NO. 17-71636

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.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

ON PETITION FOR REVIEW OF ORDER BY ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

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INTRODUCTION

This case challenges an order issued by the Administrator of the Environmental Protection Agency ("EPA"), Scott Pruitt, that denied a 2007 Petition to ban chlorpyrifos and retained food tolerances for the pesticide in blatant violation of the law. The Federal Food, Drug, and Cosmetic Act ("FFDCA") allows Administrator Pruitt to leave a tolerance in effect only if he "determines that the tolerance is safe," and mandates that the Administrator modify or revoke a tolerance if he "determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). EPA found chlorpyrifos unsafe in its risk assessments, and these findings compelled EPA to grant the 2007 Petition and revoke all chlorpyrifos tolerances, yet EPA failed to do so.

Remarkably, EPA never addresses the merits of this case. The first question presented asks whether Administrator Pruitt exceeded his authority and acted contrary to the FFDCA and EPA's scientific findings that chlorpyrifos is unsafe, when he denied the 2007 Petition and left chlorpyrifos tolerances in place for five or more years? EPA's answering brief is utterly silent on this question, offering nothing to counter the arguments made by petitioners League of United Latin American Citizens *et al.* ("LULAC") and the Intervenor States that the Pruitt Order runs afoul of the law and EPA's factual findings. When a party fails to respond to an argument in its answering brief, it waives the right to contest the issue. Waiver

is particularly appropriate here where EPA failed to address the core legal claim raised in the case.

Instead, EPA devotes its entire answering brief to offering ways to avoid judicial review of its action and inaction, none of which has merit. Delaying judicial review of the Pruitt Order would perpetuate EPA's brazen violations of the law and keep chlorpyrifos tolerances in place in the face of EPA findings that chlorpyrifos is unsafe. Nor would any purpose be served by waiting for EPA to offer its view on its statutory authority through the administrative objections process, particularly when EPA has effectively conceded that it exceeded that authority and broke the law by denying the 2007 Petition. The Court has jurisdiction and should hold EPA to its obligations under the law.

ARGUMENT

This case presents an uncontested violation of law. By denying the 2007 Petition, EPA did what Congress expressly forbade – it left tolerances in effect for a pesticide the agency has repeatedly found to be unsafe. Rather than defend the indefensible, EPA asks the Court to wait for EPA to resolve administrative objections at some undetermined future time before holding EPA to its obligations under the law. Because EPA's actions exceed its authority, nothing EPA can "resolve" in the administrative objections process can cure or explain away its violation of the law. Deferring judicial review would perpetuate EPA's illegal

action and put people—children in particular—at risk of acute poisonings and permanent brain damage from eating food, drinking water, going to school, and playing outside.

I. EPA EXCEEDED ITS STATUTORY AUTHORITY AND ACTED CONTRARY TO ITS SCIENTIFIC FINDINGS IN DENYING THE 2007 PETITION.

EPA has conceded the merits by offering no defense to LULAC's four mutually reinforcing arguments that the FFDCA expressly precluded the action EPA took on the 2007 Petition. *See Martinez v. Sessions*, 873 F.3d 655, 660 (9th Cir. 2017) ("The government does not offer any argument on the merits of this petition; therefore, it has waived any challenge to the arguments [raised by petitioner]."); *United States v. McEnry*, 659 F.3d 893, 902 (9th Cir. 2011) (when government fails to make an argument "available at the time it filed its answering brief ... [it] has waived that argument"); *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 466 (7th Cir. 2010) (failure to respond to argument results in waiver, and silence leaves the Court to conclude a concession).

A. EPA Lacks the Statutory Authority To Maintain Chlorpyrifos Tolerances Without an Affirmative Safety Finding (First Merits Argument).

The FFDCA authorizes Administrator Pruitt to leave chlorpyrifos tolerances in effect only if he finds the pesticide safe, and it gives EPA no discretion to make tolerance decisions based on any factor other than safety. The statute could hardly

be clearer. LULAC Brief at 28-30. Yet Administrator Pruitt denied the Petition and left the tolerances in place despite EPA findings that chlorpyrifos causes irreversible damage to children's brains from low-dose exposures far below what EPA's tolerances allow. EPA offers no response. Its silence confirms there is no legal defense.

Former Congressman Henry Waxman, the primary author of the Food Quality Protection Act ("FQPA"), a bipartisan bill that passed unanimously in 1996, explains that "the FQPA heightened the proof required to obtain a tolerance" and "requires a finding of *safety* to allow a tolerance." Waxman *Amicus* at 5, 14. (emphasis in original). It "creates a proactive, binary approach to pesticide safety: the EPA can only allow a pesticides' use after an affirmative finding that it is safe; if EPA finds the pesticide use unsafe, the tolerance must be lowered or revoked." *Id.* at 14. By retaining chlorpyrifos tolerances, EPA exceeded its authority, and neither it nor *amicus* Dow contends otherwise.

B. EPA's Findings that Chlorpyrifos Is Unsafe Compel Revoking the Tolerances (Second Merits Argument).

LULAC's opening brief established that "[t]he Pruitt Order is wholly at odds with EPA's repeated findings, growing in strength over the years, that chlorpyrifos is unsafe," and that in the face of these findings, "granting the Petition and revoking all chlorpyrifos tolerances is the only legally defensible course of action."

LULAC Brief at 31, 34. EPA is silent as to both the legal and factual underpinnings of this argument.

As a matter of law, the FFDCA directs EPA to "assess the risk" of the pesticide based on available information, including on children's consumption patterns, and special susceptibility to neurotoxic pesticides and prenatal exposures. 21 U.S.C. § 346a(b)(2)(C)(i) and (i)(I)-(II). As a matter of longstanding practice, EPA makes human health risk assessments the predicate for its FFDCA safety findings. *See* 40 C.F.R. § 155.53.[1] After conducting an objective and transparent review of the scientific evidence, EPA issued its 2014 revised human health risk assessment, finding that chlorpyrifos causes harm to children's brains, including impaired mental development, reduced intelligence, and developmental disorders, and that these effects occurred at exposures far below EPA's current regulatory endpoint. ER202, 231-32. The 2014 risk assessment found chlorpyrifos unsafe due to drinking water contamination. ER278-79. EPA's Scientific Advisory Panel ("SAP") repeatedly found that using 10% cholinesterase inhibition as the regulatory endpoint, as the current tolerances and the 2014 revised risk assessment

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[1] *See also* https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides (last visited Mar. 27, 2018) ("We review all scientific data on the pesticide and develop comprehensive risk assessments. When our assessments show that risks from a pesticide need to be reduced, we modify where and how it can be used. If a pesticide does not meet our safety standard…[we] will not allow it to be used.")

do, fails to protect children from brain damage associated with lower exposures. ER956, 973, 1191, 1225-26. In an effort to protect children from brain damage from lower-level exposures, EPA updated the risk assessment in 2016 and found chlorpyrifos unsafe in food, from drift to schools and homes, and from drinking water contamination. ER1249, 1253-55.

Dow dubs EPA's safety determinations "so-called findings," Dow *Amicus* at 13, calling them preliminary statements that can be changed in the deliberative agency's process. EPA does not join in this revisionist history.[2] Dow's argument conflicts with EPA's longstanding practice of making tolerance decisions based on findings made in risk assessments. EPA has completed no subsequent chlorpyrifos risk assessment, and the findings in its 2014 assessment and the 2016 update remain EPA's final pronouncement on chlorpyrifos safety. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000) (emphasis in original) (EPA cannot act contrary to the science simply "because of the possibility of contradiction in the future by evidence unavailable at the time of action – a possibility that will *always* be present").

Dow also asserts that EPA's 2006 tolerance determinations and 2001 and 2006 risk assessments for chlorpyrifos embody the agency's current safety

[2] This Court does not review issues raised only by amicus curiae. *Maloney v. T3Media, Inc.*, 853 F.3d 1004, 1019 (9th Cir. 2017).

determinations. Dow *Amicus* at 13-14. This assertion is preposterous in light of all that has transpired since 2006 in response to the 2007 Petition. EPA's 2006 findings have been supplanted by its 2014 risk assessment and the 2016 update, which address damage to children's brains from chlorpyrifos and conclude that chlorpyrifos fails under the "reasonable certainty of no harm" safety standard. As the Ninth Circuit noted, "[a]lthough EPA determined that chlorpyrifos was 'safe' in 2006, it has backtracked significantly from that pronouncement over the last several years." *In re Pesticide Action Network N. Am. v. EPA,* 798 F.3d 809, 814 (9th Cir. 2015) ("*In re PANNA*").[3]

The FQPA gives EPA only two options: (1) the agency must find that chlorpyrifos is safe based on the evidence currently before it in order to retain chlorpyrifos tolerances, which it cannot do; or (2) EPA must revoke tolerances based on its findings that chlorpyrifos is unsafe. Hiding behind stale 2006 findings that have since been reversed is not an option.

[3] Dow misrepresents a March 2015 status report in which EPA identified unsafe exposures to drinking water contamination and worker risks, but hoped to convince Dow and other registrants to take steps to eliminate the risks. *In re PANNA*, No. 14-72794 (Dkt. 14-1, 14-2). After negotiations with Dow broke down, EPA informed the Court that it would grant the Petition and propose revoking all chlorpyrifos tolerances. *Id.* Dkt. 20.

C. Continuing Scientific Study Is Not a Legally Permissible Reason To Retain Chlorpyrifos Tolerances (Third Merits Argument).

The Pruitt Order purports to justify denying the 2007 Petition and putting off regulatory action for five or more years in order to continue studying the science. ER27, 34. The Pruitt Order's invocation of scientific uncertainty rings hollow given the overwhelming scientific evidence and the unbroken series of EPA and SAP findings that chlorpyrifos is unsafe. Indeed, EPA's iterative reviews reduced uncertainties about the correlation between low-dose chlorpyrifos exposure and brain damage to children to the point where the uncertainties understate rather than overstate the risks. LULAC Brief at 14-15.

The FFDCA prohibits EPA from taking an action that maintains tolerances, like denying the 2007 Petition, unless it can find "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)(ii). Uncertainty cannot be a pretext for keeping the tolerances.

In addition, the FQPA directs EPA to act based on available information on neurodevelopmental harm to infants and children, including pre-natal toxicity, and to add a tenfold margin of safety when there are gaps in such information. *Id.* § 346a(b)(2)(C). This added margin of safety is required unless EPA has reliable information that less protection will be safe. *Nw. Coal. for Alts. to Pesticides v. U.S. EPA*, 544 F.3d 1043, 1046 (9th Cir. 2008).

Dow tries to cast doubt on the scientific evidence and EPA's findings through selective citations and misleading assertions. For example, it disparages epidemiology generally and in particular the Columbia epidemiology study that correlated low-level exposures to chlorpyrifos with damage to children's brains, yet EPA and the SAP found the Columbia study sound and robust, along with the other studies reinforcing its findings. ER786, 806, 973-74; *see Amicus* Brief of Health Professional Organizations (ECF 64) (reviewing evolution of science, including epidemiology, showing children and their brains in particular are highly susceptible to low-level exposures to pesticides). Similarly, Dow conflates (at 21) statements made by EPA and the SAP that cholinesterase inhibition provides dose-response information for use in quantitative risk assessment, without mentioning EPA and the SAP's repeated concerns about brain damage occurring at exposures far lower than EPA's cholinesterase inhibition endpoint. ER973, 979, 1191, 1225-26. In addition, Dow selectively quotes statements made by individual SAP members that were not embraced by the SAP as a whole and takes specific criticisms out of context. Dow *Amicus* at 23-26. The 2016 SAP concluded that EPA should not use a single measure (cord blood) from a single study to determine the level of exposure it would use in setting chlorpyrifos tolerances. ER1195. Instead, the SAP provided a roadmap for EPA to set such an exposure level based

on multiple sources, which is precisely what EPA did in its 2016 update.[4] ER1261-69, 1291.

It is no surprise that Dow would commission critiques of the studies correlating chlorpyrifos with harm to children's brains or that it would pull out all stops to avoid revocation of chlorpyrifos tolerances. Under the FFDCA safety standard, however, sowing seeds of doubt cannot save chlorpyrifos. Upon reviewing the evidence, EPA's literature reviews, and SAP peer reviews, EPA's risk assessments found chlorpyrifos unsafe in food and drinking water. ER1254, 1271 (food-only exposure for children ages 1-2 are 140 times higher than safe levels); ER1291 ("majority of estimated drinking water exposures…continue to exceed safe levels even taking into account more refined drinking water exposures"); ER1254, 1279 (unsafe chlorpyrifos levels from the field's edge to distances of more than 300 feet from where the pesticide is sprayed). Even if EPA had not made such strong affirmative findings that chlorpyrifos is unsafe, the

[4] Dow makes numerous other unsupported assertions (at 10, 13, 21-26), including (1) accusing EPA of finding chlorpyrifos unsafe based on one epidemiology study, even though EPA actually based its findings on multiple lines of evidence from both human and animal studies, ER231-32; ER973; (2) pointing out that the Columbia study began prior to EPA's 2006 tolerance determination, which is irrelevant, given that EPA's failure to address the study in its 2006 determination was the impetus for the 2007 Petition; and (3) claiming that the Pruitt Order marks the first time EPA considered public comments, which is belied by the record. ER188, 1251.

evidence would unquestionably stand in the way of a finding of safety, the prerequisite for retaining tolerances. No attempt by Dow to manufacture doubt can alter the inevitable legal outcome.

D. The Registration Review Deadline Is No License To Violate the FFDCA (Fourth Merits Argument).

The registration review process offers no basis for EPA to retain tolerances for unsafe pesticides. LULAC Brief at 38-40. Nowhere does EPA argue that the registration review process or its ultimate deadline authorizes EPA to deny a petition to revoke tolerances for an unsafe pesticide. Rather than provide this Court with any legal defense, EPA asserts that it should be allowed to develop its view of its legal authority through the administrative objections process. However, the time for responding to a legal argument put forward before this Court is in the agency's answering brief, not in a subsequent administrative determination.

Registration review addresses new studies, data, and risk assessment methods to determine whether the pesticide meets the FFDCA safety standard and avoids unreasonable risks to people and the environment under the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA's") registration standard. EPA complains that requiring it to make an affirmative safety finding any time someone files a petition to revoke tolerances would be unworkable and would give petitioners the power to re-order the agency's scheduling priorities. EPA Brief at 25-26.

How EPA might choose or be legally required to respond to a hypothetical petition is beside the point. Here, EPA placed chlorpyrifos at the head of the registration review queue based on the 2007 Petition and growing evidence of harm to children's brains. ER27-28. It conducted extensive internal and peer reviews of the mounting scientific evidence of brain damage to children from chlorpyrifos and completed risk assessments in which it found chlorpyrifos unsafe. In the face of these findings, only one course of action was legally available to EPA – revoking all chlorpyrifos tolerances. EPA never contends otherwise.

The Pruitt Order claimed that EPA can put off revoking chlorpyrifos tolerances based on the prerogative of a new administration to make policy choices that differ from its predecessor, citing *Fed. Commc'n Comm'n v. Fox Television Stations*, 556 U.S. 502 (2009). However, *Fox Television* requires that an agency provide a reasoned and lawful explanation for its new course of action and that it explain in detail the basis for contradicting prior factual findings. *Id.* at 515-16. EPA prioritized its review of chlorpyrifos because of the growing scientific evidence associating it with brain damage in children. It made an unbroken series of findings that chlorpyrifos is unsafe, and once EPA made such findings, this Court concluded that EPA's "assessment of the dangers to human health" and the "considerable human health interests prejudiced by the delay" compelled EPA to

act quickly. *In re PANNA*, 798 F.3d at 814. EPA also acknowledged its legal obligation to revoke tolerances if it cannot find them to be safe. ER1133-34, 1291.

The Pruitt Order, like EPA's brief, is silent as to these prior actions and findings. Contrary to this Court's admonition in *Organized Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968-69 (9th Cir. 2015) (en banc), EPA "simply discard[ed] prior factual findings without a reasonable explanation." This Court should vacate the Pruitt Order and direct EPA to finalize the proposed tolerance revocation rule.

II. THIS COURT HAS JURISDICTION.

EPA seeks to avoid judicial review of issues that are purely legal and go to the heart of its statutory authority. This Court should reject these attempts to evade review and hold EPA to the limits of its authority.

A. This Court Should Waive FFDCA Exhaustion.

EPA depicts exhaustion of administrative remedies as an absolute and unbending jurisdictional requirement, but the courts rarely treat exhaustion as a jurisdictional prerequisite. Instead, it is an element of the cause of action that can be waived on equitable grounds. Exhaustion should be waived here because it would be futile, perpetuate ongoing violations of unequivocal statutory prohibitions, and allow children to continue to be exposed to a pesticide that causes learning disabilities and other harm to children's brains.

1. Exhaustion is not jurisdictional.

For the standard of review, EPA relies on the wrong cases. It cites *Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 825 F.2d 1356 (9th Cir. 1987), which lacked a final order because the Commission had never ruled on requests for a hearing and stay of a proceeding about restarting a nuclear power plant. The Court equated the requirement for a final order with a statute of limitations, which it viewed to be jurisdictional. This view has been undermined by Supreme Court cases. *See Henderson v. Shinseki*, 562 U.S. 428 (2011) (120-day deadline for filing veteran benefits appeals non-jurisdictional); *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385 (1982) (deadline for filing EEOC complaint non-jurisdictional, but subject to waiver, estoppel, and equitable tolling).

EPA also cites *Darby v. Cisneros*, 509 U.S. 137 (1993), but *Darby* reinforced the presumption in favor of judicial review and limited the reach of judicially created exhaustion requirements. It said nothing about statutory exhaustion requirements. *See also Peter Kiewit Sons' Co. v. U.S. Army Corps of Eng'rs,* 714 F.2d 163, 168 (D.C. Cir. 1983) (applying judicial exhaustion where issue called for "discretionary sifting of facts, rather than application of law").

It is *Weinberger v. Salfi,* 422 U.S. 749, 764-66 (1975), and its progeny that address statutory exhaustion requirements, holding that they may be waived on equitable grounds unless they are central to the grant of subject matter jurisdiction.

Even where exhaustion or other procedural requirements are stated in mandatory terms, they are rarely jurisdictional. LULAC Brief at 42-43.[5]

EPA relies on *McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 978 (9th Cir. 2002), but that case held that exhaustion was not jurisdictional under a statute that provided "[n]otwithstanding any other provision of law, a person shall exhaust all administrative appeal procedures established by the Secretary [of Agriculture] or required by law before the person may bring an action in a court" against the Secretary or the Department. This Court observed that "we have rarely found exhaustion statutes to be a jurisdictional bar." *Id.* It pointed to cases holding the following exhaustion provisions to be non-jurisdictional:

> No decision which at the time of its rendition is subject to appeal to the Director or an Appeals Board shall be considered final so as to be agency action subject to judicial review under 5 U.S.C. §704 . . ..
>
> No action shall be brought with respect to prison conditions. . . until such administrative remedies as are available are exhausted . . ..

Id. at 978-79 (citing *Anderson v. Babbitt*, 230 F.3d 1158, 1162 (9th Cir. 2000), and *Rumbles v. Hill*, 182 F.3d 1064, 1067 (9th Cir. 1999)). The Supreme Court has similarly held that seemingly mandatory exhaustion requirements are not jurisdictional. *See, e.g., Reed Elsevier v. Muchnick*, 559 U.S. 154, 163-66 (2010)

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[5] *In re PANNA*, 863 F.3d 1131, 1132-33 (9th Cir. 2017), described the FFDCA's exhaustion requirements, without applying *Weinberger* to determine whether exhaustion is jurisdictional.

(federal court had jurisdiction over an unregistered copyright even though statute provides: "no civil action for infringement of the copyright in any United States work shall be instituted until the preregistration or registration of the copyright has been made"); *Bethesda Hosp. Ass'n v. Bowen,* 485 U.S. 399, 403-05 (1988) (review of Medicare reimbursement available without review by fiscal intermediary despite statute providing for hearing when dissatisfied with final determination of fiscal intermediary).[6]

The challenge of making sense of the divergent holdings in the face of statutory provisions that, on their face, seem to mandate exhaustion before proceeding to court is guided by two principles: (1) exhaustion requirements are rarely jurisdictional; and (2) the touchstone is congressional intent against the backdrop of "the strong presumption that Congress intends judicial review of administrative action." *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986); *see also Abbott Labs. v. Gardner,* 387 U.S. 136, 140 (1967) ("judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of

[6] EPA seizes on *Gallo Cattle Co. v. U.S. Dep't of Agriculture*, 159 F.3d 1194 (9th Cir. 1988), without informing the Court that the D.C. Circuit subsequently reached the opposite result, holding the statutory exhaustion provision non-jurisdictional. *Avocado Plus, Inc. v. Veneman*, 370 F.3d 1243 (D.C. Cir. 2004).

Congress"); *Sun v. Ashcroft*, 370 F.3d 932, 940 (9th Cir. 2004) ("of paramount importance to any exhaustion inquiry is congressional intent.").

EPA tries to intuit congressional intent from a legislative change to the exhaustion provision to overrule *National Coalition Against Misuse of Pesticides v. Thomas*, 809 F.2d 875, 879 (D.C. Cir. 1987), which construed the FFDCA's objections to be permissive, not mandatory. EPA cites no legislative history because there is none.

Given that the wording change was part of the FQPA, it must be understood in the context of the over-riding changes made in that law, which leads to the conclusion that exhaustion is non-jurisdictional. First, in the FQPA, Congress prohibited the very course of action taken by EPA on chlorpyrifos, denying a petition to revoke a tolerance in the face of EPA findings that the pesticide is unsafe.

Second, Congress never anticipated EPA would deny a petition to revoke tolerances when the agency has been unable to make a reasonable certainty of no harm finding. In response to a petition to revoke tolerances, the Administrator may take one of three alternative actions: (1) issue a final regulation modifying or revoking the tolerances; (2) issue a proposed regulation and thereafter a final tolerance regulation; **or** (3) issue an order denying the petition. 21 U.S.C. § 346a(d)(4). In response to the 2007 Petition, the Administrator issued a proposed

regulation to revoke all chlorpyrifos tolerances, and then after the change in administration, issued an order denying the 2007 Petition without withdrawing the proposed revocation rule. Congress never envisioned that EPA would deny a petition to revoke tolerances and leave a proposed revocation rule in limbo, concurrently pursuing two of the mutually exclusive courses of action.

Third, EPA lacks the power to exceed its statutory authority under the FFDCA. Nothing EPA can do through the objections process can arrogate to itself the power to do what Congress has forbidden. Indeed, courts routinely dispense with exhaustion requirements with respect to the agency's power to act because an agency must always ensure it is acting within its statutory authority. *See Natural Res. Def. Council v. EPA*, 755 F.3d 1010, 1022-23 (D.C. Cir. 2014) (even if not raised in comments, EPA must address its statutory authority to promulgate exemption from statute's requirements); *W. Medical Enters., Inc., v. Heckler*, 783 F.2d 1376, 1379-80 (9th Cir. 1986) (exhaustion inapplicable to claim agency exceeded its statutory authority in promulgating regulation). In light of the FFDCA's unbending mandates to revoke tolerances in the absence of an affirmative safety finding, it is inconceivable that Congress intended for EPA to avoid that result by turning the objections process into a subterfuge to avoid doing what the law compels.

Finally, EPA relies heavily on the provision prohibiting judicial review under other laws of "[a]ny issue as to which review is or was obtainable" under the FFDCA. 21 U.S.C. § 346a(h)(5). But review of the legal violation at issue is decidedly not obtainable when EPA is blatantly exceeding its legal authority. Had EPA complied with the law and finalized the tolerance revocations, chlorpyrifos would have been out of our food supply and drinking water by October 2017. EPA's plea to let the objections process run its course is a ploy to allow an illegal result at the expense of the protections Congress mandated for human health, and children's health in particular.[7]

2. *Exhaustion should be waived.*

EPA contends that it should have an opportunity to address LULAC's legal arguments in the objections process, claiming that courts favor having issues first decided by an agency equipped with pertinent expertise. *See* EPA Brief at 23-24. That principle extends to regulatory and scientific issues within the agency's expertise, but has no bearing on purely legal issues that go to the agency's

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[7] *State of New York v. EPA*, 350 F. Supp. 2d 429, 438 (S.D.N.Y. 2004), *aff'd sub nom. Natural Res. Def. Council v. Johnson*, 461 F.3d 164, 176 (2nd Cir. 2006), is inapposite because the plaintiffs there sought to bypass the FFDCA and instead brought an action in district court under the Administrative Procedure Act ("APA"). The court held that APA review is unavailable because it arises only if there is no adequate remedy at law, and the court viewed FFDCA review to be adequate. Neither the district court nor the court of appeals applied the *Weinberger* test or addressed whether resort to the objections process would be futile.

mandatory duties, as it is the province of the courts to say what the law is. *Marbury v. Madison*, 5 U.S. 137, 177 (1803). Courts have dispensed with exhaustion requirements and limitations on judicial review when an agency or government official exceeds its statutory authority, as EPA has here. *See* LULAC Brief at 46; *Martinez v. Richardson*, 472 F.2d 1121, 1125 (10th Cir. 1973) (party need not procure administrative review of claim if resulting time delays would subject substantive rights to irreparable harm). Because EPA lacks the authority to expand its statutory authority administratively, its plea to postpone judicial review must be understood for what it is: part of Administrator Pruitt's scheme to avoid revoking chlorpyrifos tolerances for as long as possible.

This is evident from the Pruitt Order itself. It put off taking regulatory action based on the 2007 Petition, but left EPA's findings that chlorpyrifos is unsafe and the proposed revocation rule in place. ER34. Specifically,

> EPA has concluded that it should alter its priorities and adjust the schedule for chlorpyrifos so that it can complete its review of the science addressing neurodevelopmental effects prior to making a final registration review decision whether to retain, limit or remove chlorpyrifos from the market. Accordingly, EPA is denying these Petition claims and intends to complete a full and appropriate review of the neurodevelopmental data before either finalizing the proposed rule of October 30, 2015, or taking an alternative regulatory path.

ER34. The Pruitt Order makes a feeble attempt to argue that this course of action is consistent with governing law, *id.*, but EPA abandons those arguments before this Court. EPA cannot defend this action because it is blatantly illegal. Putting

off judicial review until EPA resolves the objections perpetuates EPA's cynical and illegal maneuver.

EPA's recent response to a senatorial inquiry confirms the futility of allowing the objections process to run its course. EPA explained that it must complete "several additional milestones" before finalizing a registration review decision for chlorpyrifos. ECF 47-2 at 60 ("Bertrand Letter"). These milestones include additional scientific review, a new human health risk assessment, a proposed regulatory decision, several rounds of public comment, and eventually a final regulatory decision. *Id.* EPA's rough timelines will consume the bulk, if not all, of the period allowed by law for it to complete registration review for all older pesticides. *Id.*

The author of this letter submitted a declaration stating that EPA's response to the objections will not necessarily await completion of the human health component of registration review of chlorpyrifos. Bertrand Decl. ¶¶ 4-5 (ECF 62-2). She provides no timeframe for EPA's decision on the objections, nor does she disagree that EPA is planning to put off taking regulatory action on chlorpyrifos for several more years, likely until close to the 2022 registration review deadline. It must be remembered that if EPA had granted the 2007 Petition in March 2017, all chlorpyrifos tolerances would have been revoked six months later. Because the objections and this case challenge EPA's illegal postponement of that regulatory

action, EPA's attempt to separate its decision on the objections from tolerance revocation elevates form over substance.

EPA asserts that LULAC has failed to show that EPA will ignore the points made in the objections. EPA Brief at 28. This assertion rings hollow for two reasons. First, in comments on the chlorpyrifos risk assessments and the proposed revocation, petitioners repeatedly cited the FFDCA's mandates and EPA's legal obligation to revoke all tolerances. ER1532, 1727. Second, the objections present purely legal issues that EPA cannot explain away because they go to the heart of EPA's delegated authority.

While it is true that any exhaustion requirement will delay judicial review, EPA points to no case where a court has allowed an agency to exceed its statutory authority and hide behind an administrative review process to get away with it. This case presents a highly unusual situation where an agency: (1) has taken an action forbidden to it; (2) has failed to defend that action on the merits, and yet (3) asks this Court to defer to an open-ended administrative review process before holding the agency to the law. Under these circumstances, exhaustion should be waived.[8]

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[8] EPA contends the Pruitt Order is not final agency action, but neither FFDCA nor FIFRA have a final agency action requirement. EPA never applies the pertinent final agency action legal standard. Nor does it address *Natural Resources Defense Council v. Johnson*, 461 F.3d at 172, which held that denial of a petition to revoke

B. If Exhaustion Is Required Under the FFDCA, This Court Can Hear This Case Under FIFRA.

This case presents an unusual situation where EPA has found a pesticide unsafe and yet denied a petition to ban the pesticide. Normally, as required by the interplay between FFDCA and FIFRA, EPA must revoke tolerances for an unsafe pesticide (or when it is unable to make an affirmative safety finding), and cancellation of the corresponding registrations for uses of that pesticide follows as a matter of course.

Ordinarily, judicial review would proceed under the FFDCA's objections and judicial review provisions. Here, however, EPA is using the objections process to stymie judicial review of its action illegally leaving chlorpyrifos tolerances and registrations in place. If this Court decides judicial review must await EPA's resolution of the objections, then it should hear this case under FIFRA. *See* LULAC Brief at 47-50.

EPA asserts that judicial review under FIFRA is foreclosed by 21 U.S.C. § 346a(h)(5), which precludes judicial review outside the FFDCA of "[a]ny issue as to which review is or was obtainable" under the FFDCA. This provision speaks of "any issue" and review that "is or was obtainable." Review of the issues presented in this case is not obtainable through the objections process because the purely

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tolerances is final agency action. LULAC demonstrated in opposition to the motion to dismiss that the Pruitt Order constitutes final agency action. ECF 28.

legal issues go to EPA's authority, which it cannot alter. Review is also unavailable because the objections process would be futile and would perpetuate EPA's illegal conduct. Because EPA is trying to put off judicial review until it resolves the objections, it has rendered review of the issues presented unavailable and therefore Section (h)(5) erects no barrier to review under FIFRA.[9]

III. IN THE ALTERNATIVE, THE COURT SHOULD GRANT MANDAMUS RELIEF.

A. This Court Can and Should Hear LULAC's Alternative Request for Mandamus Relief.

This Court has jurisdiction and should hear LULAC's alternative request for mandamus relief if the Court decides it lacks jurisdiction to reach the merits. *See In re A Cmty. Voice*, 878 F.3d 779, 783 (9th Cir. 2017) ("Any court that would have jurisdiction to review a final rule has jurisdiction to determine if an agency's delay is unreasonable."); *see also United States v. Carter*, 270 F.2d 521, 524 (9th Cir. 1959) (courts have discretion to issue mandamus to compel performance of a duty and "its issuance is largely controlled by equitable principles"). In the interest

[9] The petitioners in *Natural Resources Defense Council*, 461 F.3d at 176 failed to invoke FFDCA remedies, sought judicial review under the APA and FIFRA in district court, and never argued, nor was there any indication, that submitting and waiting for EPA to rule on objections would be futile. *Geerston Farms v. Johanns*, 439 F. Supp. 2d 1012 (N.D. Cal. 2006), rejected an attempt to bring a tolerance challenge as an Endangered Species Act citizen suit in district court, rather than in the court of appeals under the FFDCA. In neither case was EPA keeping tolerances for an unsafe pesticide in place.

of judicial economy, LULAC briefed the unreasonable delay issue in its opening brief rather than file a separate mandamus petition. LULAC Brief at 50. This is in keeping with this Court's practice of allowing a notice of appeal and briefing as part of an appeal to substitute for a mandamus petition. *Johnson v. Consumerinfo.com, Inc.*, 745 F.3d 1019, 1023 n.2 (9th Cir. 2014); *Cordoza v. Pac. States Steel Corp.*, 320 F.3d 989, 998 (9th Cir. 2003).

EPA is incorrect in stating (at 31-32) that LULAC must request mandamus relief under Federal Rule of Appellate Procedure 21(a) ("Rule 21") because that rule applies to a writ of mandamus directed at a court, not an administrative agency. Fed. R. App. P. 21, Advisory Committee Notes 1996 Amendments ("Subdivision (a) applies to writs of mandamus or prohibition directed to a court… This language is inserted to distinguish subdivision (a) from subdivision (c). Subdivision (c) governs all other extraordinary writs, including a writ of mandamus or prohibition directed to an administrative agency…."). Under Rule 21(c), "[p]roceedings on the application must conform, so far as is practicable, to the procedures prescribed in Rule 21(a) and (b)."

LULAC substantially complied with Rule 21's requirements. Its opening brief identifies: "(i) the relief sought; (ii) the issues presented; (iii) the facts necessary to understand the issue presented by the petition; and (iv) the reasons why the writ should issue," Rule 21(a)(2)(B), and LULAC's petition for review

and excerpts of record "include a copy of any order or opinion or parts of the record that may be essential to understand the matters set forth in the petition," Rule 21(a)(2)(C). This Court should exercise its jurisdiction and consider LULAC's mandamus claim in the alternative.

B. EPA's Delay in Responding to the Objections Is Unreasonable.

EPA fails to refute LULAC's application of the factors outlined in *Telecomm. Research and Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) ("*TRAC*"). It never addresses the FFDCA's uncompromising mandates to ban unsafe pesticides, which cannot be put to the side in order to make staff available to weaken protections for workers who apply pesticides. LULAC Brief at 53, 58. Nor does EPA confront its own findings that chlorpyrifos is unsafe, including its findings that unsafe levels of the pesticide exist in our food and drinking water, and that chlorpyrifos spray drift causes acute poisonings and is found at unsafe levels hundreds of meters from where it is sprayed. Exposures cause large numbers of acute poisonings every year, as well as an unknown, but troubling, amount of brain damage to children. EPA ignores the toll that acute poisonings take on workers and communities around agricultural fields, and it turns a blind eye to the learning disabilities that impede children's potential and strain families and schools. *See* LULAC Brief at 54-58.

In issuing a writ of mandamus in the prior related case, this Court noted that:

> EPA reported that chlorpyrifos poses such a significant threat to water supplies that a nationwide ban on the pesticide may be justified. We do not take this representation lightly. Yet EPA offers no acceptable justification for the considerable human health interests prejudiced by the delay. In view of EPA's own assessment of the dangers to human health posed by this pesticide, we have little difficulty concluding it should be compelled to act quickly to resolve the administrative petition.

In re PANNA, 798 F.3d at 814; *see also Pub. Citizen Health Research Grp.*, 740 F.2d 21, 34-35 (1984) ("When the public health may be at stake, the agency must move expeditiously to consider and resolve the issues before it.").

EPA's sole response is its assertion, without citation, that its past delays, which spanned nearly a decade and were found to be "egregious" by this Court, are irrelevant. *See* EPA Brief at 33 n.8. However, courts apply a rule of reason without artificially constraining the scope of review in deciding whether an agency has unreasonably delayed taking action. *TRAC*, 750 F.2d at 80. After EPA found in 2014 that chlorpyrifos is associated with brain damage in children and is unsafe, this Court had little tolerance for further delay. *See In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016) ("EPA's nine-year delay in taking action was 'objectively extreme' when we received PANNA's petition for mandamus, and nothing has changed that would justify EPA's continued failure to respond to the pressing health concerns presented by chlorpyrifos."). Both the Pruitt Order's rationale and EPA's inaction on the objections only compound that delay, subjecting more children and families to unthinkable harm.

EPA's most glaring omission is its silence regarding what it is has done to date and its timeline for completing its decision on the objections. In the prior mandamus proceedings, EPA submitted declarations describing the steps it was taking to respond to the 2007 Petition and providing a timeline for upcoming steps and final action. *See, e.g., In re PANNA*, No. 14-72794, Dkt. 7-2 at ¶ 3 (Decl. of Dana Vogel, Dec. 23, 2014) ("This declaration describes the actions that EPA has taken and is taking to complete its response to the petition…and explains the reasons that EPA's complete response has taken longer than we had previously estimated…"). This stands in stark contrast to EPA's inaction to date on the objections and its lack of any concrete plans to move the objections forward to conclusion.

All that EPA has offered is the registration review timeline in the Bertrand Letter, which is a recipe for delay. It embodies a plan to do what the Pruitt Order set in motion – continue to study the science and put off regulatory action until the end of the registration review process in 2022. ER34. The Bertrand Letter explains that EPA's reconsideration of the epidemiology data will take 18-24 months, a new risk assessment will then be published and open for a 60-day public comment, EPA will respond to those comments and issue a proposed interim decision, that will also be open for a 60-day comment period, and after addressing those comments, EPA will then develop an interim decision for chlorpyrifos.

Bertrand Letter at 4. That interim decision could be a plan to finalize the proposed revocation rule, a modified proposed revocation, or withdrawal of that proposed rule.

EPA claims that the Bertrand Letter meant to describe regulatory action and not resolution of the objections, ECF 62-2, ¶¶4-5, but the two cannot be separated. The 2007 Petition sought revocation of chlorpyrifos tolerances – a regulatory action – and if it had been granted, the revocation would have happened already and the public would no longer be exposed to this harmful pesticide. The Pruitt Order denied the 2007 Petition stating a preference to study the science for four or five more years and the Bertrand Letter roughs out a timeline for doing so. Both presage EPA's foreordained outcome – leaving tolerances in place while conducting years of study. If EPA denied the objections tomorrow, it would unquestionably give this Court jurisdiction to rule EPA's denial of the 2007 Petition and retention of chlorpyrifos tolerances illegal. By sitting on the objections, EPA may (depending on this Court's jurisdictional ruling) be obstructing this Court's ability to hold EPA to the FFDCA's mandates. LULAC Brief at 53.

EPA is holding children's health and petitioners' rights under the FFDCA hostage to the objections process. The Court should find EPA's delay unreasonable and order Administrator Pruitt to rule on the objections in 60 days.

CONCLUSION

This Court should hold that Administrator Pruitt acted unlawfully and remand with directions to finalize the tolerance revocation rule within 60 days. Alternatively, the Court should order the Administrator to rule on the objections within 60 days.

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CERTIFICATE OF COMPLIANCE

This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1. The brief is 6,994 words, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

s/Patti A. Goldman
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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 April 5th, 2018.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/ Patti A. Goldman
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