on the chlorpyrifos tolerances. Declining to waive exhaustion at this point would make this our sixth decision on the matter without once reaching the merits, setting the stage for yet another "piecemeal appeal[]" if the EPA should someday issue a response to the petitioners' objection—something the EPA itself has strongly hinted may not come about until 2022, if then. Similarly, further development of the administrative record is of no use to judicial efficiency at this point in the proceedings; there are no factual questions, let alone "complex or technical" ones, at issue—only legal questions. And on the merits of these legal questions, the EPA offers no defense of its inaction, effectively conceding its lawlessness.

While both institutional interests favoring exhaustion are weak, this petition invokes two of the "three broad sets of circumstances in which the interests of the individual weigh heavily against requiring administrative exhaustion." *McCarthy*, 503 U.S. at 146. First, the Supreme Court has recognized that exhaustion may be excused where "requiring resort to the administrative remedy may occasion undue prejudice to subsequent assertion of a court action. Such prejudice may result, for example, from an unreasonable or indefinite timeframe for administrative action." *Id.* at 146–47. Most often, an administrative remedy is deemed inadequate "because of delay by the agency." *Id.* Here, the EPA's expressed intent to withhold action for years to come is "unreasonable" as applied here, especially as petitioners' objections concern no factual issues that would require additional time to investigate. The EPA has had over a year to respond to the objections already, with no result.

In *Coit Independence Joint Venture v. Federal Savings & Loan Insurance*, 489 U.S. 561, 586–87 (1989), the Supreme Court held that a claimant was not required to wait for a decision on its administrative appeal before seeking judicial review where the administrative appeal had been pending for over 13 months as of the date of oral argument, and there was no "clear and reasonable time limit on [the agency's] consideration of . . . claims." *See also Smith v. Ill. Bell Tel. Co.*, 270 U.S. 587, 591–92 (1926) (holding that a claimant "is not required indefinitely to await a decision of the [administrative] tribunal before applying to a federal court for equitable relief"). Like the regulation evaluated in *Coit*, the EPA's interpretation of the FFDCA's administrative review provision as providing limitless time to respond to objections would give the agency "virtually unlimited discretion to bury large claims like [petitioners'] in the administrative process, and to stay judicial proceedings for an unconscionably long period of time." *Coit*, 489 U.S. at 586. The delay is particularly prejudicial here where the continued use of chlorpyrifos is associated with severe and irreversible health effects. *See Bowen v. City of New York*, 476 U.S. 467, 483 (1986) (concluding that disability-benefit claimants "would be irreparably injured were the exhaustion requirement now enforced against them"); *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 773 (1947) (directing consideration of "irreparable injury flowing from delay incident to following the prescribed procedure" in determining whether to require exhaustion). Petitioners have been waiting over a year for EPA action on their objections, and over eleven years for an EPA decision on chlorpyrifos tolerances, while being

continually exposed to the chemical's effects. This is a sufficient basis to waive or otherwise excuse exhaustion.[2]

In light of the strong individual interests against requiring exhaustion and weak institutional interests in favor of it, we conclude that petitioners need not exhaust their administrative objections and are not precluded from raising before us the issues at hand on the merits.[3]

C. *The Merits*

We now turn to the merits. Petitioners argue that the EPA's decision in its 2017 order to maintain a tolerance for chlorpyrifos in the face of scientific evidence that its residue on food causes neurodevelopmental damage to children is flatly inconsistent with the FFDCA. Specifically, petitioners argue that a need for additional scientific research is not a valid ground for maintaining a tolerance that, after nearly two decades of studies, has not been determined safe to "a reasonable certainty," and that the EPA cannot delay a decision on tolerances to coordinate that decision with registration review under FIFRA.

The EPA presents no arguments in defense of its decision. Accordingly, the EPA has forfeited any merits-

[2] Exhaustion may also be excused where "the administrative body is shown to be biased or has otherwise predetermined the issue before it." *McCarthy*, 503 U.S. at 148. The history detailed above strongly suggests that the EPA, for whatever reason, has decided not to ban chlorpyrifos under any circumstances, even when its own internal studies show that it could not possibly make the factual findings necessary to avoid a ban.

[3] Because we find judicial review available under § 346a(h)(1), we will not address petitioners' alternative argument that judicial review is available under FIFRA, 7 U.S.C. § 136n(b).

based argument. *See Martinez v. Sessions*, 873 F.3d 655, 660 (9th Cir. 2017).

The FFDCA states unequivocally that the Administrator "shall modify or revoke a tolerance if the Administrator determines it is not safe." § 346a(b)(2)(A)(i). A tolerance is safe when "the Administrator has determined that there is a *reasonable certainty* that *no* harm will result from aggregate exposure to the pesticide, including all anticipated dietary exposures and all other exposures for which there is reliable information." § 346a(b)(2)(A)(ii) (emphasis added). Accordingly, the EPA bears a continuing obligation to revoke tolerances that it can no longer find with a "reasonable certainty" are safe.

The EPA's 2016 risk assessment concluded that its analysis of chlorpyrifos "continues to indicate that the risk from potential aggregate exposure does not meet the FFDCA safety standard" and that "expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard." This finding was the EPA's final safety determination before the 2017 EPA Order. The 2017 Order declined to revoke chlorpyrifos tolerances but did not make a finding of reasonable certainty that the tolerances were safe. Instead, it found "significant uncertainty" as to the health effects of chlorpyrifos, which is at odds with a finding of "reasonable certainty" of safety under § 346a(b)(2)(A)(ii) and therefore mandates revoking the tolerance under § 346a(b)(2)(A)(i).

"[H]owever desirable it may be for [the] EPA to consult [a Scientific Advisory Board] and even to revise its conclusion in the future, that is no reason for acting against its own science findings in the meantime." *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290 (D.C. Cir. 2000). The EPA cannot refuse to act "because of the

possibility of contradiction in the future by evidence unavailable at the time of action – a possibility that will *always* be present." *Id.* at 1290–91 (emphasis in original). Chlorpyrifos similarly does not meet the statutory requirement for registration under FIFRA, which incorporates the FFDCA's safety standard. As we have previously counseled, "evidence may be imperfect [and] the feasibility inquiry is formidable," but there remains no justification for the "EPA's continued failure to respond to the pressing health concerns presented by chlorpyrifos," which has now placed the agency in direct contravention of the FFDCA and FIFRA. *In re PANNA*, 840 F.3d at 105.

Accordingly, we **GRANT** the petition for review. The EPA's 2017 Order maintaining chlorpyrifos is **VACATED**, and the case is remanded to the EPA with directions to revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days.

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FERNANDEZ, Circuit Judge, dissenting:

League of United Latin American Citizens, Pesticide Action Network North America (PANNA), Natural Resources Defense Council (NRDC), California Rural Legal Assistance Foundation, Farmworkers Association of Florida, Farmworker Justice GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros Y Campesinos Unidos del Noroeste, and United Farm Workers (collectively, "LULAC") petition for review of the Environmental Protection Agency's (EPA) 2017 order denying a 2007 petition to revoke all tolerances for the pesticide chlorpyrifos (hereafter "the Pesticide"). *See* Chlorpyrifos; Order Denying PANNA and NRDC's Petition

to Revoke Tolerances, 82 Fed. Reg. 16,581, 16,583 (Apr. 5, 2017) (the "2017 Order").[1] In the briefs (not in the petition for review), LULAC and the States ask for a writ of mandamus ordering EPA to respond to the objections they filed to the 2017 Order. In their brief, the States also ask for a writ of mandamus compelling the EPA to issue a final rule revoking chlorpyrifos tolerances.

The EPA regulates the use of pesticides on food pursuant to the Federal Food, Drug, and Cosmetic Act[2] (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[3] At present, the Pesticide is registered as an insecticide for food crops and non-food settings. In the view of LULAC and the States, the Pesticide is unsafe[4] and the EPA should modify or revoke the tolerances it has established for the Pesticide pursuant to FFDCA. *See* 21 U.S.C. § 346a(a)(1)(A), (b)(1). For that matter, they believe that the EPA should cancel the Pesticide's registration for food crops under FIFRA. *See* 7 U.S.C. § 136a(g)(1)(A)(v). In September 2007, PANNA and NRDC filed an administrative petition with the EPA seeking revocation of the Pesticide's FFDCA food tolerances and cancellation of its FIFRA registrations (the 2007 Petition). On April 5, 2017, the EPA issued the 2017 Order in which it denied the 2007 Petition. *See* 82 Fed. Reg. at 16,581.

[1] The States of New York, Maryland, Vermont, Washington, California, and Hawaii, as well as the Commonwealth of Massachusetts and the District of Columbia (collectively, "the States"), are Intervenors in support of LULAC's petition.

[2] 21 U.S.C. §§ 301–399g.

[3] 7 U.S.C. §§ 136–136y.

[4] *See* 21 U.S.C. § 346a(a)(1).

LULAC and certain states filed objections to the 2017 Order on June 5, 2017, and on that same date, LULAC filed the instant petition for review of the merits of the 2017 Order.

JURISDICTION

The majority holds that we have jurisdiction over the petition for review. I disagree. Of course, we do have jurisdiction to determine whether we have jurisdiction over the petition for review. *See Special Invs. Inc. v. Aero Air Inc.*, 360 F.3d 989, 992 (9th Cir. 2004). Nonetheless, "'[w]e presume that federal courts lack jurisdiction unless the contrary appears affirmatively from the record.'" *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3, 126 S. Ct. 1854, 1861 n.3, 164 L. Ed. 2d 589 (2006). Thus, "the party asserting federal jurisdiction . . . has the burden of establishing it." *Id.* Here LULAC[5] attempts to meet that burden by pointing to the judicial review provisions of FFDCA. *See* 21 U.S.C. § 346a(h).[6] It also relies on FIFRA. *See* 7 U.S.C. § 136n(b). The States also point to 5 U.S.C. §§ 704, 706 as a possible source of jurisdiction. In my view, all of those attempts fail. Hence I would dismiss the petition.

A. Jurisdiction Under FFDCA

The 2017 Order was issued pursuant to § 346a(d)(4)(A)(iii). In seeking to obtain FFDCA jurisdiction, LULAC relies upon § 346a(h)(1) which, as pertinent here, provides that:

[5] What I determine hereafter regarding LULAC also applies to the States unless otherwise indicated.

[6] Hereafter, all references to § 346a are to 21 U.S.C. § 346a.

> In a case of actual controversy as to the validity of . . . any order issued under subsection . . . (g)(2)(C) [of this section], . . . any person who will be adversely affected by such order . . . 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 . . . a petition praying that the order . . . be set aside in whole or in part.

Unfortunately for LULAC's argument, the subsection referred to in the above quotation from § 346a(h)(1) is the subsection that provides for the EPA to issue an order following objections to a previous order of the EPA and that agency's processing of those objections. *See* § 346a(g)(2). That, by the way, is the process to which we pointed the parties in our earlier consideration of the EPA's proceedings regarding the Pesticide and stated that only after the review was completed "may we consider the merits of EPA's 'final agency action.'" *Nat. Res. Def. Council, Inc. v. U.S. EPA (In re PANNA)*, 863 F.3d 1131, 1133 (9th Cir. 2017). Specifically, § 346a(g)(2)(A) provides that a person may file objections to an order issued under § 346a(d)(4), as the 2017 Order was. The EPA may then hold a public evidentiary hearing upon request or upon its own initiative. *See* § 346a(g)(2)(B). An appropriate "order stating the action taken upon each such objection and setting forth any revision to the . . . prior order" must then be issued. *Id.* at (C). Pursuant to the plain reading of the above subsection taken

as a whole,[7] then, and only then, can judicial review in this court be sought pursuant to § 346a(h)(1).

But, says LULAC, the requirement is no more than a claim-processing rule[8] rather than a true jurisdictional rule.[9] The majority agrees; I am not convinced. Here Congress was very careful and very specific about the class of cases—the limited kind of orders—over which it wished to give the courts of appeals direct review. It made it plain that we could not review the EPA's actions in this specific area until the agency had developed and considered a full record regarding objections and the like. Before that occurred, judicial review was not available; we had no authority whatsoever to consider the issue. As the Second Circuit Court of Appeals has pointed out, § 346a(h)(1) is "unique in that it only commits certain specific agency actions to appellate court review." *Nat. Res. Def. Council v. Johnson*, 461 F.3d 164, 172 (2d Cir. 2006). In light of that careful restriction on judicial review, it is not at all likely that Congress would

[7] *See Nuclear Info. & Res. Serv. v. U.S. Dep't of Transp. Research & Special Programs Admin.*, 457 F.3d 956, 960 (9th Cir. 2006).

[8] *See Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 435, 131 S. Ct. 1197, 1203, 179 L. Ed. 2d 159 (2011) (claim-processing rules merely "seek to promote the orderly progress of litigation by requiring that the parties take certain procedural steps at certain specified times").

[9] "'Jurisdiction' refers to 'a court's adjudicatory authority.'" *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 160, 130 S. Ct. 1237, 1243, 176 L. Ed. 2d 18 (2010). "Accordingly, the term 'jurisdictional' properly applies only to 'prescriptions delineating the classes of cases (subject-matter jurisdiction) . . .' implicating that authority." *Id.* at 160–61, 13 S. Ct. at 1243; *see also Payne v. Peninsula Sch. Dist.*, 653 F.3d 863, 868 (9th Cir. 2011) (en banc), *overruled on other grounds by Albino v. Baca*, 747 F.3d 1162, 1171 (9th Cir. 2014) (en banc).

have authorized our seizing jurisdiction before the specific agency action was concluded. Lest there be any doubt, Congress also precluded possible bypassing of the § 346a(g)(2) provisions when it directed that no "judicial review under any other provision of law" would be permitted. Section 346a(h)(5); *see also Johnson*, 461 F.3d at 172–74. And that is further emphasized by the fact that the section does not speak in general language of finality or exhaustion;[10] it, rather, states specifically when we can assume review authority over the particular matters. Had Congress contemplated appellate court review before the EPA completed the process required by § 346a(g)(2)(C), it could easily have inserted orders under § 346a(d)(4), or, more specifically, § 346a(d)(4)(A)(iii) into the judicial review provisions of § 346a(h)(1), which, of course, it did not do. Rather, it expressly allowed judicial review only over the agency's ruling on objections that had to be filed with the agency, and not before. *See Gallo Cattle Co. v. U.S. Dep't of Agric.*, 159 F.3d 1194, 1197–98 (9th Cir. 1998); *see also McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 979–80 (9th Cir. 2002) (discussing *Gallo Cattle*). That is particularly telling because earlier iterations of the review provisions contained no such jurisdictional limitations. *See Nat'l Coal. Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 878–79 (D.C. Cir. 1987).

In short, I see no basis for deconstructing that carefully constructed jurisdictional scheme and thereby inviting

[10] *Cf. Anderson v. Babbitt*, 230 F.3d 1158, 1162 (9th Cir. 2000); *Rumbles v. Hill*, 182 F.3d 1064, 1067 (9th Cir. 1999).

premature attacks on matters committed to the expertise of the agency in the first instance.[11]

B. Jurisdiction under FIFRA

LULAC then argues that because it not only asked for the EPA to revoke all tolerances for the Pesticide but also asked the EPA to cancel all registrations for the Pesticide, the 2007 Petition to the EPA arose under both the FFDCA and FIFRA. Thus, it argues, it need not abide by the FFDCA review provisions, but can rely on the jurisdictional provisions of the FIFRA to establish our jurisdiction. *See* 7 U.S.C. § 136n(b). I do not agree.

Rather, I am persuaded by the cogent reasoning of the Second Circuit Court of Appeals in a strongly similar situation. *See Johnson*, 461 F.3d at 176. In that case, pursuant to the FFDCA provisions, NRDC also challenged the EPA's setting of tolerances for residues on food of five pesticides (not including the Pesticide). *Id.* at 169–70. NRDC added that their registration should be cancelled pursuant to FIFRA. *Id.* at 176. NRDC had brought its action in the district court, and on appeal the Second Circuit determined that the district court did not have jurisdiction to review the EPA determination under the FFDCA because, as § 346(a)(h)(1), (5) provide, jurisdiction over those claims was limited to the courts of appeals. *Id.* at 172–76. NRDC

[11] Because the completion of the administrative process is jurisdictional, I do not consider LULAC's fallback argument that it would be futile to pursue the prescribed process. *See Sun v. Ashcroft*, 370 F.3d 932, 941 (9th Cir. 2004); *see also Ross v. Blake*, __ U.S. __, __, 136 S. Ct. 1850, 1857, 195 L. Ed. 2d 117 (2016); *Gallo Cattle*, 159 F.3d at 1197.

then argued that the district court still had jurisdiction pursuant to FIFRA. The court replied:

> However, FIFRA's grant of jurisdiction to the district courts is irrelevant. The NRDC Appellants "challenge the registration of pesticides under FIFRA only through their challenge to the tolerances set under the [F]FDCA." Essentially, therefore, the violations of FIFRA alleged by the NRDC Appellants "amount to challenges to the methodologies used in reaching the reassessment determinations at issue" in this case. As such, these challenges represent an "issue as to which review is or was obtainable under Section 346a(h). Section 346a(h)(5) precludes judicial review of these issues "under any other provision of law." The NRDC Appellants' attempt to find independent jurisdiction for their claims under FIFRA is thus precluded by the express language of § 346a(h)(5). The NRDC Appellants' claims are reviewable only in the courts of appeals, and only after they have exhausted the statutory provisions for administrative review.

*Id.* at 176 (citations omitted).

I accept that reasoning and the same reasoning should apply here. It would foreclose LULAC's argument. LULAC essentially argues that the EPA has erred in maintaining tolerances for the Pesticide, which is an unsafe insecticide, and for that same reason it argues that the EPA must forthwith revoke registration of the Pesticide. It argues

that it should not have to wait for the EPA to rule on its registration claim, but that is just an allotrope of its central arguments against waiting for relief under the FFDCA tolerances provision with which its FIFRA argument is "inextricably intertwined." *See Ctr. for Biological Diversity v. U.S. EPA*, 847 F.3d 1075, 1089 (9th Cir. 2017). Therefore, the FIFRA provision does not offer a way to avoid the judicial review provisions of the FFDCA in this instance.

Thus, I would dismiss the petition for review for lack of jurisdiction.[12]

WRIT OF MANDAMUS

In its briefs, LULAC asks us to issue a writ of mandamus[13] directing that the EPA respond to its objections within sixty days. However, LULAC did not file a petition for issuance of that writ and, therefore, made no attempt to comply with the Federal Rules of Appellate Procedure when it filed its petition for review of the merits of the 2017 Order. *See* Fed. R. App. P. 21(a), (c); *see also* Fed. R. App. P. 20. I see no reason to treat LULAC's petition for review as, in fact, one for a writ of mandamus. It was not, and could not have been, a mere instance of mislabeling a request for relief that was sought. Had LULAC intended to seek a writ of

[12] I do not overlook the States' argument regarding 5 U.S.C. §§ 704, 706 (the Administrative Procedure Act provisions). But those provisions do not confer direct review jurisdiction upon this court. *See Gallo Cattle*, 159 F.3d at 1198; *see also Califano v. Sanders*, 430 U.S. 99, 106–07, 97 S. Ct. 980, 985, 51 L. Ed. 2d 192 (1977). Therefore, they add nothing of substance to the petition for review issues now before us.

[13] *See* 28 U.S.C. § 1651(a); *see also Cal. Cmtys. Against Toxics v. U.S. EPA (In re A Cmty. Voice)*, 878 F.3d 779, 783 (9th Cir. 2017).

mandamus, rather than a merits review, that would have been most peculiar because on that same day LULAC had just filed its objections to the 2017 Order. It could not honestly complain about delay in considering its objections at that point. Were I to decide otherwise, I would essentially ignore our holding, which was handed down after this petition for review was filed, but before the briefs were filed, and which declared that PANNA and NRDC must file their objections and await resolution of those objections by the EPA before we would consider the merits of the EPA's actions regarding the Pesticide. *See Nat. Res. Def. Council*, 863 F.3d at 1133.

Thus, this case is quite unlike cases where we decided that a party improperly sought to appeal an interim procedural order rather than a decision on the merits of a case, but we also considered whether we should construe the appeal as a petition for a writ of mandamus. *See Kum Tat Ltd. v. Linden Ox Pasture, LLC*, 845 F.3d 979, 983 (9th Cir. 2017) (discussing order denying arbitration request); *Johnson v. Consumerinfo.com, Inc.*, 745 F.3d 1019, 1023 & n.2 (9th Cir. 2014) (discussing order compelling arbitration and staying judicial proceedings); *see also United States v. Davis*, 953 F.2d 1482, 1497–98 (10th Cir. 1992) (dismissing request for mandamus by defense counsel in criminal conviction appeal where no petition had been filed); *EEOC v. Neches Butane Prods. Co.*, 704 F.2d 144, 146, 151–52 (5th Cir. 1983) (denying request that an appeal from a stay of proceedings pending compliance with discovery orders be treated as a mandamus petition where requesting party was represented by competent counsel and should have filed a petition therefor); *Jones & Guerrero Co., Inc. v. Sealift Pac.*, 650 F.2d 1072, 1073–74 (9th Cir. 1981) (per curiam) (refusing to construe appeal from order remanding case to

Guam Superior Court as a petition for mandamus where no mandamus petition filed).

In short, I would decline to treat LULAC's petition as one for a writ of mandamus. Of course, I express no opinion on whether or when LULAC can or should file a petition for a writ of mandamus because LULAC deems the EPA's consideration of the objections to have been unduly delayed. *See PANNA v. U.S. EPA (In re PANNA)*, 798 F.3d 809, 813 (9th Cir. 2015); *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984).

Thus, I respectfully dissent from parts A and B of the Discussion in the majority opinion. As a result, I do not decide the issue in part C although I do find the discussion therein does have some persuasive value.

**§ 348. Food additives**

**(a) Unsafe food additives; exception for conformity with exemption or regulation**

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

**(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation**

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

**(c) Approval or denial of petition; time for issuance of order; evaluation of data; factors**

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in misbranding of food within the meaning of this chapter.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a

tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

**(d) Regulation issued on Secretary's initiative**

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

**(e) Publication and effective date of orders**

Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f) of this section.

**(f) Objections and public hearing; basis and contents of order; statement**

(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

**(g) Judicial review**

(1) In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

**(h) Amendment or repeal of regulations**

The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall

conform to the procedure provided in this section for the promulgation of such regulations.

**(i) Exemptions for investigational use**

Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, § 409, as added Sept. 6, 1958, Pub. L. 85–929, § 4, 72 Stat. 1785; amended June 29, 1960, Pub. L. 86–546, § 2, 74 Stat. 255; Oct. 10, 1962, Pub. L. 87–781, title I, § 104(f)(1), 76 Stat. 785; Nov. 8, 1984, Pub. L. 98–620, title IV, § 402(25)(B), 98 Stat. 3359.)

AMENDMENTS

1984—Subsec. (g)(2). Pub. L. 98–620 struck out provision that required the court to advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

1962—Subsec. (c)(3)(A). Pub. L. 87–781 excepted proviso from applying to use of a substance as an ingredient of feed for animals raised for food production, if under conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter, or in any food from the living animal.

1960—Subsec. (g)(2). Pub. L. 86–546 substituted ''forthwith transmitted by the clerk of the court to the Secretary, or any officer'' for ''served upon the Secretary, or upon any officer'', ''shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28'' for ''shall certify and file in the court a transcript of the proceedings and the record on which he based his order'', and ''Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive,'' for ''Upon such filing, the court shall have exclusive jurisdiction'', and inserted sentence authorizing the Secretary to modify or set aside his order until the filing of the record.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE

Section effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

MORATORIUM ON AUTHORITY OF SECRETARY WITH RESPECT TO SACCHARIN

Pub. L. 95–203, § 3, Nov. 23, 1977, 91 Stat. 1452, as amended by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96–273, June 17, 1980, 94 Stat. 536; Pub. L. 97–42, § 2, Aug. 14, 1981, 95 Stat. 946; Pub. L. 98–22, § 2, Apr. 22, 1983, 97 Stat. 173; Pub. L. 99–46, May 24, 1985, 99 Stat. 81; Pub. L. 100–71, title I, § 101, July 11, 1987, 101 Stat. 431; Pub. L. 102–142, title VI, Oct. 28, 1991, 105 Stat. 910, provided that: ''During the period ending May 1, 1997, the Secretary—

''(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health and Human Services applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

''(2) may, except as provided in section 4 [enacting section 343a of this title, amending sections 321 and 343 of this title, and enacting provisions set out as notes under section 343 of this title] and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act [this chapter] to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin,

solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of the enactment of this Act [Nov. 23, 1977] which involved human studies or animal testing, or both.''

For definition of ''saccharin'' as used in this note, see section 2(d) of Pub. L. 95–203.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 379e, 453, 601, 1033 of this title; title 7 section 450i; title 15 section 1262; title 35 section 155.

**§ 349. Bottled drinking water standards; publication in Federal Register**

Whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 300g–1 of title 42, the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments.

(June 25, 1938, ch. 675, § 410, as added Dec. 16, 1974, Pub. L. 93–523, § 4, 88 Stat. 1694.)

**§ 350. Vitamins and minerals**

**(a) Authority and limitations of Secretary; applicability**

(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321(n), 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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| League of United Latin American Citizens, et al.<br><br>Petitioners,<br><br>v.<br><br>Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency, et al.<br><br>Respondents. | No. 17-71636 |

**DECLARATION OF YU-TING GUILARAN**

I, Yu-Ting Guilaran, am over 18 years of age, and I am competent to be a witness in this proceeding. I give this Declaration based on my own personal knowledge and experience from working in the Office of Pesticide Programs at the U.S. Environmental Protection Agency ("EPA" or "Agency").

1. I currently serve as Director of the Pesticide Re-Evaluation Division in the Office of Pesticide Programs ("OPP") at the EPA, a position I have held since 2016. My office is located at One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA, 22202.

2. In my role as Director of the Pesticide Re-Evaluation Division (PRD), I am responsible for managing the periodic review for registered pesticide products, known as "registration review", pursuant to section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). The general purpose of registration review is to assure

that existing pesticides continue to meet the applicable standards for registration under FIFRA. In my role as director of PRD, I have overseen the registration review of many chemicals and am familiar with the necessary statutory standards pesticides need to satisfy to remain registered under FIFRA.

3. Before serving in my current role, I held numerous staff and managerial positions in EPA beginning in 1992, and have been with OPP since 2014. My previous role included being the Director of the Biological and Economic Analysis Division in OPP.

4. In order to register a pesticide, EPA must determine that the pesticide product, when used in a manner consistent with its labeling, will not cause unreasonable adverse effects on the environment. FIFRA section 3(c)(5). The term "unreasonable adverse effects on the environment" is defined in FIFRA section 2(bb) and includes two parts: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21."

5. EPA does not register pesticides that do not meet this FIFRA registration standard. The second half of the definition for "unreasonable adverse effects" comes into play only for pesticides resulting in residues in or on food (also called "food-use pesticides"). For "food-use pesticides", the Agency is required to determine that such pesticide does not cause a human dietary risk inconsistent with the safety standard in section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). That safety standard is a "risk-only" standard, i.e., it requires consideration only of the risks to human health –

not the benefits of the use of the pesticide – and a determination that there is a "reasonable certainty of no harm" from aggregate exposure to residues of the pesticide chemical, which includes dietary exposures and other non-occupational exposures.[1] Generally, where the Agency can make this determination, it will establish a tolerance or exemption to cover the residues, which permits food containing these pesticide residues to be sold in interstate commerce and allows EPA to register the pesticide. Where that finding cannot be made, the tolerance or exemption cannot be established for the pesticide, and EPA will not register the pesticide.

6. If that finding can no longer be supported for an already-registered "food-use pesticide" and the tolerance covering those residues is revoked, those food uses would no longer meet the FIFRA unreasonable adverse effects standard and could not be maintained. EPA would need to take action under FIFRA to address that underlying registration. For example, EPA may seek voluntary cancellation of those uses or amendment of those registrations or may initiate cancellation under section 6.

7. In addition to making the determination that a "food-use pesticide" does not cause a human dietary risk inconsistent with the FFDCA safety standard (usually through the establishment of a tolerance or exemption from the requirement of a tolerance under the FFDCA), EPA considers the non-dietary risks (for example, occupational risks and risks to the environment) from that pesticide under the first part of the unreasonable adverse effects definition. In contrast to the "risk-only" standard applied to the evaluation of pesticide tolerances under the FFDCA, this approach is a "risk-benefit" standard, where EPA registers a pesticide or a specific pesticide use when

[1] This aggregation may include exposures resulting from "non-food-use pesticides."

the potential benefits to be gained from use of the pesticide outweigh the potential risks from use of the pesticide. Only upon determining that the "food-use pesticide" meets both the safety component for assessing the dietary risk and the risk-benefit component for non-dietary risks can EPA register the pesticide.

8. For a pesticide that is not used on food (also called "non-food-use pesticides"), there is no human dietary risk, so the pesticide does not have to meet the FFDCA safety standard set forth in the second part of the unreasonable adverse effects definition. For example, use on golf courses does not result in residues in or on food. No tolerance is necessary to support non-food uses before the Agency can register them. In those instances, EPA may register the pesticide uses if the "non-food use pesticide" meets the first part of the definition of unreasonable adverse effects on the environment. Under that "risk-benefit" approach, EPA considers whether there are any potential risks from use on the golf course, and if so, whether benefits of use on the golf course outweigh those risks. Where such benefits outweigh the risks, the pesticide is registered.

9. It is important to note that many pesticides are registered for use on food and on non-food sites on the same registration. For such products, EPA assesses all uses under the "risk-benefit" standard and applies the additional safety standard to ensure that use of the pesticide does not pose a human dietary risk inconsistent with that standard.

10. In order to cancel the registration of any pesticide, EPA must follow the procedures set forth in section 6 of FIFRA. If a registrant requests voluntary cancellation of its registration, EPA must provide an opportunity for public comment on the cancellation under section 6(f). In order to cancel a registration without the consent of the registrant, EPA must issue a notice of intent to cancel under section 6(b) of FIFRA,

containing the Agency's reasons for concluding that the pesticide generally causes unreasonable adverse effects on the environment. The process under section 6(b) provides registrants an opportunity to cure the defects or to request a trial-type hearing before cancellation becomes effective. EPA must follow these procedures even if EPA has revoked a tolerance for the relevant pesticide under the FFDCA.

11. At this time, the Agency does not have a basis for concluding that all "non-food uses" of chlorpyrifos cause unreasonable adverse effects on the environment. EPA has intended to consider the risks and benefits associated with the non-food uses of chlorpyrifos as part of the registration review for that chemical, which must be completed by October 1, 2022. EPA has not yet completed its evaluation of the human health risks associated with chlorpyrifos, including non-food uses. EPA has not yet conducted an ecological risk assessment for the purpose of registration review or assessed the specific benefits of non-food uses in order to make a risk-benefit determination. EPA cannot currently support cancellation under the "risk-benefit" standard applicable to these uses without these findings.

I hereby declare and affirm, subject to the penalties of perjury, that the foregoing statement is true and correct.

9/12/2018

Yu-Ting Guilaran

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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| League of United Latin American Citizens, et al.<br><br>Petitioners,<br><br>v.<br><br>Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency, et al.<br><br>Respondents. | No. 17-71636 |

**DECLARATION OF MICHAEL WALSH**

I, Michael Walsh, am over 18 years of age, and I am competent to be a witness in this proceeding. I give this Declaration based on my own personal knowledge or on a review of information contained in the records of the U.S. Environmental Protection Agency ("EPA" or "Agency").

1. I currently serve as Product Manager 11 in the Registration Division in the Office of Pesticide Programs ("OPP") at the EPA, a position I have held since March 2015. My office is located at One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA, 22202.

2. In my role as Product Manager 11, I have overseen and been responsible for the registration of conventional chemical pesticide products, including chlorpyrifos, pursuant to section 3 of the Federal Insecticide, Fungicide and Rodenticide Act

("FIFRA"). As part of that registration process, I am responsible for reviewing and approving pesticide labeling.

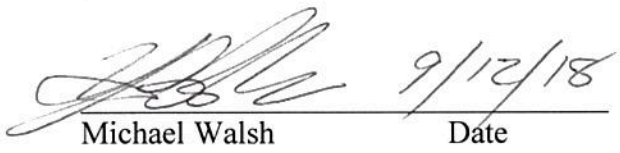
3. Before serving in my current role, I held several staff positions in OPP beginning in July 1991, including serving as a reviewer in the Herbicide Branch in the Registration Division. In these positions, I have been involved in reviewing proposed and existing label language for unregistered and registered pesticide products and generating formatting, editorial, and risk management comments on that labeling, which includes revised language where necessary to comply with current labeling requirements and to mitigate risks identified as part of pesticide product registration and reregistration processes under FIFRA section 4, and in the registration review process under FIFRA section 3(g).

4. At various times during the months of August and September 2018, I conducted a search of the Office of Pesticide Programs Information Network ("OPPIN") to identify all of the currently registered products containing the pesticide chlorpyrifos (CAS # 2921-88-2). OPPIN is the pesticide database that the EPA uses to track all registered pesticide products. All registered pesticides products are listed in the database. In addition, I used the EPA Pesticide Product Label System ("PPLS"), which is a publicly available pesticide product label repository, to locate the pesticide product labels for all currently registered chlorpyrifos products to determine the approved use patterns. OPPIN and PPLS are relied upon by the Agency and are the best available tools for generating this information.

5. Based on my search results, I calculated that there are 79 currently registered pesticide products containing the pesticide chlorpyrifos, which are registered to

over 20 different registrants. Of those 79 products, at least 28 products are registered only for "non-food uses" (that is, a use that is not expected to result in the presence of pesticide residues on food) and at least 45 other products are registered for a combination of "non-food uses" and "food uses" (that is, uses expected to result in residues on food). Based on my review of registered product labels, the approved "non-food uses" for currently registered chlorpyrifos products include, but are not limited to, golf courses, turf, road medians, exterior areas of industrial plants, mosquito control, sod farm treatments, commercial nurseries, ornamentals, non-food areas of manufacturing plants, warehouses, railroad boxcars, cut flowers, roach bait stations, wood treatment, and fire ant control. Chlorpyrifos is also registered for use on numerous food crops, including soybeans and corn.

I hereby declare and affirm, subject to the penalties of perjury, that the foregoing statement is true and correct.



Michael Walsh 9/12/18 Date

**Form 11. Certificate of Compliance Pursuant to 9th Circuit Rules 35-4 and 40-1 for Case Number** 17-71636

Note: This form must be signed by the attorney or unrepresented litigant *and attached to the back of each copy of the petition or answer.*

I certify that pursuant to Circuit Rule 35-4 or 40-1, the attached petition for panel rehearing/petition for rehearing en banc/answer to petition (check applicable option):

☒ Contains 4,179 words (petitions and answers must not exceed 4,200 words), and is prepared in a format, type face, and type style that complies with Fed. R. App. P. 32(a)(4)-(6).

**or**

☐ Is in compliance with Fed. R. App. P. 32(a)(4)-(6) and does not exceed 15 pages.

Signature of Attorney or Unrepresented Litigant: s/Phillip R. Dupre

Date: 09/24/2018

("s/" plus typed name is acceptable for electronically-filed documents)